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****(USE BELOW FOR ALL 8(a) SOLICITATIONS THAT WILL BE AWARDED UNDER THE PARTNERSHIP AGREEMENT BETWEEN HHS AND SBA.)****

NOTICE TO OFFERORS

This solicitation is being processed under a Partnership Agreement (PA) between the Department of Health and Human Services (HHS) and the Small Business Administration (SBA), under which the SBA has delegated to HHS, authority to enter into 8(a) contracts directly with eligible 8(a) firms. The PA implements innovative and effective methodology designed to streamline the acquisition process for awards under the 8(a) program. The [Name of Operating Division] is a designated pilot agency under the PA.

Any solicitation and subsequent awards processed under the referenced PA, [Name of Operating Division] will make the award directly to the 8(a) firm. SBA will not be a signatory to the award resulting from this solicitation. SBA will, however, retain responsibility for 8(a) certification, administer other eligibility related issues under the 8(a) program, and be available to 8(a) firms for counseling and assistance.

If you have any questions pertaining to this PA, please contact [insert Name & Contact Info for NIH:] .

HHS/SBA PA (OCTOBER 23, 2012 until amended)
Servicing Small Business Administration Field Office

To facilitate communications, it is requested that the 8(a) participant submitting this offer/bid provide the following information regarding the firm's cognizant servicing Small Business Administration (SBA) office.

Servicing SBA Office _____

Address _____

_____

Cognizant SBA Business Opportunity Specialist's Name _____

Phone _____

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****(USE BELOW IN ALL SOLICITATIONS.)****

PART I - THE SCHEDULE

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM** , HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS **SECTION A - SOLICITATION/CONTRACT FORM** , ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H** , HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

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****(USE BELOW FOR ALL SOLICITATIONS.)****

ADDITIONAL INFORMATION TO COMPETE THIS ITEM:

1. **BOX 1 - Purchase Authority:** In accordance with FAR 15.204-2(a)(2)(vi), this may be the "Requisition or other purchase authority."
   - Insert requisition or other purchase authority, if available, otherwise leave blank.
2. **BOX 9:** Select the appropriate "Late Proposal Clause" from the drop-down box. **[Note:** In accordance with the NIH HCA's 10/15/2010 D&F, the HHSAR Provision at 352.215-70, may only be used to consider late proposals submitted in response to a competitive R&D solicitation, when consideration is in the public interest.]
3. **BOX 12:** If authorizing facsimile proposals [see FAR 15.203(d)], make sure to add the item number " **12** ." to the text box and include the FAX # with the following statement: "Facsimile proposals are authorized in accordance with FAR Clause 52.215-5."

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1.Requisition or other Purchase Authority: _____		
2. **Request for Proposal (RFP) Number:** _____	3. **Issue Date:** _____	4. **Set Aside:** [X] No [ ] Yes See Part IV Section L
5. Title : _____		
6. ISSUED BY: Office of Acquisitions _____ National Institutes of Health _____ _____ _____ _____ _____		7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until _____ local time on _____ . Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.		

9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS. IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH [subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition,"/HHSAR Clause 352.215-70, "Late Proposals and Revisions"] LOCATED IN SECTION L.1. OF THIS SOLICITATION.	
10. Offeror must be registered in the System for Award Management (SAM) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at https://www.sam.gov/SAM/ .	
11. FOR INFORMATION CALL: _____ PHONE: _____ e-MAIL: _____ COLLECT CALLS WILL NOT BE ACCEPTED.	
	_____ Contracting Officer Office of Acquisitions _____

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

5

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

ADDITIONAL INSTRUCTIONS FOR COMPLETING THIS ITEM:

- Add a one to three sentence description of work.

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

6

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

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****(USE BELOW FOR A COST SHARING CONTRACT.)****

ARTICLE B.3. ESTIMATED COST - COST SHARING

This is a cost-sharing contract. The total estimated cost of performing the work under this contract is $ _____ . For further provisions regarding the specific cost-sharing arrangement, see the ADVANCE UNDERSTANDINGS Article in SECTION B of the Contract.

8

****(USE BELOW FOR A FULLY FUNDED COST-REIMBURSEMENT CONTRACT WITH NO FEE.)****

ARTICLE B.4. ESTIMATED COST

The estimated cost of this contract is $ _____ .

9

****(USE BELOW FOR A FULLY FUNDED CPFF-LEVEL OF EFFORT CONTRACT.)****

ARTICLE B.4. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is $ _____ .
b. The fixed fee for this contract is $ _____ .The fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.
c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is $ _____ .

10

****(USE BELOW FOR A FULLY FUNDED CPFF-COMPLETION CONTRACT WHEN PAYMENT OF FEE WILL BE BASED ON PERCENTAGE OF COMPLETION OR WORK.)****

ARTICLE B.4. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is $ _____ .
b. The fixed fee for this contract is $ _____ . The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer, and subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.
c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is $ _____ .

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****(USE BELOW FOR A FULLY FUNDED CPFF-COMPLETION CONTRACT WHEN THE PAYMENT OF FEE IS TIED TO TIME.)****

ARTICLE B.4. ESTIMATED COST AND FIXED FEE

a. The estimated cost of this contract is $ _____ .
b. The fixed fee for this contract is $ _____ . The fixed fee shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee, is $ _____ .

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****(USE BELOW FOR A COST-REIMBURSEMENT OPTION CONTRACT.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- **Subparagraph b:**
  - Eliminate Fee Language When Appropriate.
  - Select the sentence appropriate for the type of contract within the brackets below. Make sure to delete the sentence that does not apply.

ARTICLE B.5. ESTIMATED COST - OPTION

a. The estimated cost of the Base Period of this contract is $ _____ .

b. The fixed fee for the Base Period of this contract is $ _____ . [**For completion contracts:** The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer./ **For level of effort contracts:** The fixed fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended.] Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is $ _____ .

d. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost ($)	**Fixed Fee ($)**	**Estimated Cost Plus Fixed Fee ($)**
Base Period			
Option Period(s):			
Total [Base Period and Option(s)]			

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****(USE BELOW FOR A COST-REIMBURSEMENT PERFORMANCE BASED AWARD TERM CONTRACT.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

1. Eliminate Fee Language When Appropriate.
2. **Subparagraph b:** Select the sentence appropriate for the type of contract within the brackets below. Make sure to delete the sentence that does not apply.

ARTICLE B.6. ESTIMATED COST - AWARD TERM

a. The estimated cost of the Base Period of this contract is $ _____ .

b. The fixed fee for the Base Period of this contract is $ _____ . [**For completion contracts** : The fixed fee shall be paid in installments based on the percentage of completion of work, as

determined by the Contracting Officer./ **For level of effort contracts** : The fixed fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended.] Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is $ _____ .

d. If the Award Term(s) is/are earned pursuant to the AWARD TERM QUALITY ASSURANCE SURVEILLANCE PLAN (QASP) Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost ($)	**Fixed Fee ($)**	**Estimated Cost Plus Fixed Fee ($)**
Base Period			
Award Term(s):			
Total [Base Period and Award Term(s)]			

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****(USE BELOW FOR A COST-REIMBURSEMENT PERFORMANCE BASED ACQUISITION (PBA) WHERE THE INCENTIVE IS TIED TO FEE.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- An obligation of funds for award-fee shall not be made until the actual award-fee amount is determined and the contractor is notified. An award-fee is a bona fide need of the same year and appropriation that financed the related effort for which the award-fee was earned. Simplified, the same fiscal year appropriation used to fund the performance period evaluated must be used to pay the award-fee.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- **Subparagraph a.2.:** Select a subparagraph a.2.a., if appropriate, as follows:
  - If the total base fee is $0, do not include any subparagraphs (a. or b.) under subparagraph a.2. [*Note: Providing a base fee is at the discretion of the Contracting Officer. See FAR 16.405-2 for additional information about CPAF contracts* .]
  - Use the first subparagraph a.2.a. when a base fee $ amount is negotiated. Select the sentence appropriate for the type of contract within the brackets below. Make sure to delete the sentence that does not apply.
  - Use the second subparagraph a.2.b. for RFPs.
- **Subparagraph b (Table):** Include all evaluation periods and associated available award fee for the life of the contract.
- **Subparagraph c.:** The Total Estimated Cost of the contract should include Award Fee "EARNED," therefore, at the time of award, this amount will be estimated cost plus base fixed fee (if any) only. **This amount will need to be updated each time an award fee is earned to accurately reflect the total estimated cost of the contract.**

ARTICLE B.7. ESTIMATED COST PLUS AWARD FEE

a. Estimated Cost and Base Fixed Fee

1. The total estimated cost of this contract is $ _____ .
2. The total base fixed fee is $ _____ .

a. The base fixed fee shall be paid in [**For completion contracts** : installments based on the percentage of completion of work, as determined by the Contracting Officer/ **For level of effort contracts** : direct relation to the level of effort expended; that is, the percent of base fixed fee paid shall be equal to the percent of total effort expended.]
-OR-
b. The fee payment schedule will be determined during negotiations.

c. Payment shall be subject to the withholding provision of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

b. Award Fee Consideration

Based on the evaluation/determination described in subparagraph d. below, an award fee may be earned by the Contractor at regular intervals as defined in the paragraphs herein. The total

potential award fee available is $ _____ and the evaluation periods shall be as follows:

Evaluation Period(s):	Available Award Fee:

c. Total Estimated Contract Amount

The total estimated amount of the contract, represented by the sum of the estimated cost plus base fixed fee (if any), plus earned award fee is $ _____ .

d. Methodology for Award Fee Evaluation/Determination

1. The Contractor's performance hereunder will be observed and evaluated continuously by the Government. At the end of each evaluation period, the Contracting Officer will review performance based on the standards and criteria established in the Quality Assurance Surveillance Plan, dated _____ , listed in SECTION J - LIST OF ATTACHMENTS, attached hereto and made a part of this contract.
2. The findings of the evaluation will determine the amount of the available award fee (specified in subparagraph b. above) earned by the Contractor for the identified evaluation period. In no event, however, will any unearned award fee become available in subsequent evaluation periods.
3. The Contracting Officer will notify the Contractor, in writing, of the available award fee actually earned for a given evaluation period. Upon receipt of this notification, the Contractor shall submit a public voucher for payment of the total award fee earned.
4. The evaluation/determination of award fee shall be binding on both parties and not subject to the Disputes clause included in Section I of the contract.

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****(USE BELOW IN COST-REIMBURSEMENT PERFORMANCE BASED ACQUISITION (PBA) WITH OPTIONS, WHERE THE INCENTIVE IS TIED TO FEE.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- An obligation of funds for award-fee shall not be made until the actual award-fee amount is determined and the contractor is notified. An award-fee is a bona fide need of the same year and appropriation that financed the related effort for which the award-fee was earned. Simplified, the same fiscal year appropriation used to fund the performance period evaluated must be used to pay the award-fee.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- **Subparagraph a.3.:** Select a subparagraph a.3.a., if appropriate, as follows:
  - If the total base fee is $0, do not include any subparagraphs (a. or b.) under subparagraph a.3. [*Note: Providing a base fee is at the discretion of the Contracting Officer. See FAR 16.405-2 for additional information about CPAF contracts* .]
  - Use first subparagraph a.3.a. when a base fee $ amount is negotiated. Select the sentence appropriate for the type of contract within the brackets below. Make sure to delete the sentence that does not apply. Complete the information for all Option Periods.
  - Use the second subparagraph a.3.b for RFPs.
- **Subparagraph b.1 (CONTRACTS ONLY):** List all evaluation periods separately with applicable Award Fee Amounts for the Base Period Only.
- **Subparagraph b.2 (CONTRACTS ONLY):** List all options and indicate the evaluation periods and associated available award fee for each option.
- **Subparagraph c.:** The Total Estimated Cost of the contract should include Award Fee "EARNED," therefore, at the time of award, this amount will be estimated cost plus base fixed fee (if any) only. **This amount will need to be updated each time an award fee is earned to accurately reflect the total estimated cost of the contract.**

ARTICLE B.8. ESTIMATED COST PLUS AWARD FEE

a. Estimated Cost and Base Fixed Fee

1. The total estimated cost of the Base Period of this contract is $ _____ .
2. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the estimated cost shall be increased as follows:

	Estimated Cost ($)
Base Period:	
Option Period(s):	
Total [Base Period and Option(s)]	

3. The total base fixed fee for the Base Period of the contract is $ _____ .
   a. The base fixed fee shall be paid in [**For completion contracts:** installments based on the percentage of completion of work, as determined by the Contracting Office/ **For**

level of effort contracts: direct relation to the level of effort expended; that is, the percent of base fixed fee paid shall be equal to the percent of total effort expended.]

If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the base fixed fee shall be increased as follows:

	Base Fixed Fee ($)
Base Period:	
Option Period(s):	
Total [Base Period and Option(s)]	

-OR-

b. The fee payment schedule will be determined during negotiations.

c. Payment shall be subject to the withholding provision of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

b. Award Fee Consideration

1. Based on the evaluation/determination described in subparagraph d. below, an award fee may be earned by the Contractor at regular intervals as defined in the paragraphs herein. The total potential award fee available is $ _____ and the evaluation periods shall be as follows:

Base Period Evaluation Period(s):	**Available Award Fee**

2. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the total potential award fee available for the option years/periods and the evaluation periods shall be as follows:

OPTION(s) Period(s)	**Evaluation Period(s) by Option**	**Available Award Fee**

c. Total Estimated Contract Amount

1. 1. The total estimated amount of the contract, represented by the sum of the estimated cost plus the base fixed fee (if any), plus the earned award fee is $ _____ .

2. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount, represented by the sum of the estimated cost plus base fixed-fee (if any) plus the earned award fee and the period of performance will be increased as follows:

	Estimated Cost ($)	Base Fixed Fee ($)	Earned Award Fee ($)	Total Estimated Contract Amount ($)
Base Period:				
Option Period(s):				
Total [Base Period and Option(s)]				

d. Methodology for Award Fee Evaluation/Determination

1. The Contractor's performance hereunder will be observed and evaluated continuously by the Government. At the end of each evaluation period, the Contracting Officer will review performance based on the standards and criteria established in the Quality Assurance Surveillance Plan, dated _____ , listed in SECTION J - LIST OF ATTACHMENTS, attached hereto and made a part of this contract.
2. The findings of the evaluation will determine the amount of the available award fee (specified in subparagraph b. above) earned by the Contractor for the identified evaluation period. In no event, however, will any unearned award fee become available in subsequent evaluation periods.
3. The Contracting Officer will notify the Contractor, in writing, of the available award fee actually earned for a given evaluation period. Upon receipt of this notification, the Contractor shall submit a public voucher for payment of the total award fee earned.
4. The evaluation/determination of award fee shall be binding on both parties and not subject to the Disputes clause included in Section I of the contract.

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****(USE BELOW FOR A COST-REIMBURSEMENT CONTRACT FOR SEVERABLE SERVICES USING INCREMENTAL FUNDING. See HHSAR Part 332 - Contract Funding for additional information on using incremental funding.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. **Subparagraph a:** Insert the full amount of the contract.
2. **Subparagraph b:**
   - **For Solicitations:** Leave this subparagraph as is.
   - **For Contracts:**
     i. Remove the asterisk in the first sentence.
     ii. Complete the Table based on negotiations.
     iii. Remove the sentence under the Table.
3. **Subparagraph c:** Insert the amount funded to date.

ARTICLE B.9. ESTIMATED COST - INCREMENTALLY FUNDED CONTRACT

a. The total estimated cost to the Government for full performance of this contract, including all allowable direct and indirect costs, is $ _____ .

b. The following represents the schedule* by which the Government expects to allot funds to this contract:

CLIN, Task, Number, or Description	Start Date of Period or Increment of Performance	End Date of Period or Increment of Performance	Estimated Cost ($)	Fee ($) (as appropriate)	Estimated Cost Plus Fee ($) (as appropriate)
			[Total]	[Total]	[Total]

*To be inserted after negotiation

c. Total funds currently obligated and available for payment under this contract are $ _____ .

d. The Contracting Officer may issue unilateral modifications to obligate additional funds to the contract and make related changes to paragraphs b. and/or c., above.

e. Until this contract is fully funded, the requirements of the clause at FAR 52.232-22, Limitation of Funds, shall govern. Once the contract is fully funded, the requirements of the clause at FAR 52.232-20, Limitation of Cost, shall govern.

17

**** (USE BELOW FOR A CPFF CONTRACT FOR SEVERABLE SERVICES USING INCREMENTAL FUNDING.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. **Second paragraph:** consists of information in a Drop down box. Choose the applicable sentence as follows:
   - **For Level of Effort contracts:** Choose the first selection which states that fee will be paid in proportion to level of effort expended.
   - **For Completion contracts:** Choose the second selection which states that fee will be paid based on the percentage of work completed.
   - **For Completion contracts where fee is tied to time:** Use default selection, which is blank.

Note: Because some of the choices are lengthy, you will have to scroll over to the right to locate the drop down icon to select the text.

f. Payment of fee shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

[/The fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended./The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer.]

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****(USE BELOW FOR AN INCREMENTALLY FUNDED, COST-PLUS-FIXED-FEE, MULTI-YEAR CONTRACT (FAR 17.1).)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

1. **Subparagraph a:** Insert periods of performance and amounts in the table.
2. **Subparagraph b:** Select the sentence within the brackets that is appropriate for the contract type. Delete the sentence that does not apply.

Note: *Contract funding shall not be less than the full amount of the first program year in accordance with 17.106-1(g).*

ARTICLE B.10. COST-PLUS-FIXED-FEE - MULTI-YEAR CONTRACT

a. This contract is awarded in accordance with Federal Acquisition Regulation (FAR) Subpart 17.1, Multi-year Contracting. Funding will be provided incrementally to cover the following periods of performance:

Cost reimbursement multi-year table

Program Year	Estimated Cost ($)	Fixed Fee ($)	Estimated Cost Plus Fixed Fee ($)
Year 1 *[Insert Dates]*			
Year 2 *[Insert Dates]*			
Year 3 *[Insert Dates]*			
Year 4 *[Insert Dates]*			
Year 5 *[Insert Dates]*			
Total			

b. [**For completion contracts:** The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer. **- or - For level-of-effort contracts:** The fixed fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended.] Payment of fixed fee shall be subject to the clauses entitled ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

c. Total funds currently obligated under this contract are $ _____ ; of which $ _____ represents the estimated cost; $ _____ represents the fixed fee; and $ _____ represents the cancellation ceiling. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses. The Limitation of Funds clause does not apply to the cancellation ceiling.

d. It is estimated that the amount currently obligated will cover performance of the contract through _____ .

e. The Contracting Officer may obligate additional funds to the contract without the concurrence of the Contractor.

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****(USE BELOW FOR A FULLY FUNDED, COST-PLUS-FIXED-FEE, MULTI-YEAR CONTRACT (FAR 17.1).)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- **Subparagraph b:** Select the sentence within the brackets that is appropriate for the contract type. Delete the sentence that does not apply.

ARTICLE B.10. COST-PLUS-FIXED-FEE - MULTI-YEAR CONTRACT

a. This contract is awarded in accordance with Federal Acquisition Regulation (FAR) Subpart 17.1, Multi-year Contracting.

b. the estimated cost of this contract is $ _____ , and the fixed fee is $ _____ . The total estimated amount of this contract, represented by the sum of the estimated cost plus fixed fee, is $ _____ .

c. [**For completion contracts:** The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer. **- or - For level-of-effort contracts:** The fixed fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended.] Payment of fixed fee shall be subject to the clauses entitled ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

d. For further provisions on funding, see the LIMITATION OF COST clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

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****(USE BELOW FOR AN INCREMENTALLY FUNDED, COST-REIMBURSEMENT (NO FEE), MULTI-YEAR CONTRACT (FAR 17.1).)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- **Subparagraph a:** Insert periods of performance and amounts in the table.

Note: *Contract funding shall not be less than the full amount of the first program year in accordance with 17.106-1(g).*

ARTICLE B.10. COST-REIMBURSEMENT - MULTI-YEAR CONTRACT

a. This contract is awarded in accordance with Federal Acquisition Regulation (FAR) Subpart 17.1, Multi-year Contracting. Funding will be provided incrementally to cover the following periods of performance:

Program Year	**Estimated Cost ($)**
Year 1 *[Insert Dates]*	
Year 2 *[Insert Dates]*	
Year 3 *[Insert Dates]*	
Year 4 *[Insert Dates]*	
Year 5 *[Insert Dates]*	
Total	

b. Total funds obligated to this contract are $ _____ ; of which $ _____ represents the cancellation ceiling. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses. The Limitation of Funds clause does not apply to the cancellation ceiling.
c. It is estimated that the amount currently obligated will cover performance of the contract through _____ .
d. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

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****(USE BELOW FOR A FULLY FUNDED, COST-REIMBURSEMENT (NO FEE), MULTI-YEAR CONTRACT (FAR 17.1.)****

ARTICLE B.10. COST-REIMBURSEMENT - MULTI-YEAR CONTRACT

a. This contract is awarded in accordance with Federal Acquisition Regulation (FAR) Subpart 17.1, Multi-year Contracting. The estimated cost of this contract is $ _____ .
b. For further provisions on funding, see the LIMITATION OF COST clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

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****(USE BELOW IN ALL **INCREMENTALLY FUNDED,** MULTIYEAR CONTRACTS.)****

Do <u>not</u> use this Article in multi-year contracts that are fully funded at award. See note 3 below.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

Table:

- In the "Program Year" column, identify the applicable periods of performance.
- In the "Cancellation Date" column, identify the date by which the cancellation notification is to be given.
- In the "Cancellation Ceiling" column, identify the applicable dollar amount for which the contractor may be entitled if the contract is cancelled. Ceilings must exclude amounts for requirements included in prior program years. The Contracting Officer must reduce the cancellation ceiling for each program year in direct proportion to the remaining requirements subject to cancellation.

NOTES:

1. The full amount of the cancellation ceiling must be funded at award in accordance with 41 U.S.C. 254c.
2. Within the context of FAR Subpart 17.1, "program year" has the same meaning as "contract year."
3. The Government does not create a "cancellation liability" when a multi-year contract is fully funded at award. Therefore, the Article below should not be included in multi-year contracts that are fully funded at award. Cancellation of a fully funded multi-year contract is handled using termination for convenience procedures.

ARTICLE B.11. CANCELLATION CEILING

a. Performance under this contract during the second and subsequent program years is contingent upon the appropriation of funds. All program years except the first are subject to cancellation. Cancellation shall occur by the dates specified below if the Contracting Officer-

1. notifies the Contractor that funds are not available for contract performance for any subsequent program year; or
2. fails to notify the Contractor that funds are available for performance of the succeeding program year.

b. The Government's liability for cancellation charges shall not exceed $ _____ . This amount will be reduced in accordance with FAR 17.106-1(c)(1) at the conclusion of each program year, as follows:

Program Year	Cancellation Date	Cancellation Ceiling
Year 1: *[Insert Dates]* *	N/A	N/A
Year 2: *[Insert Dates]* *	*[Insert Date]*	$ *[insert amount]*
Year 3: *[Insert Dates]* *	*[Insert Date]*	$ *[insert amount]*
Year 4: *[Insert Dates]* *	*[Insert Date]*	$ *[insert amount]*
Year 5: *[Insert Dates]* *	*[Insert Date]*	$ *[insert amount]*

23

****(USE BELOW FOR SINGLE AWARD INDEFINITE QUANTITY TYPE CONTRACTS FOR SUPPLIES OR SERVICES THAT HAVE BEEN IDENTIFIED AND PRICED AT THE TIME OF AWARD.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. **Subparagraph a:** Enter the minimum and maximum dollar amounts for the supplies and/or services to be purchased over the period of performance in the spaces provided.
2. **Subparagraph b:**
   - Select the correct term "costs" or "prices" from the drop-down box.
   - Enter the period of performance in the spaces provided.
3. **Subparagraph c:**
   - Select the appropriate type of order from the drop down box as follows: Delivery Order for Supplies; Task Order for services.
   - Select the correct term "unit price(s)" or "cost(s)" within the brackets, or modify to accurately reflect your situation. Delete the brackets and inapplicable information.
   - Enter the Schedule/Line Items and associated costs/prices. Modify the Table, as necessary, to accurately reflect the costs/prices for each item/line item.

Note: *If the contract will have options, make sure to include the Article B, entitled "Option Prices" or "Estimated Cost - Option" as appropriate.*

ARTICLE B.12. PRICES/COSTS

a. This is an Indefinite Quantity contract as contemplated by FAR 16.504. The Contractor shall be reimbursed by the Government in an amount not less than a total of $ _____ (minimum) nor more than a total of $ _____ (maximum) for successful performance of this contract.

b. The [costs/prices] set forth in this ARTICLE will cover the contract period _____ through _____ .

c. The Government will issue [Task/Delivery] Orders based on the work described in SECTION C of this contract and the following schedule. Upon delivery and acceptance of the item(s) described in each Task Order, the Government shall pay to the Contractor the [unit price(s)/costs] set forth below:

SCHEDULE OF CHARGES FOR THE BASIC AWARD PERIOD

Description of Item	Unit	Price (or Cost)/Unit

24

****(USE BELOW FOR SINGLE AWARD INDEFINITE QUANTITY TYPE CONTRACTS FOR SUPPLIES OR SERVICES WHEN INDIVIDUALLY NEGOTIATED TASK ORDERS WILL BE ISSUED DURING THE PERIOD OF PERFORMANCE.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. **Subparagraph a:** Enter the minimum and maximum dollar amounts for the supplies and/or services to be purchased over the period of performance in the spaces provided.
2. **Subparagraph b:**
   - Select the correct term "costs" or "prices" from the drop-down box.
   - Enter the period of performance in the spaces provided.
3. **Subparagraph c:** Select the appropriate type of order from the drop down box as follows: Delivery Order for Supplies; Task Order for services.

Note: *If the contract will have options, make sure to include the Article B, entitled "Option Prices" or "Estimated Cost - Option" as appropriate.*

ARTICLE B.12. PRICES/COSTS

a. This is an Indefinite Quantity contract as contemplated by FAR 16.504. The Contractor shall be reimbursed by the Government in an amount not less than a total of $ _____ (minimum) nor more than a total of $ _____ (maximum) for successful performance of this contract.

b. The [costs/prices] set forth in this ARTICLE will cover the contract period _____ through _____ .

c. The Government will issue [Task/Delivery] Orders based on the work described in SECTION C of this contract.

25

****(USE BELOW FOR MULTIPLE AWARD INDEFINITE QUANTITY TYPE CONTRACTS FOR SUPPLIES OR SERVICES THAT HAVE BEEN IDENTIFIED AND PRICED AT THE TIME OF AWARD.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. **Subparagraph a:** Enter the minimum and maximum dollar amounts for the supplies and/or services to be purchased over the period of performance in the spaces provided.
2. **Subparagraph b:**
   - Select the correct term "costs" or "prices" from the drop-down box.
   - Enter the period of performance in the spaces provided.
3. **Subparagraph c:**
   - Select the appropriate type of order from the drop down box as follows: Delivery Order for Supplies; Task Order for services.
   - Select the correct term "unit price(s)" or "cost(s)" within the brackets, or modify to accurately reflect your situation. Delete the brackets and inapplicable information.
   - Enter the Schedule/Line Items and associated costs/prices. Modify the Table, as necessary, to accurately reflect the costs/prices for each item/line item.

Note: *If the contract will have options, make sure to include the Article B, entitled "Option Prices" or "Estimated Cost - Option" as appropriate.*

ARTICLE B.12. PRICES/COSTS

a. This is a Multiple Award Indefinite Quantity contract as contemplated by FAR 16.504. The Contractor shall be reimbursed by the Government in an amount not less than a total of $ _____ (minimum) nor more than a total of $ _____ (maximum) for successful performance of this contract.

b. The [costs/prices] set forth in this ARTICLE will cover the contract period _____ through _____ .

c. The Government will compete and award [Task/Delivery] Orders based on the work described in SECTION C of this contract and the following schedule. Upon delivery and acceptance of the item(s) described in each Task Order, the Government shall pay to the Contractor the [unit price(s)/costs] set forth below:

SCHEDULE OF CHARGES FOR THE BASIC AWARD PERIOD

Description of Item	Unit(s)	Price/Unit

d. Ordering procedures are described in The METHOD OF ORDERING Article in SECTION G of this contract.

26

****(USE BELOW FOR MULTIPLE AWARD INDEFINITE QUANTITY TYPE CONTRACTS FOR SUPPLIES OR SERVICES WHEN INDIVIDUALLY NEGOTIATED TASK ORDERS WILL BE ISSUED DURING THE PERIOD OF PERFORMANCE.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. **Subparagraph a:** Enter the minimum and maximum dollar amounts for the supplies and/or services to be purchased over the period of performance in the spaces provided.
2. **Subparagraph b:**
   - Select the correct term "costs" or "prices" within the brackets.
   - Enter the period of performance in the spaces provided.
3. **Subparagraph c:**
   - Select the appropriate type of order from the drop down box as follows: Delivery Order for Supplies; Task Order for services.
   - If the Statement of Work includes specific tasks areas for which each contractor will be qualified, the Contracting Officer may modify this subparagraph to include the specific information. If minimum and maximum amounts are assigned for each Task area as well as the overall contract, they may be included as well.

Note: *If the contract will have options, make sure to include the Article B, entitled "Option Prices" or "Estimated Cost - Option" as appropriate.*

ARTICLE B.12. PRICES/COSTS

a. This is a Multiple Award Indefinite Quantity contract as contemplated by FAR 16.504. The Contractor shall be reimbursed by the Government in an amount not less than a total of $ _____ (minimum) nor more than a total of $ _____ (maximum) for successful performance of this contract.

b. The [prices/costs] set forth in this ARTICLE will cover the contract period _____ through _____ .

c. The Government will compete and award [Task/Delivery] Orders based on the work described in SECTION C of this contract.

d. Ordering procedures are described in The TASK ORDER PROCEDURE Article in SECTION G of this contract.

27

****(USE BELOW FOR FIXED-PRICE CONTRACTS WHEN THE CONTRACTOR WILL BE PAID IN ONE LUMP SUM.)****

ARTICLE B.13. PRICES

a. The total fixed price of this contract is $ _____ .

b. Upon delivery and acceptance of the item(s) specified in the DELIVERY Article in SECTION F and described in SECTION C of this contract, the Government shall pay to the Contractor the total fixed price.

28

****(USE BELOW FOR SUPPLY CONTRACTS, WHEN THE CONTRACTOR WILL RECEIVE PARTIAL PAYMENTS BASED ON THE DELIVERY SCHEDULE SET FORTH IN THE CONTRACT.)****

ARTICLE B.13. PRICES

a. The total fixed price of this contract is $ _____ .
b. Upon delivery and acceptance of the item(s) described in SECTION C of this contract and identified in the schedule of charges below, the Government shall pay to the Contractor the unit price(s) set forth below:

SCHEDULE OF CHARGES FOR THE BASIC AWARD PERIOD

Description of Item	Quantity (Units)	Price ($)	Unit Price ($)	Total ($)

29

****(USE BELOW FOR SERVICE CONTRACTS, WHEN THE CONTRACTOR WILL RECEIVE PARTIAL PAYMENTS BASED ON THE DELIVERY SCHEDULE SET FORTH IN THE CONTRACT.)****

ARTICLE B.13. PRICES

a. The total fixed price of this contract is $ _____ .
b. Upon delivery and acceptance of the services described in SECTION C of this contract and identified in the schedule of charges below, the Government shall pay to the Contractor the unit price(s) set forth below:

SCHEDULE OF CHARGES FOR THE BASIC AWARD PERIOD

Description of Service	Quantity (Units)	Price ($)	Unit Price($)	Total ($)

30

****(USE BELOW FOR CONTRACTS THAT WILL RECEIVE PARTIAL PAYMENTS BASED ON A PERCENTAGE OF THE TOTAL PRICE TIED TO SPECIFIC MILESTONES IDENTIFIED.)****

Note: *The milestones and the percentage of payment MUST be set forth below.*

EXAMPLE SITUATION FOR USE:

This item could be used when the Government is purchasing a large item of equipment in which the Contractor will also be required to install, demonstrate and train personnel on its use. In this case a percentage of the total cost could be paid upon delivery of the equipment and the remaining amount could be paid upon completion of services associated with the equipment.

ARTICLE B.13. PRICES

a. The total fixed price of this contract is $ _____ .

b. Upon delivery and acceptance of the item(s) and/or service(s) specified in the DELIVERY Article in SECTION F and described in SECTION C, the Contractor shall be paid as follows:

PAYMENT SCHEDULE

Description of Service or Item to be Delivered	Percentage (%) of Total Fixed-Price Amount to be Paid	Total Payment Amount

31

****(USE BELOW FOR REQUIREMENTS TYPE CONTRACTS.)****

ARTICLE B.13. PRICES

a. The total estimated amount of this contract is $ _____ .

b. Upon delivery and acceptance of the item(s) described in SECTION C of this contract and identified in the schedule of charges below, the Government shall pay to the Contractor the unit price(s) set forth below:

SCHEDULE OF CHARGES FOR THE BASIC AWARD PERIOD

Description of Item	Quantity (Units)	Price	Unit Price	Total

c. The estimated contract amount and quantity of items set forth in paragraphs a. & b. above is not a guarantee that the estimated quantities will be required or ordered.

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****(USE BELOW FOR FIXED PRICE OPTION CONTRACTS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- **Subparagraph c:**
  - Select the appropriate Headings for the Option Table; e.g. Identify if the Option is an Item or Service;
  - Identify if there is a specific Quantity or a Minimum and Maximum required. Delete the portion of the Heading that does not apply to your contract.

ARTICLE B.14. OPTION PRICES

a. Unless the Government exercises its option pursuant to the option clause referenced in ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES, this contract consists only of the Base Period specified in the Statement of Work as defined in SECTIONS C and F, for the price set forth in ARTICLE B.2. of this contract.

b. Pursuant to [FAR Clause 52.217-6/Option for Increased Quantity/FAR Clause 52.217-7/Option for Increased Quantity-Separately Priced Line Item/FAR Clause 52.217-8/Option to Extend Services/FAR Clause 52.217-9/Option to Extend] set forth in ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES of this contract, the Government may, by unilateral contract modification, require the Contractor to perform the Option Period(s) specified in the Statement of Work as defined in SECTIONS C and F of this contract. If the Government exercises this/these option(s), notice must be given before the expiration date of the contract. Specific information regarding the time frame for this notice is set forth in the OPTION PROVISION Article in SECTION H of this contract. The fixed price of this contract will be increased as set forth in paragraph c., below.

c. Upon the delivery and acceptance of the [Option Item/Option Items/Option Service/Option Services] described in SECTION C of the contract and identified in the schedule of charges below, the Government shall pay the Contractor the unit price(s) set forth below:

Option Period	Description of Option Item(s) -or- Option Service(s)	Quantity (Units) -or- Minimum & Maximum	Unit Price	Total Price of Option -or- Minimum & Maximum

33

****(USE BELOW IN ALL COST-REIMBURSEMENT SOLICITATIONS.)****

ARTICLE B.15. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Conferences & Meetings, 2) Food for Meals, Light Refreshments & Beverages, 3) Promotional Items, 4) Acquisition, by purchase or lease, of any interest in real property; 5) Special rearrangement or alteration of facilities; 6) Purchase or lease of any item of general purpose office

furniture or office equipment regardless of dollar value; 7) Travel Costs including Foreign Travel; 8) Consultant Costs; 9) Subcontract Costs; 10) Patient Care Costs; 11) Accountable Government Property; 12) Printing costs; and 13) Research Funding.

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****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

ARTICLE B.16. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

36

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM :

- Modify the title below as needed and delete additional text.

ARTICLE C.1. [DESCRIPTION-SPECIFICATION-WORKSTATEMENT-STATEMENT OF WORK]

37

****(USE BELOW IN ALL SOLICITATIONS.)****

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated _____ , attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

38

****(USE BELOW WHEN THE PRIVACY ACT IS APPLICABLE TO THE REQUIREMENT.)****

b. The applicable Privacy Act System of Records Number will be specified and shall be used in any design, development, or operation work to be performed under the resultant contract. Disposition of records shall be in accordance with SECTION C of the contract, and by direction of the Contracting Officer Representative (COR).

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS REQUIRING THE SUBMISSION OF PROGRESS REPORTS.)****

ARTICLE C.2. REPORTING REQUIREMENTS

40

****(USE BELOW WHEN SUBMISSION OF REPORTS IN ELECTRONIC FORMAT IS REQUIRED.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. If electronic reports are required under the contract, these reports MUST be submitted Section 508 Compliant regardless of whether or not the contract is for EIT products or services.
2. **First Paragraph:** If you do not want to receive a hardcopy of the report, remove the second sentence.
3. If you would like to receive electronic reports in a particular format, this should be discussed during negotiations and specified in the contract.
4. **Third Paragraph:** If you will not be receiving paper reports/deliverables under the contract, remove this paragraph.

All reports shall be submitted electronically. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

These reports shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: https://www.hhs.gov/web/section-508/index.html and at: https://www.section508.gov/create/documents , "Create Accessible Documents."
All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post-consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

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****(USE BELOW IN NHLBI CONTRACTS WHEN CONTRACTORS ARE REQUIRED TO INCLUDE A LEGEND ON TECHNICAL PROGRESS REPORTS THAT CONTAIN INTERIM STUDY DATA AND A CLAUSE WHICH STATES THE NHLBI'S INTENT FOR THE USE OF INTERIM STUDY DATA.
NHLBI Processes/Procedures Reviewed 9/22)****

a. **Technical Progress Reports Containing Interim Study Data**

1. **Legend for Technical Progress Reports Containing Interim Study Data**

It is recommended that the Contractor incorporate the following legend on the cover of technical progress reports and reports containing study data that are prepared for use by all working committees in their monitoring of the trial. Working committees include but are not limited to the Data and Safety Monitoring Board (DSMB), Steering Committee and Executive Committee.

"The data, if any, contained in this report/deliverable are preliminary and may contain unvalidated findings. These data are not intended for public use. Public use of these data could create erroneous conclusions which, if acted upon, could threaten public health or safety."

2. **Use of Interim Study Data**

Interim data used in technical progress reports and other reports developed for the purpose of study monitoring are not intended for public use. Premature release of such data could result in interpretations that prove to be unreliable or invalid once the study is completed and the full context for the data is known. Unreliable or invalid interpretations can threaten public health and safety by leading the public and medical practitioners to pursue inappropriate measures. In addition, an interpretation of the interim data that is contrary to study protocol could cause participants to drop out of treatment groups. This could prevent completion of the study. A secondary consequence, not in terms of public health and safety, but one that is important in its own right, is that premature release of the data can lead to financial loss to the Government, since any funds spent on a trial that does not answer the questions posed by the study would be devalued.

In consideration of the above, interim data shall be used only for internal study monitoring purposes with the exception of publications and presentations approved in accordance with the programmatic protocol and study procedures.

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****(USE BELOW IN ALL SOLICITATIONS REQUIRING THE SUBMISSION OF PROGRESS REPORTS.)****

b. **Technical Progress Reports**

43

****(USE BELOW IN ALL SOLICITATIONS REQUIRING THE SUBMISSION OF PROGRESS REPORTS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- 2nd Paragraph (Listing): Check only the reports which will be required under the resulting contract(s).

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award. *[Note: Beginning May 25, 2008, the Contractor shall include the applicable PubMed Central or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]*

For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s) _ hard copies of these reports will be required as follows:

[ ] Monthly
[ ] Quarterly
[ ] Semi-Annually
[ ] Annually
[ ] Annually (with a requirement for a Draft Annual Report)
[ ] Final - Upon final completion of the contract
[ ] Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

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****(USE BELOW IN ALL SOLICITATIONS REQUIRING THE SUBMISSION OF PROGRESS REPORTS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- Delete the "Summary of Salient Results" in its entirety if not applicable to the requirement.

Summary of Salient Results

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

45

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN CONTRACT PERFORMANCE MAY INVOLVE AN AGENT OR TOXIN THAT IS LISTED IN THE UNITED STATES GOVERNMENT POLICY FOR INSTITUTIONAL OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN (DURC).)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- For a list of applicable agents or toxins, refer to Section 6 of the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern: https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf
- The Contractor must submit a progress report no less than on an annual basis.

Reporting on Dual Use Research of Concern

a. Progress Report
For work involving an agent or toxin identified in the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern or "DURC policy" (see https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf), the Contractor shall report the following information in the Annual/Semi-Annual/Quarterly/Monthly Progress report:
   i. Identification of agents or toxins that are listed in the DURC policy and used in research funded in this contract, and;
   ii. Proposed modifications, if any, to the risk mitigation plan.

b. Special Notifications
The Contractor shall report to the Contracting Officer's Representative, within 30 calendar days of:
   i. Any change in the status of the DURC project funded under this contract (including whether the research is determined by the Contractor's institutional review entity to no longer meet the definition of DURC);
   ii. Details of any changes to risk mitigation plans (such changes need to be pre-approved by the Contracting Officer Representative), or;
   iii. Instances of noncompliance with the DURC policy, as well as mitigation measures undertaken by the Contractor to prevent recurrences of similar noncompliance.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CLINICAL RESEARCH INVOLVING HUMAN SUBJECTS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

5. **First Paragraph:** For studies funded with **ARRA Funds** , add the following (or similar) language as the second sentence:
   - **"A separate" Cumulative Inclusion Enrollment Report" shall be completed for each clinical research protocol funded with ARRA funds."**
6. **Second paragraph:** Select the sentence appropriate for the type of contract within the brackets below. If appropriate, insert required information. Make sure to delete the sentence that does not apply.

Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations (when appropriate) for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Cumulative Inclusion Enrollment Report," which is set forth in SECTION J of this contract. The

Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report. If the clinical study(s) involves US and non-US sites, the US sites and non-US sites should be reported on separate Cumulative Inclusion Enrollment Reports.

[**For a completion contract add** : The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract. **OR For a Level of Effort Contract add** : The first report shall be due _____ . Thereafter, the report shall be due on or before the _____ day following each reporting period. The final report shall be due on _____].

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October 2001 applies. If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website: https://grants.nih.gov/policy/inclusion/women-and-minorities.htm.
For NIH-defined Phase III Clinical Trials: Include a description of the plans for valid analysis in the study design and outcomes. This includes designing the study in a manner that potential differences, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol could be conducted. Also, provide a description of any analyses by sex/gender, race, and/or ethnicity, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender, race and/or ethnicity.

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**** (USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN CONTRACT PERFORMANCE WILL INVOLVE POSSESSION, USE OR TRANSFER OF *SELECT AGENTS OR TOXINS* AND/OR *HIGHLY PATHOGENIC AGENTS* .

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- Select the **least** frequent applicable report from the drop-down box(es).

Note: This item is generally used for NIAID contracts. However if you have a contract that involves Select Agents or Toxins, you may wish to use this or something similar to meet your needs.

NIAID Processes/Procedures Reviewed 9/22) ****

Reporting on Select Agents or Toxins and/or Highly Pathogenic Agents

For work involving the possession, use, or transfer of a *Select Agent or Toxin* and/or a *Highly Pathogenic Agent* , the following information shall also be included in each [Annual/Semi-Annual/Quarterly/Monthly] Progress Report:

1. Any changes in the use of the Select Agent or Toxin including initiation of "restricted experiments," and/or a Highly Pathogenic Agent, that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or institutional biosafety official.

2. If work with a new or additional *Select Agent or Toxin* and/or a Highly Pathogenic Agent will be conducted in the upcoming reporting period, provide:

a. A list of each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent that will be studied;
b. A brief description of the work that will be done with each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent and whether or not the work is a Select Agent or Toxin restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b https://www.selectagents.gov/regulations/index.htm) or listed on the U.S. Federal Select Agents Registry restricted experiments website (https://www.selectagents.gov/compliance/guidance/restricted/index.htm);
c. The name and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or institutional biosafety official. It must be noted if the work is being done in a new location or different location.
d. For work with Select Agents performed in the U.S. provide documentation of registration status of all domestic organizations where Select Agent(s) will be used. For work with Select Agents performed in a non-U.S. country prior NIAID approval is required.

If the IBC or equivalent body or institutional biosafety official has determined, for example, by conducting a risk assessment, that the work that has been performed or is planned to be performed under this contract may be conducted at a biocontainment safety level that is lower than BSL3, a statement to that affect shall be included in each [Annual/Semi-Annual/Quarterly/Monthly] Progress Report.

If no work involving a Select Agent or Toxin and/or a Highly Pathogenic Agent has been performed or is planned to be performed under this contract, a statement to that affect shall be included in each [Annual/Semi-Annual/Quarterly/Monthly] Progress Report.

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****(USE BELOW WHEN ADDITIONAL REPORTING REQUIREMENTS ARE TO BE INCLUDED IN THE CONTRACT.)****

c. **Other Reports/Deliverables**

49

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR R&D EXCEPT PHASE I SBIR/STTR AND CONTRACTS WITH FEDERAL AGENCIES.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- **First paragraph:** Select the applicable submission format from the drop-down box in the first sentence.

1. **Reporting of Financial Conflict of Interest (FCOI)**

All reports and documentation required by 45 CFR Part 94, Responsible Prospective Contractors including, but not limited to, the New FCOI Report, Annual FCOI Report, Revised FCOI Report, and the Mitigation Report, shall be submitted to the Contracting Officer in [Electronic/Hard Copy] format. Thereafter, reports shall be due in accordance with the regulatory

compliance requirements in 45 CFR Part 94. 45 CFR Part 94 is available at: https://www.ecfr.gov/current/title-45/part-94.

See Part 94.5, Responsibilities of Institutions regarding Investigator financial conflicts of interest for complete information on reporting requirements.

(Reference the INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST Article in SECTION H of this contract.)

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS INVOLVING THE USE OF USDA DESIGNATED BIOBASED PRODUCTS.)****

2. **Report of USDA-Designated Biobased Products**

In accordance with FAR clause 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts, the Contractor shall report to https://www.sam.gov/SAM/ , with a copy to the Contracting Officer any USDA-designated biobased products purchased during the period of October 1-September 30 of each contract year. **This report shall be submitted no later than October 31 of each year during contract performance and on the expiration date of the contract.**

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****(USE BELOW WHEN SOFTWARE WILL BE DEVELOPED, MODIFIED, AND/OR ENHANCED UNDER THE CONTRACT.)****

3. **Source Code and Object Code**

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

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****(INCLUDE BELOW IN SOLICITATIONS WHEN IT HAS BEEN DETERMINED THAT:
• CONTRACTOR PERSONNEL MAY REQUIRE ACCESS TO HHS-CONTROLLED FACILITIES AND/OR INFORMATION SYSTEMS, INCLUDING SENSITIVE DATA/INFORMATION, IN ORDER TO PERFORM THE CONTRACT/ORDER SOW/PWS, AND/OR ;
• THE HOMELAND SECURITY PRESIDENTIAL DIRECTIVE'S (HSPD-12) MORE STRINGENT ACCESS PROCEDURES ARE EXPECTED TO APPLY, BECAUSE ACCESS WILL BE ROUTINE AND OF LONG-TERM DURATION, OR IS ROUTINE AND OF SHORT-TERM DURATION, BUT GREATER ACCESS CONTROLS ARE DEEMED NECESSARY.
ADDITIONAL INFORMATION ABOUT THIS ITEM:)****
1. For more information, see HHS OCIO Program Policies at: https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/information-security-privacy-program/index.html.
2. The Contract Specialist, Project Officer, I/C Information Systems Security Officer (ISSO), and/or Privacy Officer can assist the acquisition staff in tailoring the language in the below Article. If additional guidance is needed, contact the individual responsible for Contracts (Security Language) - located in the NIH Office of the Chief Information Officer (OCIO) - Phone: 301-496-1168; Email: nihciocommunications@mail.nih.gov.

4. **HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS**

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE CONTRACTOR ACCESS TO FEDERAL INFORMATION OR FEDERAL INFORMATION SYSTEMS.)****

INFORMATION AND/OR PHYSICAL SECURITY

A. **Assessment and Authorization (A&A)-** A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) must work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s) within three (3) months after contract award. The Contractor must conduct the A&A requirements in accordance with HHS IS2P, NIST SP 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach (latest revision).
For an existing ATO, Contracting Officer Representative must make a determination if the existing ATO provides appropriate safeguards or if an additional ATO is required for the performance of the contract and state as such.
NIH acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the system security and privacy controls are implemented and operating effectively.

B. **A&A Package Deliverables -** The Contractor (and/or any subcontractor) must provide an A&A package within 30 days of contract award to the CO and/or COR. The following A&A deliverables are required to complete the A&A package.

C. **System Security Plan (SSP) -** due within 30 days after contract award. The SSP must comply with the NIST SP 800-18, Guide for Developing Security Plans for Federal Information Systems, the

Federal Information Processing Standard (FIPS) 200, Recommended Security Controls for Federal Information Systems, and NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline requirements, and other applicable NIST guidance as well as HHS and NIH policies and other guidance. The SSP must be consistent with and detail the approach to IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The SSP must provide an overview of the system environment and security requirements to protect the information system as well as describe all applicable security controls in place or planned for meeting those requirements. It should provide a structured process for planning adequate, cost-effective security protection for a system. The Contractor must update the SSP at least annually thereafter.

D. **Security Assessment Plan/Report (SAP/SAR)** - due 30 days after the contract award. The security assessment must be conducted by the assessor and be consistent with NIST SP 800-53A, NIST SP 800-30, and HHS and NIH policies. The assessor will document the assessment results in the SAR. The NIH should determine which security control baseline applies and then make a determination on the appropriateness/necessity of obtaining an independent assessment. Assessments of controls can be performed by Contractor, government, or third parties, with third party verification considered the strongest. If independent assessment is required, include statement below. Thereafter, the Contractor, in coordination with the NIH shall conduct/assist in the assessment of the security controls and update the SAR at least annually.

E. **Independent Assessment -** due 90 days after the contract award. The Contractor (and/or subcontractor) must have an independent third-party validate the security and privacy controls in place for the system(s). The independent third party must review and analyze the Security Authorization package, and report on technical, operational, and management level deficiencies as outlined in NIST SP 800-53. The Contractor must address all "high" deficiencies before submitting the package to the Government for acceptance. All remaining deficiencies must be documented in a system Plan of Actions and Milestones (POA&M).

F. **Plan of Actions and Milestones (POA&M) -** due 30 days after contract award. The POA&M must be documented consistent with the HHS Standard for Plan of Action and Milestones and NIH policies. All findings/weaknesses must be documented in the POA&M and remediated/mitigated from the date the weaknesses are formally identified and documented by the timelines below:

- Critical within 30 days;
- High within 60 days;
- Medium within 1 year; and
- Low within 1 year.

G.

The NIH will determine the risk rating of vulnerabilities. Identified risks stemming from deficiencies related to the security control baseline implementation, assessment, continuous monitoring, vulnerability scanning, and other security reviews and sources, as documented in the SAR, must be documented and tracked by the Contractor for mitigation in the POA&M document. Depending on the severity of the risks, NIH may require designated POAM weaknesses to be remediated before

an ATO is issued. Thereafter, the POA&M must be updated at least quarterly.

H. **Contingency Plan and Contingency Plan Test -** due 60 days after contract award. The Contingency Plan must be developed in accordance with NIST SP 800-34, Contingency Planning Guide for Federal Information Systems, and be consistent with HHS and NIH policies. Upon acceptance by the System Owner, the Contractor, in coordination with the System Owner, must test the Contingency Plan and prepare a Contingency Plan Test Report that includes the test results, lessons learned and any action items that need to be addressed. Thereafter, the Contractor must update and test the Contingency Plan at least annually.

I. **E-Authentication Questionnaire -** The contractor (and/or any subcontractor) must collaborate with government personnel to ensure that an E-Authentication Threshold Analysis (E-auth TA) is completed to determine if a full E-Authentication Risk Assessment (E-auth RA) is necessary. System documentation developed for a system using E-auth TA/E-auth RA methods must follow OMB 04-04 and NIST SP 800-63, Rev. 2, Electronic Authentication Guidelines.
Based on the level of assurance determined by the E-Auth, the Contractor (and/or subcontractor) must ensure appropriate authentication to the system, including remote authentication, is in-place in accordance with the assurance level determined by the E-Auth (when required) in accordance with HHS policies.

I. **POSITION SENSITIVITY DESIGNATIONS**

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). To determine the designation, the Position Designation Tool (PDT) discussion is found at: https://www.ors.od.nih.gov/ser/dpsac/resources/Pages/investigation-requirements-for-your-position.aspx and the link to access the tool is found at: https://pdt.nbis.mil/ .

The following position sensitivity designation levels apply to this solicitation/contract:

[ ] Tier 5: Critical Sensitive and Special Sensitive National Security, including Top Secret, SCI, and "Q" access eligibility.
[ ] Tier 5SR: Reinvestigation.

[ ] Tier 4: High Risk Public Trust (HRPT).
[ ] Tier 4SR: Reinvestigation.

[ ] Tier 3: Non-Critical Sensitive, National Security, including Secret and "L" access eligibility.
[ ] Tier 3SR: Reinvestigation.

[ ] Tier 2S with Subject Interview: Moderate Risk Public Trust (MRPT).
[ ] Tier 2SR: Reinvestigation.

[ ] Tier 1: Low Risk, Non-Sensitive, including HSPD-12 Credentialing.

J. **HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12**

Roster-

The Contractor (and/or any subcontractor) must submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster must be submitted to the COR and/or CO within fourteen (14) calendar days after the effective date of this contract. Any revisions to the roster as a result of staffing changes must be submitted within seven (7) calendar days of the change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j

a. If the Contractor is filling a new position, the Contractor must provide a position description and the Government will determine the appropriate suitability level. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.
b. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor must complete and submit the required forms within 30 days of the notification.
c. The Contractor must notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.
d. All contractor and subcontractor employees must comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract. Contractors may begin work after the fingerprint check has been completed.
e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor must ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.
f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more that the cost of the additional investigation(s).
g. The Contractor must include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
h. The Contractor must direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.
i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor must return all identification badges to the Contracting Officer or designee.

K. **CONTRACT INITIATION AND EXPIRATION**

a. **General Security Requirements** - The Contractor (and/or any subcontractor) must comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the Contractor must follow the HHS EPLC framework and methodology or and in accordance with the HHS Contract Closeout Directive (2018) located at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HHS-Closeout-Directive-2018.pdf . HHS EA requirements located at: https://www.hhs.gov/sites/default/files/eplc-policy-dec-2016.pdf and NIH EA requirements are located at: https://ocio.nih.gov/PM/Pages/EPLC.aspx .

b. **System Documentation** - Contractors (and/or any subcontractors) must follow and adhere to HHS System Development Life Cycle requirements, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.

c. **Sanitization of Government Files and Information** - As part of contract closeout and at expiration of the contract, the Contractor (and/ or any subcontractor) must provide all required documentation in accordance with the NIH Media Sanitization and Disposal Policy to the CO and/ or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

d. **Notification** - The Contractor (and/ or any subcontractor) must notify the CO and/ or COR and system ISSO within fifteen days before an employee stops working under this contract.

e. **Contractor Responsibilities Upon Physical Completion of the Contract-** The Contractor (and/ or any subcontractors) must return all government information and IT resources (i.e., government information in non- government- owned systems, media, and backup systems) acquired during the term of this contract to the CO and/ or COR. Additionally, the Contractor must provide a certification that all government information has been properly sanitized and purged from Contractor- owned systems, including backup systems and media used during contract performance, in accordance with HHS and/ or NIH policies.

f. The Contractor (and/or any subcontractor) must perform and document the actions identified in the NIH Contractor Employee Separation Checklist https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf when an employee terminates work under this contract within 2 days of the employee's exit from the contract. All documentation must be made available to the CO and/ or COR upon request.

g. **Contractor Non- Disclosure Agreement (NDA)-** Each Contractor (and/ or any subcontractor) employee having access to non- public government information under this contract shall complete the NIH non- disclosure agreement: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf , as applicable. A copy of each signed and witnessed NDA must be submitted to the Contracting Officer (CO) and/ or CO Representative (COR) prior to performing any work under this acquisition.

h. **Vulnerability Scanning Reports -** The Contractor must report the results of the required monthly special vulnerability scans no later than 10 days following the end of each reporting period. If

required monthly, this report may be included as part of the Technical Progress Report. Otherwise, this report must be submitted under a separate cover on monthly basis.

i. **Government Access for Security Assessment.** In addition to the Inspection Clause in the contract, the Contractor (and/or any subcontractor) must afford the Government access to the Contractor's facilities, installations, operations, documentation, information systems, and personnel used in performance of this contract to the extent required to carry out a program of security assessment (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the confidentiality, integrity, and availability of federal data or to the protection of information systems operated on behalf of HHS, including but are not limited to:

   i. At any tier handling or accessing information, consent to and allow the Government, or an independent third party working at the Government's direction, without notice at any time during a weekday during regular business hours contractor local time, to access contractor and subcontractor installations, facilities, infrastructure, data centers, equipment (including but not limited to all servers, computing devices, and portable media), operations, documentation (whether in electronic, paper, or other forms), databases, and personnel which are used in performance of the contract. The Government includes but is not limited to the U.S. Department of Justice, U.S. Government Accountability Office, and the HHS Office of the Inspector General (OIG). The purpose of the access is to facilitate performance inspections and reviews, security and compliance audits, and law enforcement investigations. For security audits, the audit may include but not be limited to such items as buffer overflows, open ports, unnecessary services, lack of user input filtering, cross site scripting vulnerabilities, SQL injection vulnerabilities, and any other known vulnerabilities.
   ii. At any tier handling or accessing protected information, fully cooperate with all audits, inspections, investigations, forensic analysis, or other reviews or requirements needed to carry out requirements presented in applicable law or policy. Beyond providing access, full cooperation also includes, but is not limited to, disclosure to investigators of information sufficient to identify the nature and extent of any criminal or fraudulent activity and the individuals responsible for that activity. It includes timely and complete production of requested data, metadata, information, and records relevant to any inspection, audit, investigation, or review, and making employees of the contractor available for interview by inspectors, auditors, and investigators upon request. Full cooperation also includes allowing the Government to make reproductions or copies of information and equipment, including, if necessary, collecting a machine or system image capture.
   iii. Segregate Government protected information and metadata on the handling of Government protected information from other information. Commingling of information is prohibited. Inspectors, auditors, and investigators will not be precluded from having access to the sought information if sought information is commingled with other information.
   iv. Cooperate with inspections, audits, investigations, and reviews.

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****(USE BELOW IN MULTIPLE YEAR SOLICITATIONS AND CONTRACTS OVER THE SIMPLIFIED ACQUISITION THRESHOLD WHICH CONTAIN THE ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY ARTICLE IN SECTION H OF THE CONTRACT.)****

4. **Section 508 Annual Report**

The Contractor must submit an annual Section 508 report in accordance with the schedule set forth by the Contracting Officer (CO)/Contracting Officer's Representative (COR). The Section 508 Report Template and Instructions for completing the report are available at: https://www.hhs.gov/sites/default/files/web/508/contracting/technology/section_508_annual_report.doc.

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****(USE BELOW WHEN THE SOLICITATION INCLUDES LANGUAGE FOR MULTIPLE PRINCIPAL INVESTIGATORS.)****

5. **Multiple Principal Investigators Leadership Plan**

The Contractor must submit a revised/updated Leadership Plan in the event of a change in any of the Principal Investigators named in the Key Personnel Article in SECTION G of this contract. The revised plan is subject to review and approval by the Contracting Officer.

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****(NHLBI: USE BELOW FOR CONTRACTS THAT INCLUDE THE NHLBI POLICY FOR DATA SHARING FROM CLINICAL TRIALS AND EPIDEMIIOLOGICAL STUDIES CLAUSE IN SECTION H.
NHLBI Processes/Procedures Reviewed 9/22)****

6. **NHLBI Policy for Data Sharing from Clinical Trials and Epidemiological Studies**

The Contractor must provide data sets for the study with full documentation. The data set and documentation shall be prepared in accordance with the NHLBI's Data Set policy at: https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/nhlbi-policy-for-data-sharing-from-clinical-trials-and-epidemiological-studies.

57

****(USE BELOW IN NIAID SOLICITATIONS AND CONTRACTS REQUIRING THE SUBMISSION OF ELECTRONIC CONTRACT DELIVERABLES SUBMITTED VIA eRDS.
NIAID Processes/Procedures Reviewed 9/22)****

7. **REPORTING REQUIREMENTS FOR USE WITH THE ELECTRONIC REPORT DELIVERABLE SUBMISSION (eRDS) SITE**

All reports required herein must be submitted in electronic format. All electronic contract deliverables must be submitted via the NIAID electronic Report Deliverable Submission

(eRDS) Site, available at the following website: https://erds.niaid.nih.gov/ . All electronic reports submitted must be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at https://www.hhs.gov/web/section-508/index.html and at: https://www.section508.gov/create/documents , "Create Accessible Documents."

58

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHICH CONTAIN EITHER OF THE FOLLOWING PATENT RIGHTS CLAUSES: 52.227-11, Patent Rights-Ownership by the Contractor; or 52.227-13, Patent Rights-Ownership by the Government.)****

Note: *52.227-11 is included in the general clause listings for R&D contracts. See FAR 27.303(e) for applicability information relating to 52.227-13.*

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

1. **First paragraph:** Select the applicable clause from the drop-down box in the first sentence.
2. **Second paragraph:**

a. Select the sentence appropriate for the type of contract within the brackets below. If appropriate, insert required information. Make sure to delete the sentence that does not apply.
b. Include complete address.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by [FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor/FAR Clause 52.227-13, Patent Rights-Ownership by the Government] including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

[**For a completion or fixed-price contract add** : The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract/ **For a level of effort contract add**: The first annual utilization report shall be due on or before _____ . Thereafter, reports shall be due on or before the __ [Calendar/Working] day following the reporting period.] The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
_____
Office of Acquisition
_____
_____ , Room __
Bethesda, Maryland 20892 - __

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, the NIH has developed "Interagency Edison," an electronic invention reporting system. Use of Interagency Edison is required as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

59

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

SECTION D - PACKAGING, MARKING AND SHIPPING

60

****(USE BELOW WHEN NO SPECIFIC PACKAGING, MARKING AND SHIPPING INSTRUCTIONS ARE REQUIRED.)****

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

61

****(USE ALL THREE ITEMS BELOW FOR SOLICITATIONS AND CONTRACTS THAT WILL REQUIRE SPECIAL PACKAGING, MARKING AND SHIPPING SPECIFICATIONS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

Tailor each Article of this section according to the specifications given by the Program Official in the event certain deliverables must be especially packaged and marked. Examples of deliverables which would be included in this category could be, but are not limited to, the following:

- Tissues, cells, etc., packaged in dry ice;
- Animals in specific containers;
- Blood samples in specific containers; and,
- Drugs in specific containers.

ARTICLE D.1. PACKAGING

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ARTICLE D.2. MARKING

63

ARTICLE D.3. SHIPPING

64

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

SECTION E - INSPECTION AND ACCEPTANCE

65

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

1. **FOR RFP:**
   - Subparagraph b: Leave blank.
   - Subparagraph c: Provide a General Address, i.e. Name of Institute, City, State.
2. **FOR CONTRACT:**
   - Subparagraph b: Identify the individual (name and title) authorized to inspect deliverables/services; e.g. Contracting Officer's Representative (COR).
   - Subparagraph c: Provide as complete an address as possible.

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, _____ is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:

_____

_____

_____

_____

_____

_____

_____

_____

66

****(PROVIDING THE TERMS FOR ACCEPTANCE IS MANDATORY. USE BELOW WHEN A SPECIFIC INDIVIDUAL WILL SPECIFY ACCEPTANCE IN WRITING. WHEN ACCEPTANCE WILL BE ACCOMPLISHED BY A SIGNED RECEIVING REPORT, DO NOT USE THIS ITEM.)****

Note: *The number of days may be changed depending on the situation.*

IF THIS PARAGRAPH IS NOT APPROPRIATE, OR DOES NOT REFLECT THE NEEDS OF THE REQUIREMENT, MAKE SURE TO MODIFY THE LANGUAGE BELOW TO SPECIFY THE TERMS FOR ACCEPTANCE AND HOW ACCEPTANCE WILL BE CONVEYED.

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

67

****(PROVIDING THE TERMS FOR ACCEPTANCE IS MANDATORY. USE BELOW WHEN AN ACCEPTANCE WILL BE ACCOMPLISHED BY A SIGNED RECEIVING REPORT. WHEN A SPECIFIC INDIVIDUAL WILL SPECIFY ACCEPTANCE IN WRITING, DO NOT USE THIS ITEM.)****

Note: *You must include the number of days for the inspection period.*

IF THIS PARAGRAPH IS NOT APPROPRIATE, OR DOES NOT REFLECT THE NEEDS OF THE REQUIREMENT, MAKE SURE TO MODIFY THE LANGUAGE BELOW TO SPECIFY THE TERMS FOR ACCEPTANCE AND HOW ACCEPTANCE WILL BE CONVEYED.

The Government reserves the right to an Inspection period of __ calendar days, unless a different time period is stated when (the Record of Call/elsewhere in the contract). The receiving report, completed and signed by the appropriate official, constitutes acceptance and shall be acknowledged to the payment office (OFM).

68

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

69

****(USE BELOW FOR SOLICITATIONS AND CONTRACTS FOR SUPPLIES OR SERVICES THAT ARE EXPECTED TO BE AT OR BELOW THE SIMPLIFIED ACQUISITION THRESHOLD UNLESS THE CONTRACTING OFFICER HAS DETERMINED THAT THE GOVERNMENT HAS A NEED TO TEST THE SUPPLIES OR SERVICES.)****

See FAR 46.202-2.

FAR Clause **52.246-1, Contractor Inspection Requirements** (April 1984).

70

****(USE BELOW FOR FIXED-PRICE SOLICITATIONS AND CONTRACTS, OVER THE SIMPLIFIED ACQUISITION THRESHOLD, FOR SUPPLIES OR SERVICES INVOLVING THE FURNISHING OF SUPPLIES.)****

FAR Clause **52.246-2, Inspection of Supplies - Fixed Price** (August 1996).

71

****(USE BELOW FOR COST REIMBURSEMENT SOLICITATIONS AND CONTRACTS FOR SUPPLIES OR SERVICES INVOLVING THE FURNISHING OF SUPPLIES.)****

FAR Clause **52.246-3, Inspection of Supplies - Cost-Reimbursement** (May 2001).

72

****(USE BELOW FOR FIXED-PRICE SOLICITATIONS AND CONTRACTS, OVER THE SIMPLIFIED ACQUISITION THRESHOLD, FOR SERVICES OR SUPPLIES THAT INVOLVE THE FURNISHING OF SERVICES.)****

FAR Clause **52.246-4, Inspection of Services - Fixed Price** (August 1996).

73

****(USE BELOW FOR COST-REIMBURSEMENT SOLICITATIONS AND CONTRACTS WHICH ARE MORE R&D SUPPORT ORIENTED.)****
See FAR 46.305 for additional information.

FAR Clause **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).

74

****(USE BELOW FOR A TIME-AND-MATERIAL OR LABOR HOUR CONTRACT.)****
ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- Use this Clause with its ALTERNATE I, if Government inspection and acceptance are to be performed at the Contractor's plant.

FAR Clause **52.246-6, Inspection Time-and Material and Labor Hour** (May 2001).

Alternate I (April 1984) [is not/is] applicable to this contract.

75

****(USE BELOW FOR FIXED-PRICE SOLICITATIONS AND CONTRACTS, OVER THE SIMPLIFIED ACQUISITION THRESHOLD, WHEN THE PRIMARY OBJECTIVE OF THE REQUIREMENT IS THE DELIVERY OF END ITEMS OTHER THAN DESIGNS, DRAWINGS, OR REPORTS UNLESS USE OF THIS CLAUSE IS IMPRACTICABLE AND FAR CLAUSE 52.246-9, BELOW, IS MORE APPROPRIATE.)****

FAR Clause **52.246-7, Inspection of Research and Development - Fixed Price** (August 1996).

76

****(USE BELOW FOR COST REIMBURSEMENT SOLICITATIONS AND CONTRACTS WHICH ARE R&D AND THE PRIMARY OBJECTIVE IS THE DELIVERY OF END ITEMS OTHER THAN DESIGNS, DRAWINGS, OR REPORTS UNLESS ITS USE IS IMPRACTICAL AND FAR CLAUSE 52.246-9 IS MORE APPROPRIATE.)****
ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- Use this Clause with its ALTERNATE I, if the Contract is to be awarded on a no-fee basis.

FAR Clause **52.246-8, Inspection of Research and Development - Cost-Reimbursement** (May 2001).

Alternate I (April 1984) [is not/is] applicable to this contract.

77

****(USE BELOW FOR SOLICITATIONS AND CONTRACTS WHOSE PRIMARY OBJECTIVE IS THE DELIVERY OF END ITEMS SUCH AS DESIGNS, DRAWINGS, OR REPORTS AND USE OF THIS CLAUSE IS MORE APPROPRIATE THAN FAR CLAUSE 52.246-7 or 52.246-8.)****

FAR Clause **52.246-9, Inspection of Research and Development (Short Form)** (April 1984).

78

****(USE BELOW FOR FIXED-PRICE CONSTRUCTION CONTRACTS OVER THE SIMPLIFIED ACQUISITION THRESHOLD. **Note** *: This clause may be used for contracts at or below the simplified acquisition threshold at the Contracting Officer's discretion.*)****

FAR Clause **52.246-12, Inspection of Construction** (August 1996).

79

****(USE BELOW FOR ALL FIXED-PRICE SOLICITATIONS AND CONTRACTS FOR 1) SUPPLIES; 2) SERVICES INVOLVING THE FURNISHING OF SUPPLIES, OR; 3) R&D AT OR ABOVE THE SIMPLIFIED ACQUISITION THRESHOLD.)****

FAR Clause **52.246-16, Responsibility for Supplies** (April 1984).

80

****(USE BELOW FOR ALL SOLICITATIONS AND CONTRACTS.)****

SECTION F - DELIVERIES OR PERFORMANCE

81

****(USE BELOW FOR: 1) LEVEL OF EFFORT COST-REIMBURSEMENT SOLICITATIONS AND CONTRACTS, AND 2) FIXED-PRICE SOLICITATIONS AND CONTRACTS FOR SERVICES.)****

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract shall be from _____ through _____ .

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****(USE BELOW FOR SOLICITATIONS AND CONTRACTS THAT CONTAIN OPTIONS.)****

ARTICLE F.2. PERIOD OF PERFORMANCE

a. The period of performance of this contract shall be from _____ through _____ .
b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Period

83

****(THIS IS ONE OF SEVERAL DELIVERY SCHEDULES. SELECT THE DELIVERY SCHEDULE WHICH IS MOST APPROPRIATE FOR THE CONTRACT. THE CONTRACTING OFFICER SHOULD TAILOR THE SCHEDULE TO EACH INDIVIDUAL CONTRACT. ALSO, WHERE APPLICABLE, OPTIONS SHOULD BE INCLUDED.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

1. **First Paragraph:** Select the appropriate title of the Article from the Drop Down List.
2. **Subparagraph a:**
   - Eliminate bracketed sentence below, if SECTION D does not identify specific package, marking and shipping instructions.
   - If the F.O.B Destination Clause identified is not appropriate, make the necessary change.
   - Complete the information in the Table as required. Reference should be made to all items listed and described in SECTION C. including all technical reports which are considered deliverables. For Fixed-Price contracts, deliverables should be tied to prices.
3. **Subparagraph b:** Include in all required deliverables. Provide complete Titles and Addresses for each Addressee.

ARTICLE F.3. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the [Description/Specification/Workstatement/Statement of Work] Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below [and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract]:

Item	Description	Quantity	Delivery Schedule
(1)			
(2)			
(3)			

b. The above items shall be addressed and delivered to:

Addressee	Deliverable Item No	Quantity

84

****(THIS IS ONE OF SEVERAL DELIVERY SCHEDULES. SELECT THE DELIVERY SCHEDULE WHICH IS MOST APPROPRIATE FOR THE CONTRACT. THE CONTRACTING OFFICER SHOULD TAILOR THE SCHEDULE TO EACH INDIVIDUAL CONTRACT. ALSO, WHERE APPLICABLE, OPTIONS SHOULD BE INCLUDED.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

1. **Subparagraph a:**
   - Select the appropriate title of the Article from the Drop Down List.
   - Select the appropriate work from the Drop Down List.
2. **Subparagraph b:**
   - If the F.O.B Destination Clause identified is not appropriate, make the necessary change.
   - Eliminate bracketed sentence, if SECTION D does not identify specific package, marking and shipping instructions.
   - Provide a complete address for the Delivery Point.

ARTICLE F.4. DELIVERIES

a. Satisfactory performance of this contract shall be deemed to occur upon performance of the work described in the [Description/Specification/Workstatement/Statement of Work] Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the [Services/Supplies/Items] specified in the Delivery Schedule which are described in SECTION C of this contract.

b. Deliveries required by the Contractor shall be made F.o.b. destination as set forth in FAR Clause 52.247-35, F.o.b. Destination, Within consignees Premises (April 1984) [and any specifications stated in SECTION D, PACKAGING AND MARKING AND SHIPPING, of this contract] to the address/addressee listed below:

c.

Delivery Address

d. Unless otherwise specified, deliveries shall be made to the Delivery Point specified above Mondays through Fridays (excluding Federal Holidays) between the hours of 8:30 a.m. and 5:30 p.m. EST only. Supplies or services scheduled for delivery on a Federal holiday shall be made the following day.

85

****(THIS IS ONE OF SEVERAL DELIVERY SCHEDULES. SELECT THE DELIVERY SCHEDULE WHICH IS MOST APPROPRIATE FOR THE CONTRACT. THE CONTRACTING OFFICER SHOULD TAILOR THE SCHEDULE TO EACH INDIVIDUAL CONTRACT. ALSO, WHERE APPLICABLE, OPTIONS SHOULD BE INCLUDED.)****

ARTICLE F.5. TIME OF DELIVERY

a. The Government requires delivery of _____ within __ days after [Receipt of each record of call/Date of contract award] .

b. The Contractor may propose a delivery schedule which is earlier than required above. If the Contractor does not propose a different delivery schedule, the Government's desired delivery schedule shall apply.

c. Proposed Delivery Schedule: Delivery of _____ within __ days after [Receipt of each record of call/Date of contract award] .

86

****(THIS IS ONE OF SEVERAL DELIVERY SCHEDULES. SELECT THE DELIVERY SCHEDULE WHICH IS MOST APPROPRIATE FOR THE CONTRACT. THE CONTRACTING OFFICER SHOULD TAILOR THE SCHEDULE TO EACH INDIVIDUAL CONTRACT. ALSO, WHERE APPLICABLE, OPTIONS SHOULD BE INCLUDED.)****

ARTICLE F.6. TIME OF DELIVERY

a. The Government requires delivery to be made according to the following schedule:

REQUIRED DELIVERY SCHEDULE

Item Number	Description	Quantity	Within Days After Date of Contract Award

b. The Contractor may propose a delivery schedule which is earlier than required above. If the Contractor does not propose a different delivery schedule, the Government's desired delivery schedule shall apply.

c.

PROPOSED DELIVERY SCHEDULE

Item Number	Description	Quantity	Within Days After Date of Contract Award

87

****(THIS IS ONE OF SEVERAL DELIVERY SCHEDULES. SELECT THE DELIVERY SCHEDULE WHICH IS MOST APPROPRIATE FOR THE CONTRACT. THE CONTRACTING OFFICER SHOULD TAILOR THE SCHEDULE TO EACH INDIVIDUAL CONTRACT. ALSO, WHERE APPLICABLE, OPTIONS SHOULD BE INCLUDED.)****

ARTICLE F.7. DESIRED AND REQUIRED TIME OF DELIVERY

a. The Government desires delivery to be made according to the following schedule:

DESIRED DELIVERY SCHEDULE

Item Number	Description	Quantity	Within Days After Date of Contract Award

b. If the Contractor is unable to meet the desired delivery schedule, it may, propose a delivery schedule below. However, the Contractor's proposed delivery schedule must not extend the delivery period beyond the time for delivery in the Government's required delivery schedule set forth in paragraph c., below.

c.

REQUIRED DELIVERY SCHEDULE

Item Number	Description	Quantity	Within Days After Date of Contract Award

d. If the Contractor proposes no other delivery schedule, the Desired Delivery Schedule set forth in paragraph a., above will apply.

e.

CONTRACTOR'S PROPOSED DELIVERY SCHEDULE

Item Number	Description	Quantity	Within Days After Date of Contract Award

88

****(USE BELOW FOR LEVEL OF EFFORT SOLICITATIONS AND CONTRACTS WHICH DEFINE THE EFFORT IN TERMS OF HOURS, MONTHS, OR YEARS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

1. **First Paragraph:**
   - **For Solicitations:** Leave the Number of Labor Hours (Months or Years) blank.
   - **For Contracts:** Fill in the Number of Labor Hours (Months or Years)
   - Select the appropriate effort type from the Drop Down List each time it appears. For RFPs, use the combined selection: [HOURS, MONTHS, YEARS].
   - Select the appropriate inclusion factor from the Drop Down List each time it appears. For RFPs, use the combined selection: [INCLUDE/EXCLUDE].
2. **TABLE:**
   - **For Solicitations:**
     - Select the combined selection: [HOURS, MONTHS, YEARS] from the Drop Down List.
     - Leave the rest of the table blank.
   - **For Contracts:**
     - Select the appropriate effort type from the Drop Down List.
     - Itemize categories below as necessary.
     - If Options are used, make sure that this paragraph addresses option year effort and indicates that this effort is contingent upon exercising each option period.

ARTICLE F.8. LEVEL OF EFFORT

89

a. During the period of performance of this contract, the Contractor shall provide ____ direct labor [Hours/Months/Years] . The labor [Hours/Months/Years] [Include/Exclude] vacation, holiday, and sick leave. These labor [Hours/Months/Years] [Include/Exclude] subcontractor labor [Hours/Months/Years] . It is estimated that the labor [Hours/Months/Years] are constituted as specified below and will be expended approximately as follows:

Labor [HOURS, MONTHS, YEARS]

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Professional							
Other Professional							
Support							
Totals							

90

****(USE BELOW FOR ALL LEVEL OF EFFORT SOLICITATIONS AND CONTRACTS. THIS PARAGRAPH DEFINES PERCENTAGES REQUIRED BY TOTAL LEVEL OF EFFORT - HOURS, MONTHS, YEARS. THE RANGE MAY BE FROM 90% TO 110%.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

1. Fill in the Percentage of Direct Labor effort required to determine satisfactory performance. Note: It is not necessary to complete for RFPs.
2. Select the appropriate effort type from the Drop Down List. For RFPs, use the combined selection: [HOURS, MONTHS, YEARS].

b. The Contractor shall have satisfied the requirement herein if not less than __ % nor more than __ % of the total direct labor [Hours/Months/Years] specified herein are furnished. These terms and conditions do not supersede the requirements of either the "Limitation of Cost" or "Limitation of Funds" clause.

91

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT ARE TO BE CPFF, LEVEL OF EFFORT.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- Select the appropriate effort type from the Drop Down List each time it appears. For RFPs, use the combined selection: [HOURS, MONTHS, YEARS].

c. In the event fewer [Hours/Months/Years] than the minimum specified number of direct labor [Hours/Months/Years] in the total categories are used by the Contractor in accomplishing the prescribed work and the Government has not invoked its rights under FAR Clause 52.249-6, TERMINATION (Cost-Reimbursement) incorporated in this contract, these parties agree that the fee will be adjusted based solely upon the quantity of [Hours/Months/Years] by which the number of direct labor [Hours/Months/Years] furnished is less than the number of direct labor [Hours/Months/Years] specified in this ARTICLE. The resulting adjustment shall be evidenced by a contract modification.

92

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT CONTAIN THE ARTICLE H. RESEARCH AND DEVELOPMENT DATA IN THE ELECTRONIC RESEARCH ADMINISTRATION (eRA) SYSTEM.)****

ARTICLE F.9. NOTIFICATION OF COMPLETION OF RESEARCH AND DEVELOPMENT DATA ENTRY IN ELECTRONIC RESEARCH ADMINISTRATION (eRA) SYSTEM

The Contractor shall provide a written notification of completion of research and development data entry, as required in section H of this contract, in the eRA system to the NIH COR within fifteen (15) calendar days of being notified by the eRA system. [The notification will come in the form of an eRA system-generated email, sent to the Contractor's registered user(s) under the contract].

93

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- Use this Clause with its ALTERNATE I, EXCEPT for Fixed-Price contracts.
- For Fixed-Price Contracts, select "is not" from the drop-down box.

ARTICLE F.10. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEB 1998).

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: https://www.acquisition.gov/?q=browsefar.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989).

Alternate I (April 1984) [is/is not] applicable to this contract.

94

****(USE BELOW FOR FIXED-PRICE SOLICITATIONS AND CONTRACTS. THIS CLAUSE IS OPTIONAL FOR FIXED-PRICE SERVICE CONTRACTS.)****

52.242-17, Government Delay of Work (April 1984).

95

****(USE BELOW IN FIXED-PRICE SOLICITATIONS AND CONTRACTS FOR SUPPLIES, SERVICE, RESEARCH AND DEVELOPMENT WHEN THE CONTRACTING OFFICER DETERMINES LIQUIDATED DAMAGES ARE APPROPRIATE.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- Contracting Officer to insert amount of liquidated damages.

52.211-11, Liquidated Damages--Supplies, Services or Research and Development (September 2000).

"(a) If the Contractor fails to deliver the supplies or perform the services within the time specified in this contract, the Contractor shall, in place of actual damages, pay to the Government liquidated damages of $ _____ per calendar day of delay [Contracting Officer insert amount]."

96

****(USE BELOW FOR CONTRACTS WHICH DO NOT CONTAIN A DELIVERY ARTICLE, i.e. Level of Effort.)****

52.247-35, F.o.b. Destination Within Consignees Premises (April 1984).

97

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

SECTION G - CONTRACT ADMINISTRATION DATA

98

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

1. **For Solicitations:** Type: "[To be specified prior to award]" in the text box after the first sentence.
   For Contracts:
   - Type: Contracting Officer Representative (COR) Name in the text box after the first sentence.
   - If an Alternate COR will be assigned to the contract, specify the alternate's name with the title "Alternate COR" and include the third paragraph in brackets.
2. **Third paragraph [within brackets]:** Include this paragraph when an Alternate COR will be assigned to the contract. If no Alternate COR will be assigned delete the paragraph in its entirety.

ARTICLE G.1. CONTRACTING OFFICER REPRESENTATIVE (COR)

The following Contracting Officer Representative (COR) will represent the Government for the purpose of this contract:

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

[The alternate COR is responsible for carrying out the duties of the COR only in the event that the COR can no longer perform his/her duties as assigned.]

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract; or (6) sign written licensing agreements. Any signed agreement shall be incorporated by reference in Section K of the contract

The Government may unilaterally change its COR designation.

99

****(USE BELOW FOR ALL SOLICITATIONS AND CONTRACTS WHEN THE CONTRACTING OFFICER WILL REQUIRE THE CONTRACTOR TO DESIGNATE CONTRACTOR KEY PERSONNEL.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **Table:** When Multiple Principal Investigators are named, the "Contact PI" MUST be specified.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.237-75 (December 2015).

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the contractor is terminated for cause or separates from the contractor voluntarily with less than thirty days' notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

(End of clause).

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title

100

****(USE BELOW IN WORK ASSIGNMENT SOLICITATIONS AND CONTRACTS.)****

ARTICLE G.3. WORK ASSIGNMENT PROCEDURES

In providing support under this contract, the Contractor shall initiate work only when so directed by a Work Assignment (Attachment provided in SECTION J). Approval of a Work Assignment shall **not** constitute approval to exceed any item listed in the contract or general clauses of the contract. Work Assignment amounts shall not exceed the total amounts listed in the contract (time, dollars, effort, consultants, travel, etc.). The Contracting Officer Representative (COR) with Contracting Officer approval, is authorized to initiate Work Assignments and to sign Work Assignments indicating satisfactory performance/delivery of the services/product required in each Work Assignment. The Contractor shall assure, prior to commencing work on any Work Assignment, that written approval of the COR and the Contracting Officer has been obtained. A Work Assignment which does not contain both Contracting Officer and COR approval signatures shall be considered invalid and costs incurred for such work shall be considered unallowable. The Contractor shall not exceed the estimated labor hours, estimated Work Assignment amount, or change the Work Assignment leader without prior written approval of the COR and the Contracting Officer by modification of the Work Assignment. The day-to-

day operational and administrative details of the Work Assignment system will be established by the COR with input from the Contractor. The Work Assignment system will operate within the following general guidelines:

a. **Work Assignment (W.A.) Information**

1. All work to be assigned under this contract shall relate directly to one or more of the task areas listed in the Statement of Work.
2. Each W.A. shall be written for the conduct of a specific, finite task.
3. Each new W.A. shall be numbered serially beginning with 01.
4. Each W.A. shall be completed on the form entitled "Sample Contract Work Assignment" and listed as an Attachment in Section J of this contract.
5. Upon award of the contract, an Administrative Work Assignment as shown in SECTION J, Attachments, shall be issued on a yearly basis. This Work Assignment will cover the time and expenditures necessary for the administration of the contract.

b. **Initiation of a W.A.**

1. The COR will initiate Part I of the W.A.
2. The Contractor shall complete Part II and obtain the appropriate signature. The Contractor shall forward the proposed W.A. to the COR.
3. Upon receipt of the proposed W.A. and after determining that the proposed W.A. is acceptable, the COR will sign Part II to indicate recommendation for approval and forward to the Contracting Officer.
4. Upon receipt, the Contracting Officer will review the proposed W.A.
    a. If approved, the Contracting Officer will sign Part II to indicate approval and will forward the W.A. to the Contractor with a copy to the COR.
    b. If not approved, the Contracting Officer will notify the COR, stating the reasons for disapproval.
5. After receipt of the approved W.A., the Contractor shall begin work. The period of performance shall never precede the Contracting Officer Approval date.

c. **Modification to a W.A.**

1. Each amendment to an existing Work Assignment shall contain the original W.A. number and shall designate a modification number. Modification numbers for each W.A. shall be serially numbered beginning with 01 (for example, Work Assignment 01, Modification No. 01).
2. Each W.A. modification shall set forth in specific detail which portion(s) of the W.A. is to be modified. All Cost/Labor modifications shall be in the following format:

	Authorized to Date	**This Modification**	**Revised Estimate**
Labor Hours			
Cost Elements			
(List Each Element)			

d. **Conclusion of a W.A.**

1. For each W.A. performed, the Contractor shall prepare PART III of the Work Assignment for submission to the Contracting Officer.

2. This PART III submission shall include all actual information (cost, effort, and deliverables) relative to the W.A.
3. PART III of the W.A. shall be submitted as soon as possible and not to exceed three months after the closing date of the W.A. For those Work Assignments which expire within three months prior to the contract expiration date, PART III of the Work Assignment shall be submitted on the final contract day.
4. After verification that all work is complete and deliverables have been received and accepted, the COR will sign Part III of the W.A. to indicate recommendation for approval and forward the W.A. to the Contracting Officer.
5. After verification that the W.A. has been satisfactorily completed, the Contracting Officer will approve completion of the W.A. by signing Part III of the W.A. and forward to the Contractor.

101

****(USE BELOW FOR INDEFINITE QUANTITY TYPE CONTRACTS WHEN THE ITEMS OR SERVICES TO BE ORDERED ARE PRE-PRICED IN THE CONTRACT THE ORDERS WILL BE PLACED ON A FIXED-PRICE BASIS, AND NO ORDER TERMS ARE NEGOTIATED BEFORE ISSUANCE.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Subparagraph a:**
   - Check all applicable methods for issuing orders.
   - If applicable, identify the timeframe for written confirmation of oral offers.
2. **Subparagraph c:** This subparagraph applies to MULTIPLE AWARD TASK/DELIVERY ORDER contracts. If this is a SINGLE AWARD TASK/DELIVERY ORDER contract, delete this subparagraph c.

ARTICLE G.4. METHOD OF ORDERING

a. Orders issued under this contract may be placed as follows:

[ ] in writing
[ ] via telephone
[ ] via facsimile (fax)
[ ] via electronic mail (e-mail)
[ ] Oral [Oral Orders will be confirmed in writing within _ days of issuance.
[ ] Other Specify: _____

b. The Contracting Officer is authorized to issue orders and provide written confirmation of oral orders, if applicable, under the contract.

c. Fair Opportunity

1. In accordance with FAR 16.505(b)(1)(i), each awardee will be given a fair opportunity to be considered for each order exceeding the micro-purchase threshold issued under multiple delivery-order contracts or multiple task-order contracts, except:
   i The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.

ii Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.

iii The order must be issued on a sole-source basis in the interest of economy and efficiency because it is a logical follow-on to an order already issued under the contract, provided that all awardees were given a fair opportunity to be considered for the original order.

iv It is necessary to place an order to satisfy a minimum guarantee.

2. All awardees will be given a fair opportunity to be considered in accordance with the FAR as follows:

   i For orders exceeding the micro-purchase threshold up to the simplified acquisition threshold, in accordance with FAR 16.505(b)(1)(ii);

   ii For orders exceeding the simplified acquisition threshold up to $6 Million, in accordance with 16.505(b)(1)(iii); and,

   iii For orders exceeding $6 Million, in accordance with FAR 16.505(b)(1)(iv).

102

****(USE BELOW, FOR INDEFINITE QUANTITY TYPE CONTRACTS WHEN INDIVIDUALLY NEGOTIATED TASK ORDERS WILL BE ISSUED DURING THE PERIOD OF PERFORMANCE.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Subparagraph b:**
   - **Second Paragraph:** The CO may modify the list of items to be included in a Task Order Requisition for Proposal.
   - **Last (fourth) Paragraph:** Remove this paragraph for Single Award Indefinite Quantity contracts.
2. **Subparagraph c:** This subparagraph applies to MULTIPLE AWARD TASK/DELIVERY ORDER contracts. If this is a SINGLE AWARD TASK/DELIVERY ORDER contract, delete this subparagraph c.
3. **Subparagraph c.2:** FOR MULTIPLE AWARD TASK/DELIVERY ORDER Contracts ONLY:
   - The CO may modify the list of evaluation factors as needed.
4. **Subparagraph d:**
   - For **MULTIPLE AWARD TASK/DELIVERY ORDER** Contracts:
     i. **First paragraph:** Select from the drop down box, the statement which accurately states how technical, cost and other factors will be considered in the award decision.
     ii. **Second paragraph:** Select the statement: "Contractor whose proposal is most advantageous to the government" from the drop down box.
   - For **SINGLE AWARD TASK/DELIVERY ORDER** Contracts:
     i. **First paragraph:** Carefully review this paragraph to make sure that it describes the evaluation process you will use to award task/delivery orders. If necessary, revise this subparagraph accordingly.
     ii. **Second paragraph:** Select the word: "Contractor." from the drop down box.
     iii. **Third paragraph:** REMOVE
5. **Subparagraph e:** This subparagraph applies to MULTIPLE AWARD TASK/DELIVERY ORDER contracts. If this is a SINGLE AWARD TASK/DELIVERY ORDER contract, delete this subparagraph e.

ARTICLE G.5. TASK ORDER PROCEDURE

This contract provides for the issuance of Task Orders on a negotiated basis as follows:

a. **General**

Only the Contracting Officer may issue Task Orders to the Contractor, providing specific authorization or direction to perform work within the scope of the contract and as specified in the Statement of Work. Unless specifically authorized by the Contracting Officer, the Contractor shall not commence work until a fully executed Task Order has been awarded. The Contractor may incur costs under this contract in performance of task orders and task order modifications issued in accordance with this ARTICLE.

No other costs are authorized unless otherwise specified in the contract or expressly authorized by

the Contracting Officer.

b. **Requesting Task Order Proposals.**

The Contracting Officer or a designated individual may solicit responses to requirements from Contractors within a technical area covered by a task order requirement in writing. A Task Order Request for Proposals (TORFP) will be prepared and issued for each task order requirement.

Generally, the Task Order Request for Proposal (TORFP) will include but is not limited to the following:

1. Statement of Work;
2. Reporting Requirements and Deliverables;
3. Proposal Due Date and Location to Deliver Proposals;
4. Period of Performance of Task Order;
5. Anticipated type of Task Order;
6. Technical Proposal Instructions;
7. Business proposal Instructions
8. Evaluation Factors for Award

All contract clauses contained this contract shall be incorporated in the TORFP and the resultant task order. If conflicts exist between the contract clauses and the information outlined in the task order, the contract language takes precedence over the information in the task order.

Contractors are not required to propose on all TORFPs. Those eligible Contractors that decide not to submit a proposal shall advise the Contracting Officer, in writing, of their intention not to submit a proposal on or before the closing date and time established in the TORFP. An election not to propose on a given TORFP will not negatively affect or prohibit a Contractor from competing on future TORFPs. However, it may affect the Contractor's eligibility for continuations or extensions of the resultant Task Order.

c. **Competitive Ordering Process.**

1. All Contractors within a technical area will receive e-mail notification advising of the availability of each proposed task order requirement. All proposed task orders will incorporate all terms of this contract unless otherwise specified in the proposed task order.

2. Contractors will be provided an adequate time to prepare and submit responses based on the Contracting Officer's consideration of the estimated dollar value and complexity of proposed task order. Responses will not be considered a proposal as defined in FAR Part 15. However, the Contractor shall provide information sufficient for consideration in accordance with FAR Part 16. Each TORFP will indicate the criteria for the evaluation of proposals. The responses shall demonstrate capability for each criterion to be evaluated. Generally, the Contractor will be asked to demonstrate the following as appropriate:
    - Understanding of the requirements;
    - Experience and capability on similar tasks;

- Technical approach, methods and procedures for satisfying the requirements with a discussion of potential problems to be encountered and proposed solutions and/or risk mitigation strategies;
- Procedures for assuring quality of work, products, and deliverables;
- Plan for managing the task order, including meeting requirements and schedules, and performance measures (if applicable);
- Staffing plan with skill levels and level of effort for each individual proposed. Generally, resumes will be required for proposed personnel (if not previously submitted);
- References to evaluate past performance; and
- Cost/Price to perform the task order.

d. **Evaluation and Award of Task Order Proposals**

The Government will evaluate the Task Order proposals against the requirements of the TORFP. Specifically, the technical evaluation factors, cost/price, past performance and any other factor specifically identified in the TORFP will be used for evaluation of each proposal. In addition, the TORFP will identify the basis for selecting a Contractor for award. Generally, technical factors will be [significantly more important than cost or price/approximately equal to cost or price/significantly less important than cost or price] However, each TORFP will specify how the award decision will be made.

Upon completion of evaluations, the Contracting Officer will issue a task order to the [Contractor whose proposal is most advantageous to the government/Contractor.]

The Contracting Officer will notify the Contractor(s) of the selection decision in writing.

e. **Fair Opportunity**

1. In accordance with FAR 16.505(b)(1)(i), each awardee will be given a fair opportunity to be considered for each order issued exceeding the micro-purchase threshold issued under multiple delivery-order contracts or multiple task-order contracts, except:
    i The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.
    ii Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.
    iii The order must be issued on a sole-source basis in the interest of economy and efficiency because it is a logical follow-on to an order already issued under the contract, provided that all awardees were given a fair opportunity to be considered for the original order.
    iv It is necessary to place an order to satisfy a minimum guarantee.

2. All awardees will be given a fair opportunity to be considered in accordance with the FAR as follows:
    i For orders exceeding the micro-purchase threshold up to the simplified acquisition threshold, in accordance with FAR 16.505(b)(1)(ii);
    ii For orders exceeding the simplified acquisition threshold up to $5.5 Million, in accordance with 16.505(b)(1)(iii); and,
    iii For orders exceeding $5.5 Million, in accordance with FAR 16.505(b)(1)(iv).

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES AND FACILITIES SERVICES.)****

ARTICLE G.6. EQUITABLE ADJUSTMENTS DUE TO CHANGES

a. The Contractor shall submit a proposal for all changes in the work within 30 days from the effective date of the change order or request for proposal. With each proposal for a change involving an increase or decrease in the amount of the contract, the Contractor shall submit separately an itemized breakdown that will include but not be limited to the following:

1. Material quantities and unit price. (Separated into trades)\
2. Labor Costs (Separate into labor classifications and hourly rates)
3. Construction Equipment
4. Workmen's Compensation
5. Overhead
6. Profit
7. Employment taxes under FICA, FUTA and SUTA
8. Bond (Prime Contractor only)
9. Sales Tax
10. Direct Performance Time of Change
11. Impact on Schedule, if any.
12. Impact Costs, if any.

b. In considering proposals for changes involving added work, omitted work, or any combination thereof, estimates will be checked in detail by the NIH, utilizing unit prices where specified or agreed upon, with the view of arriving at equitable adjustments.

c. When the necessity to proceed with a change does not allow sufficient time to properly check a proposal, or because of failure to reach an agreement, NIH Contracting Officer may direct the Contractor to proceed immediately with the work.

d. Proposals and breakdown should be submitted as promptly as possible, but in no event later than 30 days.

e. All proposals shall be submitted in accordance with the requirements of FAR 15.404. Should a proposal cost exceed $2 million for a change, certified cost or pricing data should be submitted on SF1411 in a format which satisfies the requirements of FAR 15.403-5. When certified cost or pricing data are required, the contractor shall submit an executed Certificate of Current Cost or Pricing Data as soon as practicable after price agreement is reached.

f. Allowable overhead, profit, and percentages are given at the end of this paragraph. These percentages shall be limited to three tiers only and shall be considered to include, but not limited to, all insurance other than FICA, FUTA, SUTA and Workmen's Compensation, field and office supervisors and assistants, use of small tools, incidental job burdens, and general office expense. Incidental job burdens include, but are not limited to, review and coordination, and estimating and expediting relative to contract changes that are associated with field and office supervision.

No percentages for overhead and profit shall be allowed on FICA, FUTA or SUTA. The percentages for overhead and profit to be allowed by NIH may vary according to the nature, extent, and complexity of work involved, but in no case shall exceed the following:
The percentages of overhead to be allowed by the Contracting Officer will be 10% for all contract changes performed by prime contractor personnel and 5% for all contract change work performed by subcontract personnel.
The percentage for profit to be allowed by NIH will vary according to the nature, risk, extent, and complexity of work involved, but in no case shall exceed 10%. Percentages for overhead and profit will be as follows:

Overhead Profit

To subcontractors and/or to the Contractor for work performed with his own forces 10% 1% - 10%
To Contractor on work performed by other than his own forces... 5% 1% - 5%
The percentage of profit is to be negotiated. The burden is on the Contractor to propose and justify to the government the percentage of profit to be paid on each modification to the contract.
On proposals involving both increases and decreases in the amount of the contract, overhead and profit will be allowed on the net increases only. On net decreases, corresponding overhead and profit will be deducted.
When change proposals are not submitted with a Time Impact Analysis, it is mutually agreed that the particular change order, modification, delay or Contractor request does not require an extension of the contract time (or milestone).

g. The percentages in (f) above are the maximums that will be paid. The burden is on the contractor to propose and justify to government the percentages paid on each modification to the contract.

h. Any proposal for delay and impact costs that is not submitted within 60 days after completion of the work identified in the change will not be considered. This requirement is in addition to the scheduling updates required for construction of the project. If there are circumstances which prevent the contractor from ascertaining delay for impact during this time, a status update, including but not limited to a critical path analysis, shall be submitted within this time and at 60 day intervals thereafter, explaining why the contractor cannot yet know the extent of the impact. If this is not done, a claim for delay will not be considered unless special circumstances are shown. This requirement is necessary to enable the government to respond to any claims for delay in light of conditions then current.

104

****(USE BELOW FOR COST-REIMBURSEMENT SOLICITATIONS AND CONTRACTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Article Title** - To modify the Article title: 1) Select the "Edit" from the Tool Bar; 2) Edit the " **TOC Title** " field at the top of the screen as follows:
  - For Cost-Type Contracts requiring Financial Reporting with each Invoice (NIH(RC)-4): No change required, leave Article Title as is.
  - For Cost-Type Contracts no Financial Reporting (NIH(RC)-1): Delete the words "AND CONTRACT FINANCING REQUEST" from the "TOC Title" field.

ARTICLE G.7. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

105

****(USE BELOW WHEN THE NIH(RC)-1 OR NIH(RC)-4 WILL BE REQUIRED.)****

- **First sentence,** select the appropriate Invoice Instructions from the drop-down box.

a. [Invoice Submission/Contract Financing Request, NIH(RC)-1/Invoice Submission/Contract Financing Request and Contract Financial Reporting, NIH(RC)-4] for NIH Cost-Reimbursement Type Contracts are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

106

**** (USE BELOW IN ALL SOLICITATIONS AND CONTRACTS. EXCEPT NCI OA AND ORF.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

Please Note: NIH/OFM will NOT accept any invoices postmarked and/or delivered in-person on/after December 1, 2020.

107

****(USE BELOW IF THE CONTRACTOR HAS TRANSITIONED TO THE DEPARTMENT OF TREASURY'S INVOICE PROCESSING PLATFORM OR IF THE CONTRACTING OFFICER NEEDS TO ADD A NEW VENDOR IN NBS IN ORDER TO MAKE THE AWARD.)****

1. The Contractor must submit invoices to the Department of Treasury's Invoice Processing Platform (IPP) at https://www.ipp.gov with a copy of the invoice to the approving official, as directed below.

108

****(USE BELOW IF THE CONTRACTOR HAS **NOT** TRANSITIONED TO THE DEPARTMENT OF TREASURY'S INVOICE PROCESSING PLATFORM.)****

NOTE: THE AWARD MUST INCLUDE AN ADVANCE UNDERSTANDING COVERING THE INVOICE PROCESSING PLATFORM.

1. Until the Contract has transitioned to IPP as specified on the OALM IPP website, the Contractor must follow step-by-step instructions as stated in the NIH/OFM Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract. The invoice submitted to the NIH/OFM must be transmitted as an attachment via email to the address listed above in one of the following formats: Word, or Adobe Portable Document Format (PDF). The Contractor must submit only one invoice per email. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your invoice unless specified elsewhere in the contract or requested by the Contracting Officer.

109

****(USE IN ALL AWARDS.)****

The Contractor shall submit a copy of the electronic invoice to the following Approving Official (Contracting Officer) and Contracting Officer Representative:

Official: Contracting Officer

Name-_____ Email Address- _____

Contracting Officer Representative

Name-_____ Email Address- _____

For inquiries regarding the status of invoices, contact OFM Customer Service via email at ofm_customer_service@mail-cmp.niceincontact.com or via phone at 301-496-6088. To send your inquiries via other available communication methods refer to the OFM Customer Service website at https://ofm.od.nih.gov/Pages/Customer-Service.aspx.

Note: The OFM Customer Service is open Eastern Standard Time Monday - Friday from 8:30 a.m. to 5:00 p.m. and is closed between 12:00 p.m. to 1:00 p.m.

110

**** (NCI OA Only: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.

ADDITIONAL INSTRUCTIONS FOR COMPLETING THIS ITEM:

- Select the appropriate Central Point of Distribution.

NCI Processes/Procedures Reviewed 9/22)***

111

****(USE BELOW IF THE CONTRACTOR HAS TRANSITIONED TO THE DEPARTMENT OF TREASURY'S INVOICE PROCESSING PLATFORM OR IF THE CONTRACTION OFFICER NEEDS TO ADD A NEW VENDOR IN NBS IN ORDER TO MAKE THE AWARD.)****

1. The Contractor must submit invoices to the Department of Treasury's Invoice Processing Platform (IPP) at https://www.ipp.gov with a copy to the approving official, as directed below.

112

****(USE BELOW IF THE CONTRACTOR HAS **NOT** TRANSITIONED TO THE DEPARTMENT OF TREASURY'S INVOICE PROCESSING PLATFORM. THE AWARD MUST INCLUDE AN ADVANCE UNDERSTANDING COVERING THE INVOICE PROCESSING PLATFORM.)****

1. Until the Contractor has transitioned to IPP as specified on the OALM IPP website, the Contractor must follow step-by-step instructions as stated in the NIH/OFM Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract. The invoice submitted to the NIH/OFM must be transmitted as an attachment via email to the address listed above in one of the following formats: Word, or Adobe Portable Document Format (PDF). The Contractor must submit only one invoice per email. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your invoice unless specified elsewhere in the contract or requested by the Contracting Officer.

113

****(USE IN ALL AWARDS.)****

The Contractor must submit a copy of the electronic invoice to the following Approving Official (Contracting Officer) and Contracting Officer Representative:

Approving Official: Contracting Officer

Name- _____ Email Address- _____

Contracting Officer Representative

Name- _____ Email Address- _____

For inquiries regarding the status of invoices, contact OFM Customer Service via email at ofm_customer_service@mail-cmp.niceincontact.com or via phone at 301-496-6088. To send your inquiries via other available

communication methods refer to the OFM Customer Service website at https://ofm.od.nih.gov/Pages/Customer-Service.aspx .

Note: The OFM Customer Service is open Eastern Standard Time Monday - Friday from 8:30 a.m. to 5:00 p.m. and is closed between 12:00 p.m. to 1:00 p.m.

One courtesy copy of the original invoice shall be submitted electronically as follows:

The Central Point of Distribution:

NCI OA Branch A - ncibranchainvoices@mail.nih.gov

NCI OA Branch B - ncibranchbinvoices@mail.nih.gov

NCI OA Branch C - ncibranchcinvoices@mail.nih.gov

NCI OA Branch D - ncibranchdinvoices@mail.nih.gov

NCI OA Branch E - ncibrancheinvoices@mail.nih.gov

NCI OA Branch F - ncibranchfinvoices@mail.nih.gov

Invoices shall be submitted in accordance with Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract.

114

****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.
ORF Processes/Procedures Reviewed 11/22)****

115

****(USE BELOW IF THE CONTRACTOR HAS TRANSITIONED TO THE DEPARTMENT OF TREASURY'S INVOICE PROCESSING PLATFORM OR IF THE CONTRACTION OFFICER NEEDS TO ADD A NEW VENDOR IN NBS IN ORDER TO MAKE THE AWARD.)****

1. The Contractor must submit invoices to the Department of Treasury's Invoice Processing Platform (IPP) at https://www.ipp.gov with a copy to the approving official, as directed below.

116

****(USE BELOW IF THE CONTRACTOR HAS **NOT** TRANSITIONED TO THE DEPARTMENT OF TREASURY'S INVOICE PROCESSING PLATFORM. THE AWARD MUST INCLUDE AN ADVANCE UNDERSTANDING COVERING THE INVOICE PROCESSING PLATFORM.)****

1. Until the Contractor has transitioned to IPP as specified on the OALM IPP website, the Contractor must follow step-by-step instructions as stated in the NIH/ OFM Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract. The invoice submitted to the NIH/OFM must be transmitted as an attachment via email to the address listed above in one of the following formats: Word, or Adobe Portable Document Format (PDF). The Contractor must submit only one invoice per email. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your invoice unless specified elsewhere in the contract or requested by the Contracting Officer.

117

****(USE IN ALL AWARDS.)***

The Contractor shall submit a copy of the electronic invoice to the following Approving Official (Contracting Officer) and Contracting Officer Representative:

Approving Official: Contracting Officer

Name- _____ Email Address- _____

Contracting Officer Representative

Name- _____ Email Address- _____

For inquiries regarding the status of invoices, contact OFM Customer Service via email at ofm_customer_service@mail-cmp.niceincontact.com or via phone at 301-496-6088. To send your inquiries via other available communication methods refer to the OFM Customer Service website at https://ofm.od.nih.gov/Pages/Customer-Service.aspx.

Note: The OFM Customer Service is open Eastern Standard Time Monday - Friday from 8:30 a.m. to 5:00 p.m. and is closed between 12:00 p.m. to 1:00 p.m.

The Contractor shall submit one copy of the electronic invoice to the Office of Research Facilities (ORF) invoice processing email distribution mailbox:

ORFOAInvoice3Way@mail.nih.gov. The Contractor will receive an automated email reply confirming that your invoice has been received for processing. If you do not receive an email notification within 24 hours, it indicates that we did not receive your invoice for processing. In which case double check (1) that your email contained the scanned attachment of your invoice and that (2) you sent it to our inbox at ORFOAInvoice3Way@mail.nih.gov. If you have any questions or concerns, please call the Intake Center at 301-402-0878.

118

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS (EXCEPT for NCI OA).)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Subparagraph a:** Insert the name of the applicable Office of Acquisition.
2. **Subparagraph d:** Select appropriate payment method from the Drop Down List. *[Note: Payment under a two-way match is processed after matching the award (contract/order) with the invoice. Generally, a two-way match will be used for contracts/orders that acquire services, where payment is not tied to specific deliverables. Payment under a three-way match is processed after matching the award (contract/order) with the invoice and evidence of receipt/acceptance entered into NBS. Generally, a three-way match will be used for contracts/orders that acquire supplies, where payment is tied to specific deliverables.]*
3. **Subparagraph f:** Use at the Contracting Officer's discretion when the Contract Title is not clearly identified on the face page of the Contract.
4. **Subparagraph g:** Use at the Contracting Officer's discretion when Contract Line Items are not clearly identified on the face page of the Contract.

For guidance on selecting the appropriate Invoice Matching Option, see https://nbrssprod.cit.nih.gov:8050/NBRSSDocs/Job_Aids/Acquisition/2 way 3 way match 8 20 07.doc

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is _____ .
   b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, Unique Entity Identifier (UEI), or VIN, contact the Contracting Officer. Note: The Contractor shall not include TIN if it is a Social Security Number.

c. Unique Entity Identifier (UEI). The UEI is located in the System for Award Management (SAM) and replaces the Dun & Bradstreet Data Universal Numbering System (DUNS) number. The UEI number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid UEI number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, UEI, or VIN, contact the Contracting Officer.

d. Invoice Matching Option. This contract requires a [two-way/three-way] match.

e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

f. The Contract Title is:

g. Contract Line Items as follows:

Line Item #	Line Item Description

119

****(NCI OA Only: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Subparagraph d:** Select appropriate payment method from the Drop Down List. *[Note:\Payment under a two-way match is processed after matching the award (contract/order) with the invoice. Generally, a two-way match will be used for contracts/orders that acquire services, where payment is not tied to specific deliverables. Payment under a three-way match is processed after matching the award (contract/order) with the invoice and evidence of receipt/acceptance entered into NBS. Generally, a three-way match will be used for contracts/orders that acquire supplies, where payment is tied to specific deliverables.]*
2. **Subparagraph f** : Use at the Contracting Officer's discretion when the Contract Title is not clearly identified on the face page of the Contract.
3. **Subparagraph g** : Use at the Contracting Officer's discretion when Contract Line Items are not clearly identified on the face page of the Contract.

For guidance on selecting the appropriate Invoice Matching Option, see https://nbrssprod.cit.nih.gov:8050/NBRSSDocs/Job_Aids/Acquisition/2 way 3 way match 8 2007.doc.

NCI Processes/Procedures Reviewed 9/22)****

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Cancer Institute .
   b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, Unique Entity Identifier (UEI), or VIN, contact the Contracting Officer. Note: The Contractor shall not include TIN if it is a Social Security Number.
   c. Unique Entity Identifier (UEI). The UEI is located in the System for Award Management (SAM) and replaces the Dun & Bradstreet Data Universal Numbering System (DUNS) number. The UEI number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid UEI number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [*Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, UEI, or VIN, contact the Contracting Officer.
   d. Invoice Matching Option. This contract requires a [two-way/three-way] match.

e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

f. The Contract Title is:

g. Contract Line Items as follows:

Line Item #	Line Item Description

120

****(USE BELOW IN ALL RFPs AND CONTRACTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **For R&D contracts:** Select phone number ending **6452** from the drop down box.
2. **For Non R&D contracts:** Select phone number ending **6088** from the drop down box.

b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) [496-6452/496-6088] .

121

**** (THE FOLLOWING CERTIFICATION IS OPTIONAL FOR USE AT THE CONTRACTING OFFICER'S DISCRETION EXCEPT FOR NCI OA (See below). NOTE: Fixed-Price Completion contracts do NOT apply here, however, Fixed-Price Level of Effort or Time & Material contracts are to be included when using this item.

FOR NCI OA: THE FOLLOWING IS **MANDATORY** FOR ALL EXTRAMURAL R&D CONTRACTS THAT REQUIRED THE SUBMISSION OF COST AND PRICING DATA.

NCI Processes/Procedures Reviewed 9/22) ****

c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

122

****(USE BELOW FOR FIXED-PRICE SOLICITATIONS AND CONTRACTS.)****

ARTICLE G.8. INVOICE SUBMISSION

123

****(USE BELOW WHEN THE NIH(RC)-2 WILL BE REQUIRED.)****

a. Invoice Instructions for NIH Fixed-Price Type Contracts, NIH(RC)-2, are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

124

**** (USE BELOW IN ALL SOLICITATIONS AND CONTRACTS. EXCEPT NCI OA AND ORF.)****
ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:
Please Note: NIH/OFM will NOT accept any invoices postmarked and/or delivered in-person on/after December 1, 2020.

125

****(USE BELOW IF THE CONTRACTOR HAS TRANSITIONED TO THE DEPARTMENT OF TREASURY'S INVOICE PROCESSING PLATFORM OR IF THE CONTRACTING OFFICER NEEDS TO ADD A NEW VENDOR IN NBS IN ORDER TO MAKE THE AWARD.)****

1. The Contractor must submit invoices to the Department of Treasury's Invoice Processing Platform (IPP) at https://www.ipp.gov with a copy of the invoice to the approving official, as directed below.

126

****(USE BELOW IF THE CONTRACTOR HAS **NOT** TRANSITIONED TO THE DEPARTMENT OF TREASURY'S INVOICE PROCESSING PLATFORM.)****
NOTE: THE AWARD MUST INCLUDE AN ADVANCE UNDERSTANDING COVERING THE INVOICE PROCESSING PLATFORM.

1. Until the Contract has transitioned to IPP as specified on the OALM IPP website, the Contractor must follow step-by-step instructions as stated in the NIH/OFM Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract. The invoice submitted to the NIH/OFM must be transmitted as an attachment via email to the address listed above in one of the following formats: Word, or Adobe Portable Document Format (PDF). The Contractor must submit only one invoice per email. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your invoice unless specified elsewhere in the contract or requested by the Contracting Officer.

127

****(USE IN ALL AWARDS.)****

The Contractor must submit a copy of the electronic invoice to the following Approving Official (Contracting Officer) and Contracting Officer Representative:

Official: Contracting Officer

Name-_____ Email Address- _____

Contracting Officer Representative

Name-_____ Email Address- _____

For inquiries regarding the status of invoices, contact OFM Customer Service via email at ofm_customer_service@mail-cmp.niceincontact.com or via phone at 301-496-6088. To send your inquiries via other available communication methods refer to the OFM Customer Service website at https://ofm.od.nih.gov/Pages/Customer-Service.aspx.

Note: The OFM Customer Service is open Eastern Standard Time Monday - Friday from 8:30 a.m. to 5:00 p.m. and is closed between 12:00 p.m. to 1:00 p.m.

128

**** (NCI OA Only: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.

ADDITIONAL INSTRUCTIONS FOR COMPLETING THIS ITEM:

- Select the appropriate Central Point of Distribution.

NCI Processes/Procedures Reviewed 9/22)***

129

****(USE BELOW IF THE CONTRACTOR HAS TRANSITIONED TO THE DEPARTMENT OF TREASURY'S INVOICE PROCESSING PLATFORM OR IF THE CONTRACTION OFFICER NEEDS TO ADD A NEW VENDOR IN NBS IN ORDER TO MAKE THE AWARD.)****

1. The Contractor must submit invoices to the Department of Treasury's Invoice Processing Platform (IPP) at https://www.ipp.gov with a copy to the approving official, as directed below.

130

****(USE BELOW IF THE CONTRACTOR HAS **NOT** TRANSITIONED TO THE DEPARTMENT OF TREASURY'S INVOICE PROCESSING PLATFORM. THE AWARD MUST INCLUDE AN ADVANCE UNDERSTANDING COVERING THE INVOICE PROCESSING PLATFORM.)****

1. Until the Contractor has transitioned to IPP as specified on the OALM IPP website, the Contractor must follow step-by-step instructions as stated in the NIH/OFM Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract. The invoice submitted to the NIH/OFM must be transmitted as an attachment via email to the address listed above in one of the following formats: Word, or Adobe Portable Document Format (PDF). The Contractor must submit only one invoice per email. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your invoice unless specified elsewhere in the contract or requested by the Contracting Officer.

131

****(USE IN ALL AWARDS.)****

The Contractor must submit a copy of the electronic invoice to the following Approving Official (Contracting Officer) and Contracting Officer Representative:

Approving Official: Contracting Officer

Name- _____ Email Address- _____

Contracting Officer Representative

Name- _____ Email Address- _____

For inquiries regarding the status of invoices, contact OFM Customer Service via email at ofm_customer_service@mail-cmp.niceincontact.com or via phone at 301-496-6088. To send your inquiries via other available communication methods refer to the OFM Customer Service website at https://ofm.od.nih.gov/Pages/Customer-Service.aspx.

Note: The OFM Customer Service is open Eastern Standard Time Monday - Friday from 8:30 a.m. to 5:00 p.m. and is closed between 12:00 p.m. to 1:00 p.m.

One courtesy copy of the original invoice shall be submitted electronically as follows:

The Central Point of Distribution:

NCI OA Branch A - ncibranchainvoices@mail.nih.gov

NCI OA Branch B - ncibranchbinvoices@mail.nih.gov

NCI OA Branch C - ncibranchcinvoices@mail.nih.gov

NCI OA Branch D - ncibranchdinvoices@mail.nih.gov

NCI OA Branch E - ncibrancheinvoices@mail.nih.gov

NCI OA Branch F - ncibranchfinvoices@mail.nih.gov

Invoices shall be submitted in accordance with Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract.

132

****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS. ORF Processes/Procedures Reviewed 11/22)****

133

****(USE BELOW IF THE CONTRACTOR HAS TRANSITIONED TO THE DEPARTMENT OF TREASURY'S INVOICE PROCESSING PLATFORM OR IF THE CONTRACTION OFFICER NEEDS TO ADD A NEW VENDOR IN NBS IN ORDER TO MAKE THE AWARD.)****

1. The Contractor must submit invoices to the Department of Treasury's Invoice Processing Platform (IPP) at https://www.ipp.gov with a copy to the approving official, as directed below.

134

****(USE BELOW IF THE CONTRACTOR HAS **NOT** TRANSITIONED TO THE DEPARTMENT OF TREASURY'S INVOICE PROCESSING PLATFORM. THE AWARD MUST INCLUDE AN ADVANCE UNDERSTANDING COVERING THE INVOICE PROCESSING PLATFORM.)****

1. Until the Contractor has transitioned to IPP as specified on the OALM IPP website, the Contractor must follow step-by-step instructions as stated in the NIH/ OFM Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract. The invoice submitted to the NIH/OFM must be transmitted as an attachment via email to the address listed above in one of the following formats: Word, or Adobe Portable Document Format (PDF). The Contractor must submit only one

invoice per email. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your invoice unless specified elsewhere in the contract or requested by the Contracting Officer.

135

****(USE IN ALL AWARDS.)***

The Contractor must submit a copy of the electronic invoice to the following Approving Official (Contracting Officer) and Contracting Officer Representative:

Approving Official: Contracting Officer

Name- _____ Email Address- _____

Contracting Officer Representative

Name- _____ Email Address- _____

For inquiries regarding the status of invoices, contact OFM Customer Service via email at ofm_customer_service@mail-cmp.niceincontact.com or via phone at 301-496-6088. To send your inquiries via other available communication methods refer to the OFM Customer Service website at https://ofm.od.nih.gov/Pages/Customer-Service.aspx.

Note: The OFM Customer Service is open Eastern Standard Time Monday - Friday from 8:30 a.m. to 5:00 p.m. and is closed between 12:00 p.m. to 1:00 p.m.

The Contractor must submit one copy of the electronic invoice to the Office of Research Facilities (ORF) invoice processing email distribution mailbox: ORFOAInvoice3Way@mail.nih.gov. The Contractor will receive an automated email reply confirming that your invoice has been received for processing. If you do not receive an email notification within 24 hours, it indicates that we did not receive your invoice for processing. In which case double check (1) that your email contained the scanned attachment of your invoice and that (2) you sent it to our inbox at ORFOAInvoice3Way@mail.nih.gov. If you have any questions or concerns, please call the Intake Center at 301-402-0878.

136

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS (EXCEPT for NCI OA).)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Subparagraph a:** Insert the name of the applicable Office of Acquisition.
2. **Subparagraph d:** Select appropriate payment method from the Drop Down List. *[Note: Payment under a two-way match is processed after matching the award (contract/order) with the invoice. Generally, a two-way match will be used for contracts/orders that acquire services, where payment is not tied to specific deliverables. Payment under a three-way match is processed after matching the award (contract/order) with the invoice and evidence of receipt/acceptance entered into NBS. Generally, a three-way match will be used for contracts/orders that acquire supplies, where payment is tied to specific deliverables.]*
3. **Subparagraph f:** Use at the Contracting Officer's discretion when the Contract Title is not clearly identified on the face page of the Contract.
4. **Subparagraph g:** Use at the Contracting Officer's discretion when Contract Line Items are not clearly identified on the face page of the Contract.

For guidance on selecting the appropriate Invoice Matching Option, see https://nbrssprod.cit.nih.gov:8050/NBRSSDocs/Job_Aids/Acquisition/2 way 3 way match 8 20 07.doc

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is _____ .
   b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, Unique Entity Identifier (UEI), or VIN, contact the Contracting Officer. Note: The Contractor shall not include TIN if it is a Social Security Number.
   c. Unique Entity Identifier (UEI). The UEI is located in the System for Award Management (SAM) and replaces the Dun & Bradstreet Data Universal Numbering System (DUNS) number. The UEI number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid UEI number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, UEI, or VIN, contact the Contracting Officer.

d. Invoice Matching Option. This contract requires a [two-way/three-way] match.
e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.
f. The Contract Title is:

g. Contract Line Items as follows:

Line Item #	Line Item Description

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****(NCI OA Only: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Subparagraph d:** Select appropriate payment method from the Drop Down List. *[Note:\Payment under a two-way match is processed after matching the award (contract/order) with the invoice. Generally, a two-way match will be used for contracts/orders that acquire services, where payment is not tied to specific deliverables. Payment under a three-way match is processed after matching the award (contract/order) with the invoice and evidence of receipt/acceptance entered into NBS. Generally, a three-way match will be used for contracts/orders that acquire supplies, where payment is tied to specific deliverables.]*
2. **Subparagraph f** : Use at the Contracting Officer's discretion when the Contract Title is not clearly identified on the face page of the Contract.
3. **Subparagraph g** : Use at the Contracting Officer's discretion when Contract Line Items are not clearly identified on the face page of the Contract.

For guidance on selecting the appropriate Invoice Matching Option, see https://nbrssprod.cit.nih.gov:8050/NBRSSDocs/Job_Aids/Acquisition/2 way 3 way match 8 2007.doc.

NCI Processes/Procedures Reviewed 9/22)****

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Cancer Institute .

b. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. *[Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, Unique Entity Identifier (UEI), or VIN, contact the Contracting Officer. Note: The Contractor shall not include TIN if it is a Social Security Number.

c. Unique Entity Identifier (UEI). The UEI is located in the System for Award Management (SAM) and replaces the Dun & Bradstreet Data Universal Numbering System (DUNS) number. The UEI number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid UEI number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [*Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.]* If the Contractor has neither a TIN, UEI, or VIN, contact the Contracting Officer.

d. Invoice Matching Option. This contract requires a [two-way/three-way] match.

e. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.

f. The Contract Title is:

g. Contract Line Items as follows:

Line Item #	Line Item Description

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****(USE BELOW IN ALL RFPs AND CONTRACTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **For R&D contracts:** Select phone number ending **6452** from the drop down box.
2. **For Non R&D contracts:** Select phone number ending **6088** from the drop down box.

b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) [496-6452/496-6088] .

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**** (THE FOLLOWING CERTIFICATION IS OPTIONAL FOR USE AT THE CONTRACTING OFFICER'S DISCRETION EXCEPT FOR NCI OA (See below).
NOTE: Fixed-Price Completion contracts do NOT apply here, however, Fixed-Price Level of Effort or Time & Material contracts are to be included when using this item.
FOR NCI OA: THE FOLLOWING IS **MANDATORY** FOR ALL EXTRAMURAL R&D CONTRACTS THAT REQUIRED THE SUBMISSION OF COST AND PRICING DATA.
NCI Processes/Procedures Reviewed 9/22) ****

c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of the above referenced contract."

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****(USE BELOW IN ANY COST-REIMBURSEMENT CONTRACT WHERE THE CONTRACTING OFFICER REQUIRES AN ADDITIONAL LEVEL OF DETAIL NOT PROVIDED IN THE INVOICE, e.g., when the RC-1 invoice is used instead of the RC-4.)****

DO NOT USE THIS ARTICLE WITH NIH(RC)-4 OR WHEN SUBMISSION OF FINANCIAL/PERSONNEL REPORTING WILL BE REQUIRED AS AN ADVANCE UNDERSTANDING IN SECTION B SINCE BOTH SATISFY THE REQUIREMENT FOR FINANCIAL REPORTING.
Note: *See NIH Manual Chapter 6342-70, Item F. for more information about when financial reporting, in addition to invoice submission, is required.*

ARTICLE G.9. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the 30th working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.
b. Unless otherwise stated in that part of the Instructions for Completing Form NIH 2706, entitled " **PREPARATION INSTRUCTIONS** ," all columns A through J, shall be completed for each report submitted.
c. The first financial report shall cover the period consisting of the first full [Calendar Month/Three Calendar Months] following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a [Monthly/Quarterly] basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The following is a listing of expenditure categories to be reported:

Expenditure Category A	Percentage of Effort/Hours
(1) Direct Labor	
(a) Principal Investigator	
(b) Co-Principal Investigator	
(c) Key Personnel	
(i)	
(ii)	
(iii)	
(2) Other Professional Personnel	
(3) Personnel - Other	
(4) Fringe Benefits	
(5) Accountable Personal Property	
(6) Materials/Supplies	
(7) Patient Care Costs	
(8) Travel	
(9) Consultant Costs	
(10) Premium Pay	
(11) Computer Costs	
(12) Subcontract Costs	
(13) Other Direct Costs	
(14) Indirect Costs	
(15) G&A Expense	
(16) Total Cost	
(17) Fee	
(18) Total Cost Plus Fixed Fee	

f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

ARTICLE G.10. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (Nov 2021).

a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

b. The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.
c. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of clause).

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****(USE BELOW IN COST-REIMBURSEMENT SOLICITATIONS AND CONTRACTS TO BE AWARDED TO PROFIT MAKING ORGANIZATIONS.)****
ADDITIONAL INSTRUCTIONS FOR COMPLETING THIS ARTICLE:
- Substitute the Name and Address of the cognizant audit agency, below, if it is NOT DFAS.

ARTICLE G.11. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the cognizant Contracting Officer Representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6011 EXECUTIVE BLVD, ROOM 549C, MSC-7663
BETHESDA MD 20892-7663

These rates are hereby incorporated without further action of the Contracting Officer. Go to the Indirect Cost Submission web page: https://oamp.od.nih.gov/division-of-financial-advisory-services/indirect-cost-branch/indirect-cost-submission for electronic copies of the Branch's information package documents.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT WILL INVOLVE CONTRACTOR STAFF WORKING AT A GOVERNMENT SITE OR INSTALLATION AND USING GOVERNMENT PROPERTY.)****

ARTICLE G.12. ON-SITE CONTRACTOR ACCESS TO GOVERNMENT PROPERTY

The Contractor shall be held responsible for Government Property, regardless of dollar value, when:
- The contract requires Contractor personnel to be located on a Government site or installation;
- The property utilized by Contractor personnel is incidental to the place of performance; and,
- The property used by the Contractor remains accountable to the Government.

Responsibility includes physical presence, proper use and handling, normal maintenance, and reporting loss, damage or destruction.

Responsibility for government property shared by two or more Contractors or located in space shared by two or more Contractors, shall be determined and documented by the contractors involved. In cases where the parties cannot reach agreement on shared responsibility, the matter will be referred to the NIH Property Officer for resolution.

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****(EXCEPT AS NOTED BELOW, INCLUDE THE FOLLOWING ARTICLE IN: 1) ALL SOLICITATIONS AND CONTRACTS OVER THE SIMPLIFIED ACQUISITION THRESHOLD; 2) ORDERS, OVER THE SIMPLIFIED ACQUISITION THRESHOLD, PLACED AGAINST FEDERAL SUPPLY SCHEDULES, AND; 3) OTHER AGENCY CONTRACTS, SUCH AS GWACs AND MACs.

- **FOR CONSTRUCTION CONTRACTS:** INCLUDE IN SOLICITATIONS AND CONTRACTS OF $750,000 OR MORE. USE OF THIS ARTICLE MAY ALSO BE PREPARED FOR CONSTRUCTION SOLICITATIONS AND CONTRACTS BELOW $750,000.
- **FOR ARCHITECT-ENGINEER SERVICES:** INCLUDE IN SOLICITATIONS AND CONTRACTS OF $35,000 OR MORE. USE OF THIS ARTICLE MAY ALSO BE PREPARED FOR A&E SOLICITATIONS AND CONTRACTS BELOW $35,000.)****

Note: *COs shall not evaluate performance for contracts awarded under FAR Subpart 8.7., Acquisition from Nonprofit Agencies Employing People Who Are Blind or Severely Disabled. For additional information regarding preparation past performance evaluations, see FAR 42.1502.*

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- **Subparagraph a:**
  - **Contracts or Orders with a Period of Performance (Including Options) exceeding one year** - An Interim evaluation must be conducted at least at 12-month intervals after award. Insert dates as required.
  - **Contracts or Orders with a Period of Performance of one year or less** - The Contracting Officer may determine that Interim evaluations are not required. In this case, both paragraphs in subparagraph a. need to be modified to remove the requirement for Interim evaluations.

ARTICLE G.13. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually as follows on _____ [Insert Dates].

Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, Contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address:

https://www.cpars.gov

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****(USE BELOW AS DEEMED APPROPRIATE AND NECESSARY BY THE CONTRACTING OFFICER.)****

ARTICLE G.14. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "HHS Contracting Guide for Contract of Government Property," Appendix Q, which can be found at:

https://oamp.od.nih.gov/sites/default/files/DGS/HHS Contracting Guide for Contract of Government Property-Appendix Q.pdf.

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****(INCLUDE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

SECTION H - SPECIAL CONTRACT REQUIREMENTS

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****(USE IN ALL SOLICITATIONS, CONTRACTS AND ORDERS INVOLVING HUMAN SUBJECTS.)****

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015).

a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance.

b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or its employees.

c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP Website at: https://www.hhs.gov/ohrp/index.html).

d. If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

(End of clause).

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****(USE BELOW, WHEN RESEARCH INVOLVING HUMAN SUBJECTS IS NOT TO BE CONDUCTED UNDER THE CONTRACT.)****

Note: *There is no legal objection to the restriction imposed by the phrase "..., or any subsequent modification of such material,..." contained in this provision. However, inclusion of this phrase is NOT a requirement. Therefore, this language may be modified based on negotiations and/or Contracting Officer's discretion.*

ARTICLE H.2. HUMAN SUBJECTS

It is hereby understood and agreed that research involving human subjects shall not be conducted under this contract, and that no material developed, modified, or delivered by or to the Government under this contract, or any subsequent modification of such material, will be used by the Contractor or made available by the Contractor for use by anyone other than the Government, for experimental or therapeutic use involving humans without the prior written approval of the Contracting Officer.

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****(THE FOLLOWING MAY BE USED FOR CLINICAL TRIALS OR SIMILAR STUDIES WHERE PROTOCOLS WILL BE PERFORMED AFTER 1st PHASE OF THE STUDY/CONTRACT.)****

Note for Contracts: *This should be used only for Contractors who have a multiple project assurance or already received the single project assurance from OHRP. Single Project Assurances which have not yet obtained prior approval from OHRP before contract award will require the use of restricted language contained in the NEXT Item.*

ARTICLE H.3. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by _____ (INSERT IC), written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self-designated form, **provided** that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR RESEARCH INVOLVING HUMAN SUBJECTS.)****

Note: *It is anticipated that this NIH Policy will be superseded by DHHS ORI's institutional assurance once this requirement has been incorporated.*

ARTICLE H.4. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated August 25, 2000 at the following website:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html.

The information below is a summary of the NIH Policy Announcement:

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

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****(USE BELOW IN CONTRACTS AND ORDERS IF THE CONTRACTORS HAS AN APPROVED FWA OF COMPLIANCE IN PLACE, BUT CANOT CERTIFY PRIOR TO AWARD THAT AN IRB REGISTERED WITH OHRP REVIEWED AND APPROVED THE RESEARCH.)****
See HHSAR 370.304(b) for more information.

ARTICLE H.5. RESTRICTION ON USE OF HUMAN SUBJECTS, HHSAR 352.270-6 (December 2015).

Pursuant to 45 CFR part 46, Protection of Human Research Subjects, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human subjects research activity prior to the Contracting Officer's receipt of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) registered with OHRP. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

(End of clause).

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****(USE BELOW FOR CLINICAL TRIALS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **Last (4th) Paragraph:**
  - **For Contracts:** Select the appropriate wording from the Drop Down List. Note: Phase III Clinical Trials generally require both a DSMB and a Plan. Phase I and Phase II Clinical Trials generally require only a Plan.
  - **For RFPs:** Select "Board and/or Plan" from the Drop Down List.

ARTICLE H.6. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

The Contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring [Board/Plan/Board and Plan/Board and/or Plan] shall be established and approved prior to beginning the conduct of the clinical trial.

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****(FOR NHLBI: USE IN CONTRACTS AND RFPs WHEN THE NHLBI WILL ESTABLISH A DSMB OR AN OSMB.

NHLBI Processes/Procedures Reviewed 9/22)****

ARTICLE H.7. DATA AND SAFETY MONITORING IN CLINICAL TRIALS AND EPIDEMIOLOGICAL STUDIES

For informational purposes, the Contractor is directed to the full text of the NHLBI policies regarding Data and Safety Monitoring Boards (DSMBs) and Observational Study Monitoring Boards (OSMBs), which may be found at:

https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/nhlbi-policy-data-and-safety-monitoring-extramural-clinical-studies

a. Establishing Data and Safety Monitoring Boards and Observational Study Monitoring Boards.
b. Data Quality Assurance in Clinical Trials and Observational Studies-Guidelines.
c. Responsibilities of DSMBs Appointed by the NHLBI.
d. Responsibilities of OSMBs Appointed by the NHLBI.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE NIH-FUNDED CLINICAL TRIALS.)****

NIH Policy on "Good Clinical Practice Training for NIH Awardees Involved in NIH-Funded Clinical Trails" can be found at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-148.html.

ARTICLE H.8. GOOD CLINICAL PRACTICE TRAINING FOR NIH AWARDEES INVOLVED IN NIH-FUNDED CLINICAL TRIALS

All NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2). GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. GCP training should be refreshed at least every three years to remain current with regulations, standards and guidelines. The Contractor shall provide completion of training documentation to the Contracting Officer's Representative (COR).

Investigator: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Clinical Trial Staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE WHOLLY OR PARTIALLY NIH-FUNDED CLINICAL TRIALS.)****

A clinical trial that uses NIH-supported infrastructure but **does not** receive NIH funds to support its conduct is not subject to the NIH policy on the Dissemination of NIH-Funded Clinical Trial Information.

ARTICLE H.9. CLINICAL TRIAL REGISTRATION AND RESULTS INFORMATION SUBMISSION

The Contractor conducting clinical trials, funded wholly or partially through the NIH extramural and intramural programs, shall ensure that its NIH-funded clinical trials are registered at, and summary results information is submitted to, www.clinicaltrials.gov for public posting. See NIH Guide Notice NOT-OD-16-149 dated September 16, 2016.

All NIH- funded clinical trials shall be registered and results information submitted to www.clinicaltrials.gov regardless of study phase, type of intervention, or whether they are subject to the regulation 42 CFR Part 11. Clinical trials subject to the regulation are called " applicable clinical trials."

The Contractor must submit a plan with its proposal to meet the regulatory requirements of the dissemination of information of NIH-funded Clinical Trials. The Contractor and investigators are required to comply with all terms and conditions of award, including following their acceptable plan for the dissemination of NIH-funded clinical trial information.

The Contractor must register all NIH-funded clinical trials in www.clinicaltrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information from those trials must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of a new use is being sought. The Contractor shall include the trial registration number (NCT number) in the Technical Progress Report covering the period in which registration occurred, and as a standalone notification to the Contracting Officer within ten (10) calendar days of the registration. Each NIH-funded clinical trial must have only one entry in ClinicalTrials.gov that contains its registration and results information.

The Contractor shall include a specific statement in all informed consent documents relating to posting of clinical trials information to www.clinicaltrials.gov. The responsibilities of the Contractor will fall within one of the following three categories:

1. If the NIH-funded clinical trial is an applicable clinical trial under the regulation and the Contractor is the responsible party, the Contractor will ensure that all regulatory requirements are met.
2. If the NIH-funded clinical trial is an applicable clinical trial under the regulation but the Contractor is not the responsible party, the Contractor will coordinate with the responsible party to ensure that all regulatory requirements are met.
3. If the NIH-funded clinical trial is not an applicable clinical trial under the regulation, the Contractor will be responsible for carrying out the tasks and meeting the timelines described in NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information. Such tasks include registering the clinical trial in ClinicalTrials.gov and submitting results information to ClinicalTrials.gov.

Failure to comply with the terms and conditions of the award may provide a basis for enforcement actions. Identifying clinical trial record as non-compliant in ClinicalTrials.gov may lead to termination, consistent with 45 CFR 75.371 and/or other authorities, as appropriate. If the NIH-funded clinical trial is also an applicable clinical trial, non-compliance with the requirements specified in 42 USC 282(j) and 42 CFR Part 11 may also lead to the actions described in 42 CFR 11.66.

The Contracting Officer may take one or more of the following enforcement actions, if the Contractor fails to provide evidence of compliance within 30 days.

1. Temporary withhold payments pending correction of the deficiency;
2. Disallow all or part of the cost of the activity or action not in compliance;
3. Wholly or partly suspend or terminate the contract award;
4. Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and HHS awarding regulations at 2 CFR part 376;
5. Withhold further awards for the project and program;
6. Take other remedies that may be legally available.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE WHOLLY OR PARTIALLY FUNDED NIH-FUNDED CLINICAL TRIALS.)****

Note:

Contractor submits clinical trial information dissemination plan in the proposal.

1. If plan is not acceptable, CO work with the Contractor to obtain an acceptable plan.
2. If Contractor cannot provide an acceptable plan, the award cannot be made.

Once accepted, the plan is incorporated as a term and condition of award.

ARTICLE H.10. CLINICAL TRIAL REGISTRATION AND RESULTS INFORMATION SUBMISSION PLAN

The special terms and conditions in the Contract Award that include a clinical trial:

1. The clinical trial(s) supported by this award is subject to the plan dated [DATE] submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan must state that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant. The plan also must state that primary summary results shall be reported in ClinicalTrials.gov, including adverse event information, not later than one year after the primary completion date of the trial. The reporting of summary results is required by this term of award.
2. This award is subject to reporting requirements with each submission of the annual report. Contractor shall agree to the following annual certification. By affirming this annual certification:

   The Contractor hereby certifies that all investigators conducting NIH-funded clinical trials under the NIH contract number _____ are in compliance with the Contractor's plan addressing compliance with the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded wholly or partially under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Primary summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the primary completion date of the trial.

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****(USE INSTRUCTIONS BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE BIOMEDICAL, BEHAVIORAL, CLINICAL OR OTHER RESEARCH IN WHICH IDENTIFIABLE, SENSITIVE INFORMATION IS COLLECTED OR USED (INCLUDING RESEARCH ON MENTAL HEALTH AND RESEARCH ON THE USE AND EFFECT OF ALCOHOL AND OTHER PSYCHOACTIVE DRUGS.)****

ARTICLE H.11. CERTIFICATE OF CONFIDENTIALITY

Section 2012 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions governing the authority of the Secretary of Health and Human Services (Secretary) to protect the privacy of individuals who are the subjects of research, including significant amendments to the previous statutory authority for such protections, under subsection 301(d) of the Public Health Service Act.

Effective October 1, 2017, all research that was commenced or ongoing on or after December 13, 2016 and is within the scope of the NIH Policy for Issuing Certificate of Confidentiality (CoC) NOT-OD-17-109, the Contractor shall protect the privacy of individuals who are subjects of such research in accordance

with subsection 301(d) of the Public Health Service Act as a term and condition of the contract. The certificate will not be issued as a separate document.

NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research (except for human subjects' research that is determined to be exempt from all or some of the requirements of 45 CFR 46) if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects);
- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

The Contractor shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

The Contractor is permitted to disclose only in below circumstances. The Contractor shall notify the CO minimum ten (10) calendar days prior to disclosure.

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

In accordance with 45 CFR Part 75.303(a), the Contractor shall maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal Statutes and regulations.

The recipient of CoCs shall ensure that any company/institution/individual not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate understand that they are also subject to the requirements of subsection 301(d) of the Public Health Service Act. The Contractor shall ensure that Subcontractors who receive funds to carry out part of the Federal award understand they are also subject to subsection 301(d) of the Public Health Service Act and the NIH Policy for Issuing CoC.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHERE MORE THAN ONE DOMESTIC SITE WILL CONDUCT THE SAME PROTOCOL INVOLVING NON-EXEMPT HUMAN SUBJECTS RESEARCH.)****

SEE NIH NOTICE- NOT-OD-16-094.

NOTES- Types of awards typically will follow one of the examples below.

- Award to a Single Contractor with Multiple Sites participating as subcontractors; sIRB may be a separate subcontractor or a part of one of the existing sites
- Awards to Multiple Sites. A Central IRB (CIRB) or sIRB, either as part of a lead Contractor, or under a separate contract
- Award to a lead Contractor as set forth in the RFP, e.g., a Data Coordinating Center. The sIRB will be a part of the DCC, or as a separate IRB Contractor

ARTICLE H.12. SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)

For Institutional Review Board (IRB), the Contractor shall use the single Institutional Review Board (sIRB) of record for cooperative/multi-site research. All domestic sites participating in multi-site studies involving a non-exempt human subjects research funded wholly or partially by the National Institutes of Health (NIH) shall use a sIRB to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46 and the NIH Policy on the Use of Single Institutional Review Board for Multi-Site Research . Any IRB serving as the sIRB of record for NIH funded research shall be registered with the HHS Office for Human Research Protections (OHRP) and shall have membership sufficient to adequately review the proposed study.

The Contractor shall provide to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 certifying IRB review and approval of the research that encompasses all sites of performance.

This paragraph applies only if the Government provided a sIRB through a separate entity as stated in section- C . When the Government provided sIRB through a separate entity, the Contractor agrees to use of the sIRB. The Contractor shall provide to the Contracting Officer sIRB information and data in a timely manner as necessary to meet the policy and/or regulatory requirements of the Protection of Human Subjects at 45 CFR Part 46.

Exceptions to the NIH Single IRB Policy

The Contractor may request an exception in the following instances:

1. Where review by the proposed sIRB would be prohibited by Federal, state, or tribal laws, regulations or policies (policy-based exceptions);
2. *Other exceptions,* to be determined by NIH if there is a compelling justification; and
3. Time Limited Exception: ancillary studies to ongoing research without a sIRB- new multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use a sIRB of record until the parent study is expected to comply with the sIRB policy.

Policy-based exceptions and time limited exceptions are automatically granted when identified in the sIRB Plan.

Other exceptions must be reviewed by NIH OD and are expected to be granted rarely. *Other exceptions* when Offeror believes that one or more research sites should be exempt from use of the single IRB of record to conduct local IRB review based on compelling justification -

1. Offerors should request an exception in the sIRB plan attachment within the contract proposal (section 3.2 in the Study Record: PHS Human Subjects and Clinical Trials Information form).
2. Offerors must include the name of the site(s) for which an IRB other than the sIRB of record is proposed to review the study for the sites(s).
3. Offerors must substantiate their exception request with sufficient information that demonstrates a compelling justification for *other exceptions* to the sIRB policy. The rationale should include why the sIRB of record cannot serve as the reviewing IRB for the site(s), and why the local IRB is uniquely qualified to be the reviewing IRB for the specific site(s).

- For instance, the justification may consider ethical or human subjects protections issues, population needs, or other compelling reasons that IRB review for the site(s) cannot be provided by the single IRB of record.

4. Note that the proposed budget in the proposal must reflect all necessary sIRB costs without an approved *other exception.* The Offerors should not assume that *another exception* will be granted when considering what sIRB costs to include in the budget.

Post-Award Exception Requests

For any post-award changes that necessitate an exception request, such as the addition of a new domestic site that may be unable to use the sIRB Contractor shall contact their Contracting Officer (CO). For policy-based exceptions, the Contractor shall provide the appropriate citation to verify the requirement for local IRB review for the newly added site(s) to the CO. For *other exceptions* , the Contractor shall provide compelling justification to the CO to be reviewed by the NIH Exceptions Review Committee (ERC) (see **Steps to Request an Other Exception to the sIRB Policy** above). For time limited exceptions, Contractor shall provide the parent contract number to the CO. For time limited exceptions, Contractor shall provide the parent contract number to the CO.

Notice of Approval or Disapproval of *Other Exception* Requests

The sIRB exception requests will be considered after peer review for proposals in the competitive range. The decision of NIH OD is final. Offerors will be notified of the final decision by their CO prior to award. Approved exceptions will be incorporated as a term and condition in the contract award. Also, any exception requests submitted after award must be submitted to the CO and reviewed by the NIH ERC. No further revisions of the exception request will be accepted.

The award budget may need to be adjusted if an exception is granted.

Exception To the Revised Common Rule's Single IRB Review Requirement for Cooperative Research

NIH can only issue exceptions to the requirement at 45 CFR 46 that domestic sites participating in non-exempt human subjects research use a single IRB when authority to provide such exceptions is explicitly granted to NIH by the Office for Human Research Protections (OHRP).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHERE NON-EXEMPT HUMAN SUBJECTS RESEARCH IS BEING CONDUCTED AT MORE THAN ONE DOMESTIC SITE.)****

NOTE THAT THE NIH SINGLE IRB REVIEW POLICY ONLY APPLIES WHEN THE SAME PROTOCOL IS BEING CONDUCTED.

SEE 45 CFR 46 AND NIH NOTICE- NOT-OD-16-094.

ARTICLE H.13. PLAN FOR SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)

For this multi- site study, the _____ (Contractor/each Contractor) agrees to adhere to applicable single IRB review requirements specified in 45 CFR 46 and the NIH sIRB policy, and the _____ (IRB Name) IRB shall serve as the single IRB of record. All participating sites have agreed to rely on the _____ (IRB Name) IRB, and a written authorization/ reliance agreement shall be developed. Any additional sites added after contract award shall also agree to rely on this study's single IRB of record. Communication plans for interactions between the sIRB and participating sites shall be described in the authorization/ reliance agreement. All participating sites shall, prior to initiating the study, sign the authorization/ reliance agreement that shall clarify the roles and responsibilities of the sIRB and participating sites. The _____ (Contractor Name/ Name of the Coordinating Center or Contract Research Organization (CRO)/Names of Contractor's Lead Person and Alternate Person) shall maintain records of the authorization/reliance agreements, including the communication plans. The approved sIRB plan will be incorporated as a term and condition of the award. Any updates/ changes to the plan shall be provided to the Contracting Officer Representative with a copy submitted to the Contracting Officer within 30 calendar days.

Exceptions to the Single IRB Plan

The Contractor may request an exception to the sIRB plan under the following instances:

- Sites for which federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions)
  Review by a single IRB of record will not be possible for ***(sites)*** *because of federal/state/tribal law, regulation, or policy* ***(provide specific citation(s))***
- *Other exceptions,* to be determined by NIH if there is a compelling justification
  Review by a single IRB of record will not be possible for ***(this contractor)*** *because of* ***(provide compelling justification and rationale why local IRB is uniquely qualified to be the reviewing IRB for the specific site(s)).***
- Time Limited Exceptions: New multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use the sIRB of record until the parent study is expected to comply with the sIRB policy.

Review by a single IRB of record will not be possible for ***(sites)*** *because of ongoing multi- site parent study* ***(provide parent contract number).***

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS DURING THE CORONAVIRUS DISEASE 2019 PUBLIC HEALTH EMERGENCY WHEN MORE THAN ONE DOMESTIC SITE WILL CONDUCT THE SAME PROTOCOL INVOLVING NON-EXEMPT HUMAN SUBJECTS RESEARCH.)****

SEE NIH NOTICE NOT-OD-21-006 , Exceptions to Use of a Single IRB During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (COVID-19 PHE). Note - This Article shall remain in effect for use during the period of the COVID-19 Public Health Emergency, which has an effective date of October 23, 2020, until rescinded.

Above is the original Prescription which was provided when the COVID-19 PHE was officially declared on 23 October 2020. Even though the above original Prescription is no longer in effect both the Prescription and Article are being retained in their original forms for purposes of historical reference. However, as of Thursday, 11 May 2023, the COVID-19 PHE is officially rescinded and this Article will no longer be in effect.

Note - See NIH NOTICES NOT-OD-23-095 https://grants.nih.gov/grants/guide/notice-files/not-od-23-095.html , *Expiration of the COVID-19 Public Health Emergency*, and NOT-OD-23-097 https://grants.nih.gov/grants/guide/notice-files/NOT-OD-23-097.htmlSee NIH NOTICES NOT-OD-23-095, Expiration of the COVID-19 Public Health Emergency, and NOT-OD-23-097, NIH Can No Longer Grant Common Rule Exceptions to the Use of a Single IRB for Multi-site Research after the COVID-19 Public Health Emergency Expiration Date of May 11, 2023, for further information and guidance.

ARTICLE H.14. EXCEPTIONS TO THE REVISED COMMON RULE REQUIREMENT TO USE A SINGLE INSTITUTIONAL REVIEW BOARD (sIRB) DURING THE CORONAVIRUS DISEASE 2019 (COVID-19) PUBLIC HEALTH EMERGENCY.

On October 8, 2020, as specifically permitted by 45 CFR 46.114(b)(2)(ii), the Office for Human Research Protections (OHRP) issued in the Federal Register its determination of Exception to the Single IRB Review Requirements for Certain HHS-Conducted or -Supported Cooperative Research Activities Subject to the 2018 Requirements During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency (PHE) (OHRP COVID-19 Exception Determination). The determination states that, for certain studies that are conducted or supported by HHS and subject to the 2018 Requirements, as per 45 CFR 46.114(b)(1), and for purposes of 45 CFR 46.114(b)(2)(ii), an exception to the above requirement to use a single IRB is appropriate for the following category:

- Cooperative research that is ongoing or initially reviewed by the IRB during the COVID-19 PHE, as declared by the Secretary of Health and Human Services at: https://www.phe.gov/emergency/news/healthactions/phe/Pages/2019-nCoV.aspx;
- where reliance on a single IRB would not be practical; and
- for which the HHS division supporting or conducting the research approves of the use of this exception.

NIH will make a determination for exception to the NIH sIRB policy at the same time based on the same information. For information about the NIH single IRB Policy for studies not subject to 2018 Requirements, including exceptions, see the following Notices:

- NOT-OD-16-094, Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research;
- NOT-OD-17-076, Revision, Notice of Extension of Effective Date for Final NIH Policy on the Use of Single Institution Review Board for Multi-Site Research;
- NOT-OD-18-004, Guidance on Implementation of the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research;
- NOT-OD-18-003, Guidance on Exceptions to the NIH Single IRB Policy;
- NOT-OD-20-058, Additional Guidance on the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research; and
- NOT-OD-21-174c, Reminder of Guidance on Requirement for NIH Single Institutional Review Board (IRB) Plan.

Pre-Award Exception Requests

During the COVID-19 PHE NIH will consider exception requests to the Revised Common Rule requirement to use a single IRB for studies subject to the 2018 Requirements. To request an exception to the use of a single IRB (sIRB), offerors for NIH-conducted or -supported cooperative research must submit an exception request to NIH as an attachment within the contract proposal (Section 3.2 in the Study Record, PHS Human Subjects and Clinical Trials Information form), and include justification as to why an sIRB is not practical during the COVID-19 PHE. Additionally, offerors must include the name of the site(s) for which an IRB, other than the single IRB of record, is proposed to review the study for the site(s) and the initial IRB approval date(s), if applicable. In the absence of any such initial IRB approval date/data offerors may indicate "not applicable" or "to be determined," as appropriate, in any required fields to allow processing. The proposed budget in the proposal must reflect all necessary sIRB costs without an approved exception. Offerors should not assume that an exception will be granted when considering what sIRB costs to include in the budget.

Pre-award exception requests must be submitted with the original proposal and will be considered separate from the NIH peer review of technical proposals. Offerors will be issued written notification of approval or denial by the NIH Contracting Officer (CO) of any exception request(s) prior to award. Any decision by NIH on an Offeror's request for an exception to the use of a single IRB shall be final.

Post-Award Exception Requests

For any post-award changes that necessitate an exception request due to the COVID-19 PHE, effective October 23, 2020, until the PHE is rescinded, requests shall be sent to the CO and shall include the following:

- Study Title.
- Contract Number.
- A brief summary or abstract of the Study.
- Estimated Study Completion Date.

- Initial IRB Approval Date.
- Indication of whether Study already has an sIRB Exception.
- If the study transitioned to 2018 Revised Common Rule (rCR) if Study was originally subject to the Pre-2018 Common Rule.
- Justification of why sIRB is not practical during the COVID-19 PHE.
- PI (Principal Investigator) Name.
- Name of Contracting Officer's Representative.
- Name of Participating Site(s) where an IRB other than the sIRB of record will review.

Notice of Approval or Disapproval of Exception Requests

Exception requests to the 2018 Requirements, also known as the Revised Common Rule (rCR), made during the COVID-19 PHE during the period of the declared PHE will be reviewed by NIH and the CO will notify the Contractor of approval or denial of the exception request.

If an exception is approved, the CO shall request that the Contractor revise its proposed costs during and in negotiations, both pre- or post-award, in order to reflect any associated decreases in estimated costs that result from the exception being granted. The CO shall also determine if any changes to the terms and conditions of the Contract, as applicable, need to be made, based on approval of the exception.

The cost proposal shall then be adjusted accordingly, at award or via modification, if approval of an exception is granted by NIH.

Once a request for an exception is denied, no further revisions of the exception request will be considered or accepted by NIH. NIH anticipates that the use of sIRB exceptions will be rare.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT INVOLVE HUMAN SUBJECTS.)****

ARTICLE H.15. INCLUSION OF WOMEN AND MINORITIES IN RESEARCH INVOLVING HUMAN SUBJECTS

NIH-conducted and supported clinical research must conform to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research in accord with Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2. The policy requires that women and members of minority groups and their subpopulations must be included in all NIH-conducted or supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant NIH Institute/Center (IC) Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an IC Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended November 2017," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm.

The Contractor must submit the results of valid analyses by sex/gender and race/ethnicity to Clinicaltrials.gov for all NIH-conducted or supported applicable NIH-defined Phase III clinical trials. This requirement does not apply to NIH-defined Phase III trials not considered to applicable clinical trials under 42 CFR Part 11. The Contractor must report applicable NIH-defined Phase III clinical trials involving research subjects of all ages, including foreign awards and domestic awards with a foreign component. The Contractor must specify outcomes on sex/gender and race/ethnicity, as required based on prior evidence, and as explained in the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research.

Note: Applicable clinical trials are required to be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information, including the results of the valid analyses by sex/gender and race/ethnicity, from those trials must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of new use is being sought.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT INVOLVE HUMAN SUBJECTS.)****

ARTICLE H.16. INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

Section 2038 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions requiring NIH to address the consideration of age as an inclusion variable in research involving human subjects, to identify criteria for justification for any age-related exclusions in NIH research, and to provide data on the age of participants in clinical research studies. The NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accordance with Sections 101(b) and 401(b) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects.

Effective on all solicitations issued on or after January 25, 2019, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

The Contractor must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. The Contractor must provide a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the contractor must provide acceptable justification for the exclusion.

The Contractor must submit cumulative data as prescribed in the Age Enrollment Report template on participant age at enrollment in monthly progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual level

participant data on sex/gender, race, ethnicity, and age at enrollment may be provided in progress reports.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE HUMAN SUBJECTS.)****

ARTICLE H.17. POSTING CLINICAL TRIAL INFORMED CONSENT FORMS TO CLINICALTRIALS.GOV

The Revised Common Rule sections 46.102(b) and 46.116(h) requires Contractors to post one IRB-approved version of an Informed Consent Form that has been used to enroll participants on a public federal website designated for posting such Consent Forms. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database ClinicalTrials.gov . Note: ClinicalTrials.gov only accepts Informed Consent Forms written in English; non-English language forms must be submitted to Regulations.gov . The Informed Consent Form must be posted after recruitment closes, and no later than 60 days after the final study visit. The Contracting Officer (CO) and/or Contracting Officer Representative (COR) may permit or require redactions as appropriate.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR APPLICABLE CLINICAL TRIALS.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. For information about how to determine "applicable clinical trials" see Step 1 of the following link: http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm#whatsteps
2. For information about how the "Sponsor" role is determined, see the flowchart at: http://grants.nih.gov/ClinicalTrials_fdaaa/docs/registration_flow_chart.pdf

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

3. CLINICAL TRIALS CONDUCTED UNDER INVESTIGATIONAL NEW DRUG/INVESTIGATIONAL DEVICE EXEMPTION (IND/IDE) REQUIREMENTS:
   a. INCLUDE this Article in all contracts as follows:
      - When the Contractor is the IND/IDE holder (Sponsor) select the words: "Contractor is the Sponsor, therefore the" from the drop down box.
      - When the Government is the IND/IDE holder (Sponsor) **AND** the Government will delegate the role of "Responsible Party" to the Principal Investigator, select the words: "Government is the Sponsor and delegates the Contractor's Principal Investigator as" from the drop down box.
      - When the Government is the IND/IDE holder (Sponsor) **AND** will not delegate a PI as "Responsible Party," select the words: "Government is the Sponsor, therefore" from the drop down box.
      - If neither the Government nor the Contractor is the IND/IDE holder, consult with the Project Officer to determine how to address this situation. Note: If none of the choices in the drop down box apply in this situation, you can delete the drop down box and insert the appropriate Sponsor information.
4. SINGLE CENTER TRIALS (not conducted under IND/IDE requirements):
   a. INCLUDE this Article in all contracts as follows:

- When the Government will not delegate the PI as "Responsible Party," select the words, "Government is the Sponsor, therefore" from the drop-down box.
- When Government will delegate the PI as the "Responsible Party," select the words: "Government is the Sponsor and delegates the Contractor's Principal Investigator as" from the drop down box.
- If neither the Government nor the Contractor has initiated the trial (neither is the "Sponsor"), consult with the Project Officer to determine how to address this situation. Note: If none of the choices in the drop down box apply in this situation, you can delete the drop down box and insert the appropriate Sponsor information.

5. MULTICENTER TRIALS (not conducted under IND/IDE requirements):
   a. INCLUDE this Article in the contract as follows:
      - When the Government will not delegate a PI as "Responsible Party," select the words, "Government is the Sponsor, therefore" from the drop-down box **AND** include this Article in all of the multi-center trial contracts.
      - When Government will delegate a PI as "Responsible Party," select the words: "The Government is the Sponsor and delegates the Contractor's Principal Investigator as" from the drop down box **AND** include this Article in only the contract that has been delegated "Responsible Party" (generally the designated lead clinical site) *Note: Contractors involved in the Multi-Center trial, but not designated "Responsible Party, will require the clause in the next item (Below)* .

Note: *The Contracting Officer should consult with the Project Officer/Contracting Officer Representative (COR) to assist in making this determination.*

ARTICLE H.18. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS IN CLINICALTRIALS.GOV

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf , Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov and imposes new requirements that apply to specified "applicable clinical trials," including those supported in whole or in part by NIH funds. FDAAA requires:

- the registration of certain "applicable clinical trials" (see Definitions at: https://grants.nih.gov/grants/policy/nihgps/html5/section_1/1.2_definition_of_terms.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

In addition, the Contractor shall notify the Contracting Officer's Representative (COR), with the trial registration number (NCT number), once the registration is accomplished. This notification may be

included in the Technical Progress Report covering the period in which registration occurred, or as a stand-alone notification.

The [Contractor is the Sponsor, therefore/Government is the Sponsor and delegates the Contractor's Principal Investigator as/Government is the Sponsor, therefore] the "Responsible Party" for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (https://www.ClinicalTrials.gov). The Contractor shall provide the "Responsible Party" with all essential data for timely compliance with ClinicalTrials.gov reporting requirements.

Additional information is available at: https://prsinfo.clinicaltrials.gov/.

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****(USE BELOW IN EACH CONTRACT PARTICIPATING IN A MULTI-CENTER "APPLICABLE CLINICAL TRIAL," **EXCEPT** DO NOT USE IF THE CONTRACTOR IS DESIGNATED AS THE "RESPONSIBLE PARTY.")****

Note: *The Contractor that is designated as the "Responsible Party" will use the previous Article, above.*

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Second paragraph:** Insert the Name of the Individual (and Contractor) designated as the "Responsible Party" of the Multi-Center Trial.

Note: *The Contracting Officer should consult with the Project Officer/Contracting Officer Representative (COR) to assist in making this determination.*

ARTICLE H.19. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS CLINICALTRIALS.GOV

The Food and Drug Administration Amendments Act of 2007 (FDAAA), at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf, Title VIII, expands National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov and imposes new requirements that apply to specified "applicable clinical trials," including those supported in whole or in part by NIH funds. FDAAA requires:

- the registration of certain "applicable clinical trials" (see Definitions https://grants.nih.gov/grants/policy/nihgps/html5/section_1/1.2_definition_of_terms.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

_____ is the "Responsible Party" for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of the applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (https://www.clinicaltrials.gov/). The Contractor shall provide the "Responsible Party" with all essential data for timely compliance with ClinicalTrials.gov reporting requirements.

Additional information is available at: https://prsinfo.clinicaltrials.gov/.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INVOLVING RESEARCH & DEVELOPMENT (R&D) OR OTHER REQUIREMENTS THAT REQUIRE RCDC (Research, Condition, and Disease Categorization) REPORTING.)****

Note: Do not include the below article for requirements that are incidental to R&D, **where research data is not being generated.** (It is recommended, however, that you consult with the respective Contracting Officer Representative for the requirement, in determining whether inclusion of this article is appropriate). Also, do not include the below article for R&D support procurements, such as equipment, materials, or supplies.

ARTICLE H.20. RESEARCH AND DEVELOPMENT DATA IN ELECTRONIC RESEARCH ADMINISTRATION (eRA) SYSTEM

The Contractor shall enter and/or update research and development data fields at the contract project level in Electronic Research Administration (eRA) system within fifteen (15) calendar days of being notified by the eRA system. [The notification will come in the form of an eRA system-generated email, sent to the Contractor's registered user(s) under the contract.]

The eRA system website may be accessed at: https://public.era.nih.gov/commonsplus/public/login.era?TARGET=https%3A%2F%2Fpublic.era.nih.gov%3A443%2Fcommonsplus. Please note that if your organization does not currently have an account in eRA Commons, you will first need to register your organization at https://public.era.nih.gov/commonsplus/public/registration/initRegistration.era. Once your organization is registered, your signing official is then able to create new eRA system user accounts (such as for a Project Director/Principal Investigator). For information on how to create/manage accounts, using the Account Management System (AMS) in eRA system, please refer to: https://www.era.nih.gov/register-accounts/create-and-edit-an-account.htm. [Note: You must be logged into the eRA system, with appropriate role(s), in order to complete these activities.]

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR HIV ANTIRETROVIRAL TREATMENT TRIALS THAT WILL TAKE PLACE IN WHOLE OR IN PART IN DEVELOPING COUNTRIES - DEFINED AS THE LOW- AND MIDDLE-INCOME ECONOMIES, USING WORLD BANK CLASSIFICATIONS - AND THE OFFEROR PLANNED TO DEVELOP SOURCES TO PROVIDE TREATMENT OF TRIAL PARTICIPANTS AFTER THEIR COMPLETION OF THE TRIAL.)****

ARTICLE H.21. HIV ANTIRETROVIRAL TREATMENT TRIALS

The Contractor shall work with the host countries' authorities and other stakeholders in accordance with the approved plan to develop sources to provide HIV antiretroviral treatment to participants of the trials contracted for under this contract after the participants' completion of the trial.

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****USE BELOW IN ALL COVID-19 SOLICITATIONS, CONTRACTS, LETTER CONTRACTS, MODIFICATIONS, AND EXERCISING OPTIONS.****

Contracting Officers (CO) shall include the following language in all COVID-19 solicitations, contracts, letter contracts, modifications, and exercising options that involves recovery efforts necessary to address the 2019 Novel Coronavirus (COVID-19).

Note: The CO shall incorporate the following language by bilateral modification in contracts that requires a modification to include the COVID-19 recovery efforts.

ARTICLE H.22. CORONAVIRUS DISEASE 2019 (COVID-19) - HHS RECOVERY EFFORTS

"HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System."

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INCLUDE IN ALL SOLICITATIONS AND CONTRACTS

For all onsite contracts as contractors return to physical workspace or utilize NIH COVID-19 asymptomatic testing program:

Modify contract to 1) include the following language in section H, and 2) email certification by the contractor that its contractor personnel have signed the Code of Conduct forms.

ARTICLE H.23. CORONAVIRUS DISEASE 2019 (COVID - 19) - ONSITE CONTRACTORS RETURN TO PHYSICAL WORKSPACE

Coronavirus disease 2019 (COVID-19) - NIH policy may allow for voluntary or mandatory COVID-19 testing for contractor personnel. Contractor personnel who test positive for COVID-19 or who do not wish to submit to mandatory COVID-19 testing will not have access to or be permitted to work in NIH [ICs] until they have satisfied the access requirements in the NIH policy. A contractor personnel's decision to opt out of mandatory COVID-19 testing will not automatically constitute grounds for any performance delays or establish any government liability for additional costs. The Contracting Officer may determine that an excusable delay is appropriate under applicable FAR clauses (e.g., 52.242-14 (Suspension of Work), 52.242-15 (Stop-work Order), 52.249-14 (Excusable Delays), and 52.212-4(f) (Excusable Delays)) in cases where a positive test result is recorded and contract personnel must be quarantined due to an exposure to COVID-19. However, cases where a positive test result is recorded will not establish any government liability for additional costs.

Contractors shall ensure compliance with all Federal, HHS, NIH and individual IC COVID-19 policies related to health and safety, including relevant Codes of Conduct and reporting requirements applicable to contractor personnel. The Contractor shall discuss the Code of Conduct with contractor personnel, retain signed Codes of Conduct, and confirm their signature with the Contracting Officer. Reporting requirements include: 1) Ensure open reporting of safety and health related concerns; 2) Ensure staff understand reporting of COVID-like symptoms to contract supervisors, if they have had a high-risk exposure to someone with COVID disease, or if they have tested positive for COVID-19, and that staff do not report to the workplace with symptoms or if they have tested positive for COVID-19; 3) Ensure staff are complying with the return to work plans, policies and reporting requirements and enforcing these requirements when necessary; and 4) Ensure contract supervisors inform the Contracting Officer of personnel with COVID-19 symptoms.

The Return-to-Work Guidance and Code of Conduct for On-Site Contractors (Appendix 1) are incorporated into this contract. Contractors shall ensure contract personnel are aware they are to contact their company/supervisor for guidance.

Testing conducted by the NIH Occupational Medical Service (OMS) falls within Privacy Act System of Records Notice (SORN), 09-25-0105, Administration: Health Records of Employees, Visiting Scientists and Others Who Receive Medical Care through Employees Health Unit, HHS/NIH/ORS.

Information regarding the Countermeasures Injury Compensation Program under the Health Resources and Services Administration is available at 1-855-266-2427 or http://www.hrsa.gov/cicp/.

(If your IC is not doing testing through CC OMS, the IC would they have to identify another SORN and incorporate prior to beginning any testing)

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****(USE BELOW, WHEN HUMAN MATERIALS WILL BE ACQUIRED AND/OR GENERATED UNDER THE CONTRACT.)****

ARTICLE H.24. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

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****(USE BELOW WHEN THE CONTRACTOR WILL BE RECEIVING HUMAN MATERIALS FROM AN OUTSIDE SOURCE, ANOTHER CONTRACT OR FROM A SUBCONTRACTOR.)****

ARTICLE H.25. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE RESEARCH INVOLVING HUMAN FETAL TISSUE.)****

ARTICLE H.26. RESEARCH INVOLVING HUMAN FETAL TISSUE

Research involving Human Fetal Tissue (HFT) must be conducted in accordance with applicable Federal, State and local laws, regulations, and policies. Selected Federal statutes, regulations, and policies are provided below:

42 U.S.C. 289g-1 and 289g-2 set forth specific requirements and prohibitions on research involving human fetal tissue. For example, among other prohibitions, 42 U.S.C. 289g-2 provides:

"Prohibitions regarding human fetal tissue:

a. Purchase of tissue

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce.

The full text of 42 U.S.C. 289g-1 is available at:
http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap6A-subchapIII-partH-sec289g-1.htm

The full text of 42 U.S.C. 289g-2 is available at:
http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap6A-subchapIII-partH-sec289g-2.htm

Research involving HFT is also subject to the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B). The following provisions may be specifically relevant:

§ 46.204 Research involving pregnant women or fetuses.

~ (a) - (g)

h. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
i. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
j. Individuals engaged in the research will have no part in determining the viability of a neonate. § 46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

§ 46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

a. Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.
b. If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

The full text of the HHS Regulations for the Protection of Human Subjects is available at: https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/ohrpregulations.pdf.

Furthermore, per NOT-OD-16-033 at: https://grants.nih.gov/grants/guide/notice-files/not-od-16-033.html, when obtaining primary HFT for research purposes, The Contractor shall maintain appropriate documentation, such as an attestation from the health care provider or a third party supplier, that informed consent was obtained at the time of tissue collection.

Non-Transplantation Research on Fetal Tissue Obtained from Elective Abortions

The Contractor shall adhere to NIH Policy NOT-OD-19-128 on all contracts that involves the use of HFT obtained from elective abortions. The HFT is defined as research involving the study, analysis, or use of primary HFT, cells, and derivatives, and human fetal primary cell cultures obtained from elective abortions and includes the following (the definition implements the statute (42 U.S.C. Chapter 6A, Subchapter III, Part H, Sec. 289):

- human fetal primary or secondary cell cultures, whether derived by the investigator or obtained from a vendor.
- animal models incorporating HFT from elective abortions, including obtaining such models from a vendor.
- derivative products from elective abortion tissues or cells such as protein or nucleic acid extracts.
- any human extra- embryonic cells and tissue, such as umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi, if obtained from the process of elective abortion.

The definition of research involving HFT **does not** include the following:

- human fetal primary or secondary cell cultures, if cells were not derived from an elective abortion.
- already-established (as of June 5, 2019) human fetal cell lines (e.g. induced pluripotent stem cell lines from human fetal tissue, immortalized cell lines, differentiated cell lines).
- derivative products from human fetal tissue or cells (e.g. DNA, RNA, protein) **if not derived** from elective abortion.
- human extra-embryonic cells and tissue, including, but not limited to, umbilical cord tissue, cord blood, placenta, amniotic fluid, and chorionic villi **if not derived** from elective abortion.
- human fetal cells present in maternal blood or other maternal sources.
- embryonic stem cells or embryonic cell lines.
- research on transplantation of HFT for therapeutic purposes (because of the statutory provision(s) addressing such research).

To assure compliance with all applicable laws and HHS/NIH policies concerning the acquisition and use of HFT obtained from elective abortions, the Contractor shall submit detailed information addressing the use of HFT to Contracting Officer Representative (COR) in monthly progress reports.

The Contractor shall comply with the following terms and conditions:

1. The Contractor shall comply with all HHS/ NIH policies specific to HFT.
2. The Contractor shall justify the continued use of HFT obtained from elective abortions in their monthly progress reports by describing the ongoing scientific necessity for the use of HFT.
3. Informed consents for use of HFT in research, containing certain statements/ representations that acknowledges informed consent for donation of HFT was obtained by someone other than the

person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and the informed consent will be signed by both the woman and the person who obtains the informed consent.

4. The Contractor shall maintain documentation from the HFT donating organization assuring adherence to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration. The Contractor will acquire this assurance for each year of the award HFT research is conducted for the life of the award and maintain this documentation in accordance with the NIH Record Retention and Access policy.
5. HFT was not obtained or acquired for valuable consideration, as such term is defined in 42 USC § 289g-2.
6. The treatment of HFT, and the disposal of HFT when research is complete, shall be consistent with the plans outlined in the HFT proposal justification.

Requests to Add New or Additional Non-Transplantation Research on Human Fetal Tissue from Elective Abortions after Contract Award:

The Contractor shall submit a justification request to the Contracting Officer and COR to modify the contract to add either new or additional sources of HFT obtained from elective abortions.

The Contractor shall include the following information in the justification package:

- Use the specific heading:" Human Fetal Tissue Obtained from Elective Abortions Justification". The justification should be in detail for review by NIH.
- The Contractor must include the following in the justification:

1. Indicate why the research goals cannot be accomplished using an alternative to HFT (including, but not limited to, induced pluripotent cells not developed from HFT, organoids not developed from HFT, neonatal human tissue, human tissue obtained from adults, HFT not derived from elective abortion, animal models, and in vitro models that are not developed from HFT, and computational models).
2. Indicate the methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments).
3. Describe results from a literature review used to provide justifications.
4. Describe plans for the treatment of HFT and the disposal of HFT when research is complete.
5. Describe planned written, voluntary, informed consent process for cell/ tissue donation, or description and documentation of process if cells/ tissue were already obtained. Include a draft informed consent form for planned use under the proposed research. The informed consent for donation of HFT for use in research requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and to be signed by both the woman and the person who obtains the informed consent.
6. Budget Justification: Describe and document the quantity, type, and source of the HFT, and include a line item cost for the acquisition of HFT or indicate the cost is $ 0 if using donated or existing HFT.

7. HFT Compliance Assurance: The Contractor shall provide a letter signed by the PD/ PI assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration.

Research using HFT shall be in compliance with all applicable federal, state, or local laws, regulations, and policies, including 42 USC 289g-1 and g-2, the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B), NOT-OD-16-033, and NOT-OD-19-128.

Research on Transplantation of Human Fetal Tissue

Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) contain additional requirements for research on the transplantation of human fetal tissue for therapeutic purposes conducted or supported by NIH. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as the following NIH guidance.
Under section 498A, the official who signs the application is certifying that the research on transplantation of human fetal tissue will adhere to the following provisions. The woman who donates the fetal tissue must sign a statement declaring that the donation is being made:

- for therapeutic transplantation research
- without any restriction regarding the identity of individuals who may receive the transplantation, and
- without the donor knowing the identity of the recipient.

The attending physician must sign a statement that they have:

- obtained the tissue in accordance with the donor's signed statement and
- fully disclosed to the donor their intent, if any, to use the tissue in research and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks associated with the woman's medical care.

In the case of tissue obtained pursuant to an induced abortion, the physician's statement also must state that they:

- obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used;
- did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and
- performed the abortion in accordance with applicable State and local laws.

The Program Director/Principal Investigator (PD/PI) must sign a statement certifying that they are aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The PD/PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information. The PD/PI must certify in writing that they have had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

In submitting an application to NIH, the individual that signs the application is certifying that, if research on the transplantation of human fetal tissue is conducted under the grant-supported project, the organization will make available for audit by the HHS Secretary or designee, the physician statements, the PD/PI's statements, and informed consents required by subsections 498A(b)(2) and (c) of the PHS Act or will ensure HHS access to those records, if maintained by an entity other than the recipient. This requirement is in addition to the requirements concerning human subjects in research.

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****(USE BELOW IN ALL SOLICITATIONS THAT INVOLVE HUMAN SUBJECTS, INCLUDING RESEARCH INVOLVING HUMAN SPECIMENS, SAMPLES, AND/OR DATA.)****

SEE NIH NOTICE NOT-OD-22-001, NIH Implementation of the Revised Common Rule Provision Regarding Public Health Surveillance Activities Deemed Not to Be Research at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-001.html .

ARTICLE H.27. PUBLIC HEALTH SURVEILLANCE EXCLUSION

The Contractor may request an exclusion from applicability of the "revised Common Rule"[1] if it believes that the NIH-funded or -conducted activities associated with this contract should be considered "public health surveillance activities deemed not to be research" for the purposes of the revised Common Rule. All requests for exclusion from the revised Common Rule for NIH-funded research-whether conducted or supported-must receive NIH approval, as per the process outlined below, to be considered a public health surveillance activity deemed not to be research under the revised Common Rule's Sections §46.102(k), Public health authority, and §46.102(l)(2), Public health surveillance activities. NIH expects that NIH-supported or -conducted research will be determined to be a public health surveillance activity only in extremely rare cases. **Please note that NIH will not consider any NIH-defined clinical trials for a public health surveillance exclusion request. In addition, NIH will not consider studies that contain any activity that does not meet the requirements for an exclusion for a public health surveillance determination, which includes any intent to store specimens and/or data for future use, for a request for exclusion.**

Contractor shall provide a compelling justification as to why NIH-funded or -conducted activities should be considered public health surveillance activities deemed not to be research for the purposes of the revised Common Rule, a template of which is included as an attachment in Section J, LIST OF ATTACHMENTS - CONTRACT, of this Contract.

Contractor shall complete and submit the PHS Human Subjects and Clinical Trials Information Form, following instructions in the solicitation or contract, as applicable. Contractor should not assume that approval of an exclusion will be granted when completing the PHS Human Subjects and Clinical Trials Information Form.

Note that the proposed budget in the proposal must reflect all necessary/required costs for the full and proper conduct of research involving human subjects, in complete compliance with all applicable laws, protocols, rules, and/or regulations at all levels, without approval of any exclusion. Contractor

should not assume that approval of an exclusion will be granted when considering the costs to include in any proposed budget and therefore, must respond and price accordingly.

Notice of Approval or Disapproval of Request for Exclusion

Exclusion requests will be considered separate from the NIH peer review of technical proposals. Offerors will be issued written notification of approval or denial by the NIH Contracting Officer of any request(s) for exclusion prior to award. Any decision by NIH on an Offeror's request for a Public Health Surveillance Exclusion shall be final.

If a Public Health Surveillance exclusion is approved, the Contracting Officer shall request that the Contractor revise its proposed costs during negotiations, in order to reflect any associated decreases in estimated costs, as a result of the exclusion being granted. The Contracting Officer shall also determine if any changes to the terms and conditions of the contract, as applicable, need to be made, based on the exclusion.

The cost proposal will then be adjusted accordingly at award if approval of an exclusion is granted by NIH.

[1] Code of Federal Regulations (CFR) Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects, Revised 19 January 2017, Effective 19 July 2018, with a General Compliance Date of 21 January 2019 (45 CFR part 46)), and not its predecessor, the Pre-2018 Common Rule (Common Rule). The revised Common Rule is also known or referred to as the "2018 Requirements" or the "2018 Rule."

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE RESEARCH INVOLVING RECOMBINANT DNA OR SYNTHETIC NUCLEIC ACID MOLECULES (INCLUDING HUMAN GENE TRANSFER RESEARCH.))****

ARTICLE H.28. RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (Including Human Gene Transfer Research)

All research projects (both NIH-funded and non-NIH-funded) involving recombinant or synthetic nucleic acid molecules that are conducted at or sponsored by an entity in the U.S. that receives any support for recombinant or synthetic nucleic acid research from NIH shall be conducted in accordance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) available at: https://osp.od.nih.gov/biotechnology/nih-guidelines/). All NIH-funded projects abroad that include recombinant or synthetic nucleic acid molecules must also comply with the *NIH Guidelines.*

The *NIH Guidelines* stipulate biosafety and containment measures for recombinant or synthetic nucleic acid research, which is defined in the *NIH Guidelines* as research with (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally

occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2). The *NIH Guidelines* apply to both basic and clinical research.

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of the contract for any work related to recombinant or synthetic nucleic acid research or a requirement for the Contracting Officer to approve any or all recombinant or synthetic nucleic acid molecule projects under this contract. This includes the requirement for the institution to have an Institutional Biosafety Committee (IBC) registered with the NIH Office of Science Policy that complies with the requirements of the *NIH Guidelines* . Further information about compliance with the *NIH Guidelines* can be found on the NIH Office of Science Policy website available at: https://osp.od.nih.gov/biotechnology/nih-guidelines/.

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****(USE BELOW IN SOLICITATIONS THAT INVOLVE HUMAN STEM CELL RESEARCH.)****

ARTICLE H.29. HUMAN STEM CELL RESEARCH

All research conducted under this contract shall be in accordance with NIH Guidelines on Human Stem Cell Research (https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research), and shall involve the use of approved human embryonic stem cells (hESCs) or derivatives that are listed on the NIH Human Embryonic Stem Cell Registry (https://grants.nih.gov/stem_cells/registry/current.htm).

- Sections II and III of the National Institutes of Health Guidelines for Research Using Human Stem Cells (https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research) apply specifically to human embryonic stem cells (hESCs).
    - Section II details the eligibility criteria used by NIH to determine if specific hESC lines are eligible for use in NIH-funded research.
    - Section III explains the responsibility of NIH-funding recipients to assure that hESCs used in NIH-funded research are approved by NIH.
- Section IV sets limits on certain animal studies using all types of human pluripotent stem cells, including, but not limited to, those developed by methods such as the expression of genes involved in establishing pluripotency (e.g. the "Yamanaka factors") and the culturing of embryonic germ cells from primordial germ cells. Prohibited experiments include those in which the cells are introduced into non-human primate blastocysts and the breeding of animals in which the cells may contribute to the germ line.
- Section V details other types of research not eligible for NIH funding: the derivation of stem cells from human embryos and research using hESCs derived from sources other than human embryos created using in vitro fertilization for reproductive purposes.

Research involving the use of human embryonic stem cells, or derivatives, that are not listed on the NIH Registry may not be conducted with Federal funding. Derivatives include, but are not limited to, subclones of hESC lines, modified hESC lines (such as a line expressing green fluorescent protein), differentiated cells developed from hESC lines (such as muscle progenitor cells), and cellular materials (such as DNA, RNA, and proteins). Thus, no federal funds may be used for the generation of new data from unapproved hESC lines or derivatives. However publicly accessible data from unapproved lines or derivatives are not considered "derivative" and therefore not subject to this prohibition. Such publicly accessible data can be used and analyzed with federal funds.

The Contractor shall not conduct research in which human pluripotent stem cells are introduced into non-human vertebrate animal pre-gastrulation stage embryos.

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USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT INCLUDE THE SALE OF RESEARCH SUBSTANCES AND/OR LIVING ORGANISMS.

NOTES:

1. Carefully read the OALM/OAMP/DAPE Guidance on the REIMBURSEMENT FOR RESEARCH SUBSTANCES AND LIVING ORGANISMS before including this Article in solicitations/contracts.
2. Include the following attachments in solicitations/contracts when using this Article: Monthly Summary of Sales; Sample Recipient Invoice; NIH Pay.gov User Guide; and price list (optional for solicitation).
3. The contract shall describe any relevant standards for the safety and use of the research substances and/or living organisms. This information must also be furnished to eventual recipients of such research materials before they are physically transferred. Where appropriate, recipients shall be required to execute an assurance certificate whereby they agree not to use the research substances and/or living organisms in any unauthorized or unsafe manner. Such assurances shall be obtained by the Contractor before the research substances and/or living organisms are shipped/transferred to the recipient and shall be forwarded to the Government and retained as part of the contract file.
4. The Program Office shall perform an assessment of the nature of the research substances and/or living organisms to be made available to potential recipients to determine whether the contract should include a requirement to obtain a release and indemnification agreement from recipients (whether payment is requested or the substances/organisms are provided free of charge). If the Program Office determines that there is potential risk (e.g., risk of property damage or personal injury resulting from use of the research substances and/or living organisms), consultation with the General Law Division, Office of General Counsel, HHS, is recommended and language similar to that provided in Section F.4. of the Guidance should be incorporated into any resultant contract.

ARTICLE H.30. REMITTANCE PROCEDURES FOR SALE OF RESEARCH SUBSTANCES AND LIVING ORGANISMS

a. The Contractor shall make available to individuals and entities, for biomedical and behavioral research, research substances and/or living organisms under the terms and conditions specified below and in Section C, Description/Specifications/Statement of Work, of this contract.
b. The Contractor shall bill recipients directly for the research substances and/or living organisms provided, including any shipping and handling costs, which shall be itemized separately on the recipient's invoice. The prices charged for research substances and/or living organisms shall be as specified in the price list, which is included as an attachment in Section J of this contract. Under no circumstances shall the Contractor bill prices other than those included in the price list unless directed to do so by the Contracting Officer or his/her designated representative. The Government, without the concurrence of the Contractor, may revise the price of the research substances and/or

living organisms being made available. The Contracting Officer or his/her designated representative may direct the Contractor to make the research substances and/or living organisms available free of charge to recipients, including any shipping and handling costs.

c. The Contractor shall include with each shipment/transfer of research substances and/or living organisms to recipients an invoice substantially the same as the Sample Recipient Invoice, which is included as an attachment in Section J of this contract, and instruct the recipients how and when to make payments.
d. The Contractor shall assign a unique invoice number to each invoice and instruct recipients to remit payment to the Contractor in U.S. dollars by check or other method acceptable to the Contractor within 15 calendar days from the date of the invoice. All payments shall be made payable to the Contractor.
e. The Contractor shall inform the recipients of the research substances and/or living organisms prior to shipment/transfer that: 1) such research materials are not returnable and the costs associated with providing them, including shipping and handling, are not refundable; and 2) failure to pay an invoice may result in future purchase requests being denied. The Contractor shall contact the Contracting Officer and his/her designated representative immediately if there are any issues with the research substances and/or living organisms provided to the recipients.
f. Shipping and handling costs are defined as follows: 1) shipping costs are costs charged for delivering the research substances and/or living organisms to the recipient, including insurance, if required; and 2) handling costs are the costs charged for preparing the research substances and/or living organisms for shipment/transfer, including labor, packaging, and invoicing. Excessive shipping and handling charges are to be avoided. Establishment of flat rate shipping and handling charges is encouraged; however, such charges must be approved in advance by the Contracting Officer or his/her designated representative.
g. The Contractor shall keep an accurate account of all sales of research substances and/or living organisms on a calendar month basis and report the following information to the Government: 1) recipient's name, address, and contact information; 2) quantity; 3) item shipped/transferred; 4) unit price; 5) shipping and handling charges; 6) total charges; 7) shipment/transfer date; 8) invoice number; and 9) payment due date. This information shall be reported on the form, Monthly Summary of Sales, which is included as an attachment in Section J of this contract, and submitted to the Government in accordance with the delivery schedule in Section F of this contract. **[Identify designated staff in Section F, Deliveries, to receive a copy of the Monthly Summary of Sales, which will be used to enter accounts receivables in the NIH Business System (NBS), as well as for contract administration purposes. The delivery date for the Monthly Summary of Sales should not extend beyond 10 business days from the close of the reporting period, i.e., the end of each calendar month.]**
h. Upon receipt by the Government of the Monthly Summary of Sales, the Government will provide the Contractor with an invoice number needed to process payments through the U.S. Department of Treasury's government-wide collection portal, Pay.gov. Within 30 calendar days of receipt of the invoice number from the Government, the Contractor shall submit payment to the Government through Pay.gov for the research substances and/or living organisms associated with the invoice number received from the Government. Before submitting payment through Pay.gov, the Contractor shall reconcile the sales of research substances and/or living organisms reported on the Monthly Summary of Sales with the payment to be submitted to the Government.

[NIH staff responsible for providing the invoice number to the Contractor shall clearly identify

the contract/order number and calendar month of sales to which it applies.]

For assistance with Pay.gov, reference the NIH Pay.gov User Guide included as an attachment in Section J of this contract. For further assistance, contact _____

i. Examination of costs and transaction records related to the sale of research substances and/or living organisms shall be subject to the terms and conditions of this contract, including FAR Clause 52.215-2, Audit and Records-Negotiation, and its applicable Alternates.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR R&D REQUIREMENTS INCLUDING SBIRs.)****

ARTICLE H.31. NIH POLICY ON ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

Contractors shall adhere to the NIH policy of enhancing reproducibility through rigor and transparency by addressing each of the four areas of the policy in performance of the Statement of Work and in publications, as applicable: 1) Scientific Premise; 2) Scientific Rigor; 3) Consideration of Relevant Biological Variables, including Sex; and 4) Authentication of Key Biological and/or Chemical Resources. This policy applies to all NIH funded research and development, from basic through advanced clinical studies. See NIH Guide Notice, NOT-OD-15-103 , "Enhancing Reproducibility through Rigor and Transparency" and NOT-OD-15-102 , "Consideration of Sex as a Biological Variable in NIH-funded Research" for more information. In addition, publications are expected to follow the guidance at https://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research, whether preclinical or otherwise, as appropriate. More information is available at https://grants.nih.gov/policy/reproducibility/index.htm, including FAQs and a General Policy Overview.

178

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INVOLVING NIH -FUNDED RESEARCH THAT GENERATES LARGE-SCALE HUMAN OR NON-HUMAN GENOMIC DATA ON OR AFTER JANUARY 25, 2015.)****

ARTICLE H.32. DATA SHARING IN LARGE-SCALE HUMAN OR NON-HUMAN GENOMIC DATA

The Contractor shall comply with the NIH "Genomic Data Sharing Policy" located at: https://grants.nih.gov/grants/guide/notice-files/not-od-14-124.html . The Contractor shall submit and certify data obtained in the genomic data study to the data repository in accordance with the policy. The Contractor shall also submit the data to the Contracting Officer and Contracting Officer's Representative.

Large-scale data include genome-wide association studies, single nucleotide polymorphisms arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism.

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****(FOR USE IN ALL SOLICITATIONS AND CONTRACTS THAT INCLUDE HeLa CELL WHOLE GENOME SEQUENCE DATA.
NLM Processes/Procedures - HeLa Cell NIH Guidance - Reviewed 9/22)****

ARTICLE H.33. SHARING HeLa CELL WHOLE GENOME SEQUENCE DATA AND FAMILY ACKNOWLEDGEMENT

All research using HeLa Cell Whole Genome Sequence data shall be conducted in accordance with NIH notice NOT-OD-13-099, entitled, "Notice of NIH Guidance on the Family Acknowledgement and Use of HeLa Cell Whole Genome Sequence Data" located at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-099.html . The Contractor shall submit HeLa Whole Genome Sequence Data generated under this contract to the database of Genotypes and Phenotypes (dbGaP) available at: https://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs000640.v10.p1 , in accordance with the HeLa Genome Data Use Agreement available at: https://dbgap.ncbi.nlm.nih.gov/aa/wga.cgi?view_pdf&stacc=phs000640.v1.p1 .

NIH-funded investigators who have generated and submitted HeLa cell whole genome sequence data from DNA or RNA to dbGaP must submit a data access request if they plan to use these data in any analyses. The process for accessing these data is outlined on the HeLa Cell Genome Sequencing Studies page (available at http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs000640).

The following acknowledgment, or a variation of it that has been reviewed by the HeLa Genome Data Access Working Group, shall be made in any dissemination of research findings:

"The genome sequence described/used in this research was derived from a HeLa cell line (URL to dbGaP). Henrietta Lacks, and the HeLa cell line that was established from her tumor cells without her knowledge or consent in 1951, have made significant contributions to scientific progress and advances in human health. We are grateful to Henrietta Lacks, now deceased, and to her surviving family members for their contributions to biomedical research. This study was reviewed by the NIH HeLa Genome Data Access Working Group."

Contact helagenome@nih.gov for acknowledgement variation requests.

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****(INCLUDE THE FOLLOWING IN ALL SOLICITATIONS AND CONTRACTS FOR R&D REQUIREMENTS. IN ACCORDANCE WITH THE "NIH POLICY FOR DATA MANAGEMENT AND SHARING," NOTICE NOT-OD-21-013 WITH A RELEASE DATE OF 29 OCTOBER 2020 AND AN EFFECTIVE DATE OF 25 JANUARY 2023, INCLUDE THE FOLLOWING IN ALL SOLICITATIONS RELEASED AFTER 01 JULY 2022 WITH AN ORIGINAL PROPOSAL RECEIPT DATE OF 25 JANUARY 2023 OR LATER, AND ANY CONTRACTS RESULTING FROM THESE SOLICITATIONS THAT HAVE R&D (RESEARCH & DEVELOPMENT) REQUIREMENTS.
NLM Processes/Procedures - PubMed Central Manuscripts - Reviewed 9/22)****

ARTICLE H.34. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from any NIH-funded or conducted research, supported in whole or in part with direct costs from NIH regardless of NIH funding mechanism. NIH defines the author's final manuscript as the final version

accepted for journal publication, which includes all modifications that result from the publishing and peer review process, and which should be made accessible as soon as possible, and no later than the time of an associated publication or the end of the award/support period, whichever comes first. The PMC archive will permanently preserve and retain these manuscripts for use by the public, health care providers, educators, scientists, and NIH. NIH Policy directs electronic submissions to the NIH/NLM/PMC: https://www.ncbi.nlm.nih.gov/pmc/.

Additional information is available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html and https://publicaccess.nih.gov/.

181

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN CONTRACT PERFORMANCE MAY INVOLVE AN AGENT OR TOXIN THAT IS LISTED IN THE UNITED STATES GOVERNMENT POLICY FOR INSTITUTIONAL OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN (DURC).)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

• For a list of applicable agents or toxins, refer to Section 6 of the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern: http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf.

ARTICLE H.35. DUAL USE RESEARCH OF CONCERN

The Contractor shall comply with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (https://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) or "DURC policy". The responsibilities of the Contractor include but are not limited to:

1. Establishing internal policies and practices that provide for the identification and effective oversight of DURC;
2. Establishing an institutional review entity (IRE);
3. Ensuring that laboratory personnel conducting research have received education and training;
4. Maintaining records of institutional DURC reviews and completed risk mitigation plans related to research conducted under this contract, for the term of the contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation;
5. Promptly providing records upon request by the U.S. Government, of institutional DURC reviews and completed risk mitigation plans related to research conducted under this contract;
6. Obtaining pre-approval from the Contracting Officer's Representative for all communications with third-parties, involving DURC funded by this contract, and;
7. Obtaining pre-approval from the Contracting Officer for subcontracts, subgrants, consultant agreements, or any other subaward involving research subject to the DURC policy and funded by this contract. The contractor shall ensure that the substantive requirements of this article are included in any such agreements.

Non-compliance with the DURC policy or with this article may result in suspension, debarment or termination for default.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INVOLVING HUMAN SUBJECTS.)****

ARTICLE H.36. NEEDLE EXCHANGE, HHSAR 352.270-12 (December 2015).

The Contractor shall not use any funds obligated under this contract to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

(End of clause).

183

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

ARTICLE H.37. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

184

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR INVOLVING HUMAN SUBJECTS.)****

ARTICLE H.38. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015).

a. The Contractor shall not use any funds obligated under this contract for any abortion.
b. The Contractor shall not use any funds obligated under this contract for the following:
1. The creation of a human embryo or embryos for research purposes; or
2. Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
c. The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.
d. The Contractor shall not use any Federal funds for the cloning of human beings.

(End of clause).

Furthermore, per the NIH Director's Statement of April 28, 2015, NIH will not fund any use of gene-editing technologies in human embryos.

185

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN THE CONTRACT IS EXPECTED TO INVOLVE THE USE OF DRUGS OR OTHER SUBSTANCES INCLUDED IN SCHEDULE I OF THE SCHEDULES OF CONTROLLED SUBSTANCES ESTABLISHED BY SECTION 202 OF THE CONTROLLED SUBSTANCES ACT (21 U.S.C. 812.)****

ARTICLE H.39. LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES

The Contractor shall not use contract funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act, except for normal and recognized executive-congressional communications. This limitation shall not apply when the Government determines that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

186

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT REQUIRE THE DISSEMINATION OF INFORMATION.)****

ARTICLE H.40. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

187

****(USE BELOW WHEN THE SOLICITATION OR CONTRACT HAS BEEN SELECTED TO INCLUDE THE OPTION FOR PROPOSING MULTIPLE PRINCIPAL INVESTIGATORS UNDER THE CONTRACT.

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **Second Paragraph:**
  - Complete the date of the Leadership Plan.
  - Select the appropriate location for the Leadership Plan from the Drop Down List.)****

ARTICLE H.41. MULTIPLE PRINCIPAL INVESTIGATORS

The NIH awarded this contract as a multiple Principal Investigators project. The Key Personnel Article in SECTION G of this contract designates the Contact Principal Investigator and all other Principal Investigators.

Contracts designating multiple Principal Investigators require a current Leadership Plan with updates as needed. The Contractor's Leadership Plan, dated _____, (and as modified thereafter, in accordance with the Reporting Requirements Article in SECTION C of this contract), is hereby [incorporated by reference./included as an Attachment in SECTION J of this contract.]

188

****(USE BELOW IN SOLICITATIONS, CONTRACTS AND ORDERS THAT REQUIRE THE DESIGN, DEVELOPMENT, OR OPERATION OF A SYSTEM OF RECORDS TO NOTIFY THE CONTRACTOR THAT IT AND ITS EMPLOYEES ARE SUBJECT TO CRIMINAL PENALTIES FOR VIOLATIONS OF THE PRIVACY ACT (5 U.S.C. 552A(I) TO THE SAME EXTENT AS HHS EMPLOYEES.)****

See HHSAR 324.105(a) for more information .

ARTICLE H.42. PRIVACY ACT, HHSAR 352.224-70 (December 2015).

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations.

The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)).

The Contractor shall ensure that each of its employees knows the prescribed rules of conduct in CFR 45 part 5b and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement:

(a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and

(b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause).

189

****(USE BELOW WHEN THE CONTRACT IS FUNDED WITH 1% SET-ASIDE EVALUATION FUNDS.

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **2nd Paragraph:** Insert the NIH Evaluation Project Number and Contract Number.)****

ARTICLE H.43. EVALUATION PROJECTS

All publications including reports, compilations of data, articles and the like resulting from this contract shall contain the statement below. It shall be located on the cover, inside cover, or title page.

This project, _____ received support from the evaluation set-aside Section 513, Public Health Service Act.

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****(USE IN ALL SOLICITATIONS, CONTRACTS AND ORDERS INVOLVING LIVE VERTEBRATE ANIMALS.)****

ARTICLE H.44. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015).

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 2.11, or from a source that is exempt from licensing under those sections.

c. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c)above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note : The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS/AC, 4700 River Road, Unit 84, Riverdale, Maryland 20737 (Email: animalcare@usda.gov ; Web site: https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare.)

(End of clause).

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INVOLVING LIVE VERTEBRATE ANIMALS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Second paragraph:** Insert the date of the contractor's Vertebrate Animal Section (VAS) from the technical proposal, as applicable. For additional information about the VAS, see NIH Notice NOT-OD-16-006 available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html .

ARTICLE H.45. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: https://olaw.nih.gov/policies-laws/phs-policy.htm .

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor's technical proposal, as modified in the Final Proposal Revision (FPR), dated _____ , which is incorporated by reference.

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****(USE BELOW AS REQUIRED.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

a. **First sentence:** Insert the appropriate I/C and contract number in each text box.

b. **Fifth sentence:** Insert the appropriate I/C in the text box.

ARTICLE H.46. INTRODUCTION OF RODENTS AND RODENT PRODUCTS

No rodent or rodent product shall be delivered into the NIH, ___ environment (NIH) directly, or through collaborative research or holding facilities under contract to ___ except by permit. Direct shipments to NIH from a Division of Veterinary Resources (DVR), Office of Research Services (ORS) approved source will be considered exempt. Non-exempt sources must be approved by permit issued through the DVR, ORS. The permit must be obtained by the Contractor prior to the shipment to NIH of the rodents and/or rodent products. The Contractor must be sure that this permit exists and is current before transferring rodents or rodent products into the NIH, ___ environment. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Applications for permits should be submitted by facsimile not less than 30 days prior (60 days in situations where quarantine is likely) to shipping date to: NIH Division of Veterinary Resources (DVR), Office of Research Services (ORS), Building 14G, Service Rd. South, Room 102, BETHESDA MD 20892-5210, (301)496-2527, FAX: (301) 402-0352.

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****(FOR NIEHS USE ONLY AS REQUIRED.

NIEHS Processes/Procedures Reviewed 9/22)****

ARTICLE H.47. INTRODUCTION OF RODENTS AND RODENT PRODUCTS - NIEHS

No rodent or rodent product shall be delivered to NIEHS directly or through collaborative research or holding facilities under contract to NIEHS except by prior approval by the Comparative Medicine Branch, NIEHS. The approval form, Application to Introduce Rodents and Rodent Products into NIEHS, is available by contacting the Comparative Medicine Branch, Quality Assurance Laboratory at 984-287-3912. Approval must be obtained by the Contractor prior to shipment to NIEHS of the rodents and/or rodent products. The Contractor must be sure that this approval exists and is current before transferring rodents or rodent products into the NIEHS. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Requests for approval should be submitted within 30 days of the shipping date to: NIEHS, Comparative Medicine Branch, Quality Assurance Laboratory, PO Box 12233, MD C1-06, Building 101, Room C128, Research Triangle Park, NC, 27709. United States Department of Agriculture permits are required for the importation of monoclonal antibodies, hybridoma cell lines, cell cultures, and other biologic materials that have been in contact with material of animal origin. USDA permit forms and information are available online (https://www.aphis.usda.gov/aphis/resources/permits). A copy of the completed permit form should be submitted to the Comparative Medicine Branch.

194

****(USE BELOW WHEN THE CONTRACT WILL INCLUDE RESEARCH INVOLVING NON HUMAN PRIMATES.)****

ARTICLE H.48. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL: https://policymanual.nih.gov/3044-2.

195

****(USE BELOW ONLY IF OER, OLAW HAS GRANTED APPROVAL TO AWARD TO A CONTRACTOR NOT CURRENTLY COVERED BY AN APPROPRIATE ANIMAL WELFARE ASSURANCE AND VALID INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) APPROVAL. THE FOLLOWING **MUST** BE INCLUDED IN ANY CONTRACT RECEIVING THIS CONDITIONAL PREAWARD APPROVAL FROM OLAW.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:
Select and/or remove the approval required from the choices in the brackets, as appropriate.

ARTICLE H.49. RESTRICTION FROM USE OF LIVE VERTEBRATE ANIMALS

UNDER GOVERNING POLICY, FEDERAL FUNDS ADMINISTERED BY THE PUBLIC HEALTH SERVICE (PHS) SHALL NOT BE EXPENDED FOR RESEARCH INVOLVING LIVE VERTEBRATE ANIMALS WITHOUT PRIOR APPROVAL BY THE OFFICE OF LABORATORY ANIMAL WELFARE (OLAW), OF [**AN ANIMAL WELFARE ASSURANCE THAT COMPLIES WITH THE PHS POLICY ON HUMANE CARE AND USE OF LABORATORY ANIMALS AND/OR A VALID INSTITUTIONAL ANIMAL CARE AND USE COMMITTEE (IACUC) APPROVAL**]. THIS RESTRICTION APPLIES TO ALL PERFORMANCE SITES (e.g. COLLABORATING INSTITUTIONS, SUBCONTRACTORS, SUBGRANTEES) WITHOUT OLAW-APPROVED ASSURANCES, WHETHER DOMESTIC OR FOREIGN.

196

****(USE BELOW AS NECESSARY.)****

ARTICLE H.50. OMB CLEARANCE

In accordance with HHSAR 352.211-3, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Contracting Officer Representative (COR) and the Contracting Officer has issued written approval to proceed.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

ARTICLE H.51. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS)****

ARTICLE H.52. GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

199

****(USE BELOW WHEN THE CONTRACT WILL CONTAIN OPTIONS. COMPLETE ACCORDING TO TIME PERIODS NEGOTIATED. INCLUDE APPROPRIATE CLAUSE IN SECTION I.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

1. Select the applicable Option Clause from the Drop Down List.
2. Select the appropriate information within the brackets. Delete the information that does not apply.

ARTICLE H.53. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to [FAR Clause 52.217-6, Option for Increased Quantity/FAR Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item/FAR Clause 52.217-8, Option to Extend Services/FAR Clause 52.217-9, Option to Extend the Term of the Contract] set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the [**Use for Cost-Reimbursement Contracts:** estimated cost [plus fixed fee] of the contract will be increased as set forth in the ESTIMATED COST [PLUS FIXED FEE]/ **Use for Fixed-Price Contracts:** price of the contract will be increased as set forth in the OPTION PRICES] Article in SECTION B of this contract.

200

****(USE BELOW WHEN THE CONTRACT WILL BE PERFORMANCE-BASED AND OUTSTANDING PERFORMANCE IS REWARDED BY AN EXTENSION OF THE CONTRACT PERIOD (AWARD TERM.)****

Notes: *(1) This "award term" incentive differs from the "award option" incentive in the next Article in that this item is a contractual entitlement earned by the contractor and, once earned, should be awarded contingent only upon lack of funds availability or continued need for the supplies/services; and,*

(2) When awarding a Performance Based Acquisition using an "Award Term" incentive, make sure to include the cost/price information for the Award Term(s) in the appropriate Article in Section B. of your contract.

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

1. **Paragraph a:** When no FEE, remove [ ] language in paragraph, below. If FEE, keep the language and remove the brackets.
2. **Paragraph b.1:** Fill in the information as appropriate. Make sure to delete any sentences that do not apply.
3. **Subparagraph b.3.a:** Insert the date of the "Contractor Assessment Report/Performance Indicators and Standards."
4. **Subparagraph b.3.b.(1) & (2):** IMPORTANT NOTE: The language contained within the brackets in subparagraphs (1) and (2), is suggested only. It is set for a Five year base with two Award Term years. If this is not appropriate for your project, modify the paragraphs to be consistent with your requirement.

ARTICLE H.54. AWARD TERM

a. Award Term Contract

This contract contains Award Term incentive(s). Award Terms will be awarded based on the criteria set forth in paragraph b. below. The final decision whether the Award Term has been earned will be made annually and is at the sole discretion of the Contracting Officer.

Award Terms that have been earned, but not yet awarded are contingent on the availability of funds and/or the continuing need of the items or services set forth in the Statement of Work. As the determination not to award the Award Term is not considered a termination, no equitable adjustments to the contract price will be made. There is no guarantee the Government will continue Performance beyond the base performance period.

If the Contracting Officer determines that the Award Term has been earned and the Government's need for the items or services still exists and funds are available, the estimated cost [plus fixed fee] will be increased as set forth in the ESTIMATED COST, [FIXED FEE] AND AWARD TERM Article in SECTION B of this contract.

b. Award Term Provisions

1. This contract has a base performance period of _ years _____ [insert dates]. The Contractor will have the opportunity to earn _ additional years of

work _____ [insert dates here] using the evaluation process described herein. These additional years of work are called Award Terms. The total duration of this contract, including all Award Terms, shall not exceed a period of _ years _____ [insert dates].

2. A unilateral contract modification to add the Award Term will be issued when scoring meets or exceeds that set forth in the contract. The Government shall issue this modification at least 60 days prior to contract expiration. The Award Term determination and the methodology for determining the award term are unilateral decisions made solely by the Government and are not subject to dispute.

3. Quality Assurance Surveillance Plan (QASP)
    a. The Contractor's performance under this contract will be observed and evaluated continuously by the Government. The Contractor Assessment Report will be used to assess Contractor performance and determine whether the Contractor will receive Award Term(s). The Contractor Assessment Report includes Performance Indicators and Standards which identify the indicators to be evaluated and the associated standards for each indicator. A copy of the "Contractor Assessment Report/Performance Indicators and Standards," dated _____ is included as an attachment in SECTION J of this contract.
    b. The "Contractor Assessment Report/Performance Indicators and Standards" will be prepared by the Government, resulting in an overall rating which will be disseminated to the Contractor annually. The Award Term earned will be determined based upon review of the Contractor's performance against the performance indicators and standards as follows:
        1. [*Using the 0-5 point score in the Plan, the Contractor must receive an average of 3.5 or better for the first three years of Contractor performance. In years four and five, the Contractor must receive an average of 3.8 or better in each year to earn the Award Term.]* These goals are intended to be a stretch for the Contractor, but achievable.
        2. [*At the conclusion of year four, in addition to the year four "Contractor Assessment Report/Performance Indicators and Standards," the Government will prepare a summary report which will set forth the average rating for the first three years' of performance and the year four rating. This summary report will be used to determine if the Award Term for year six has been earned. Likewise, at the conclusion of year five, the Government will prepare a "Contractor Assessment Report/Performance Indicators and Standards" and a summary report of year five to determine if the Award Term for year seven has been earned.]*

            The advance evaluation of performance is required to allow adequate time for recompetition of the requirement in the event that Contractor performance does not meet the Award Term requirements. If the Contractor does not earn the first Award Term, there will be no opportunity to earn

subsequent Award Term(s) and the contract expiration date will remain unchanged.

c. The "Contractor Assessment Report/Performance Indicators and Standards" described herein contains rating criteria used solely to assess whether the Contractor has earned the award term specified in this contract. This report differs from the Contractor Performance Report described in the POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE Article in SECTION G of this contract, which uses a standard rating criteria established for the Federal Contractor Performance System to evaluate overall contract performance. For this reason, the Contractor's performance scores for determining authorization of the award term(s) may differ from the Contractor's performance scores for overall contract performance.

4. Changes to the Contractor Assessment Report/Performance Indicators and Standards

Unilateral changes to the Contractor Assessment Report/Performance Indicators and Standards may be made if the Contractor is provided written notification by the Contracting Officer at least 30 days before the start of the upcoming evaluation period. Changes affecting the current evaluation period must be by mutual agreement of both parties.

5. Contractor Performance Assessment

The Contracting Officer Representative (COR), and other Government personnel as appropriate, will use the "Contractor Assessment Report/Performance Indicators and Standards" and the associated performance elements and standards to score contract performance for the Award Term determination. The Contracting Officer is responsible for making the final decision on the Contractor's score and for determining whether the Contractor has earned the Award Term.

6. Contractor Performance Evaluation

The COR and Contracting Officer will prepare reports required by FAR 42.15 and described in the POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE Article in SECTION G of this contract to determine the Contractor's overall contract performance. Unless specifically identified as a rating criterion in the "Contractor Assessment Report/Performance Indicators and Standards," this evaluation report will not be used in the Award Term determination.

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****(USE BELOW WHEN THE CONTRACT WILL BE PERFORMANCE-BASED, WITH THE INCENTIVE OF AN AWARD OPTION FOR EXCELLENT PERFORMANCE. THIS ITEM SHOULD BE USED WHEN THE CONTRACTING OFFICER HAS DETERMINED THAT IT IS IN THE BEST INTEREST OF THE GOVERNMENT TO HAVE THE AWARD TERM EVALUATION SERVE AS THE PRECURSOR TO THE DECISION TO EXERCISE THE AWARD OPTION.)****

Note: *This item may be more appropriate in high dollar and/or highly complex contracts.*

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

1. **Subparagraph a (last paragraph):** When no FEE, remove [ ] language in paragraph, below. If FEE, keep the language and remove the brackets.
2. **Subparagraph b.1:** Fill in the information as appropriate. Make sure to delete any sentences that do not apply.
3. **Subparagraph b.3.a:** Insert the date of the "Contractor Assessment Report/Performance Indicators and Standards."
4. **Subparagraph b.3.b.(1) & (2):** IMPORTANT NOTE: The language contained within the brackets in subparagraphs (1) and (2), is suggested only. It is set for a Five year base with two Award Term years. If this is not appropriate for your project, modify the paragraphs to be consistent with your requirement.

ARTICLE H.55. AWARD OPTION

a. Award Option Contract

This Contract contains Award Option(s). The Contractor is not entitled to the exercise of any Award Options solely by meeting the criteria of the Quality Assurance Surveillance Plan (QASP). The Award Option evaluation serves as a precursor to the Government exercising its unilateral rights in accordance with FAR Part 17.2. A successful Award Option evaluation precedes the Government's review and determination to exercise or not to exercise the Award Option, in accordance with FAR Part 17.2. There is no guarantee the Government will continue Performance beyond the base performance period.

Award Option(s) will be exercised based on the criteria set forth below, and the final decision whether to exercise the Award Option(s) will be made annually and is at the sole discretion of the Contracting Officer. If the Contracting Officer determines that the standards for the Award Option have been met, and the Government exercises its option, the estimated cost [plus fixed fee] will be increased as set forth in the ESTIMATED COST, [FIXED FEE] AND AWARD TERM Article in SECTION B of this contract.

b. Award Option Provisions

1. This contract has a base performance period of _ years _____ . The Contractor will have the opportunity to earn additional _ years of work _____ using the evaluation process described herein. These additional years of work are called Award Option(s). The total duration of this contract, including all Award Option(s), shall not exceed a period of _ years _____ .

2. A unilateral contract modification to add the Award Option may be issued when scoring meets or exceeds that set forth in the contract. The Award Option determination and the methodology for determining the award option are unilateral decisions made solely by the Government and are not subject to dispute.

3. Quality Assurance Surveillance Plan (QASP)
    1. The Contractor's performance under this contract will be observed and evaluated continuously by the Government. The Contractor Assessment Report will be used to assess Contractor performance and determine whether the Contractor will receive Award Option(s). The Contractor Assessment Report includes Performance Indicators and Standards which identify the indicators to be evaluated and the associated standards for each indicator. A copy of the "Contractor Assessment Report/Performance Indicators and Standards," dated _____ is included as an attachment in SECTION J of this contract.

    2. The "Contractor Assessment Report/Performance Indicators and Standards" will be prepared by the Government, resulting in an overall rating which will be disseminated to the Contractor annually. The Award Option earned will be determined based upon review of the Contractor's performance against the performance indicators and standards as follows:
        1. [Using the 0-5 point score in the Plan, the Contractor must receive an average of 3.5 or better for the first three years of Contractor performance. In years four and five, the Contractor must receive an average of 3.8 or better in each year to earn the Award Option.] These goals are intended to be a stretch for the Contractor, but achievable.

        2. [At the conclusion of year four, in addition to the year four "Contractor Assessment Report/Performance Indicators and Standards," the Government will prepare a summary report which will set forth the average rating for the first three years' of performance and the year four rating. This summary report will be used to determine if the Award Option for year six has been earned. Likewise, at the conclusion of year five, the Government will prepare a "Contractor Assessment Report/Performance Indicators and Standards" and a summary report of year five to determine if the Award Option for year seven has been earned.]

            The advance evaluation of performance is required to allow adequate time for recompetition of the requirement in the event that Contractor performance does not meet the Award Option requirements. If the Contractor does not earn the first Award Option, there will be no opportunity to earn subsequent Award Option(s) and the contract expiration date will remain unchanged.

3. The "Contractor Assessment Report/Performance Indicators and Standards" described herein contains rating criteria used solely to assess whether the Contractor has earned the Award Option

specified in this contract. This report differs from the Contractor Performance Report described in the POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE Article in SECTION G of this contract, which uses a standard rating criteria established for the Federal Contractor Performance System to evaluate overall contract performance. For this reason, the Contractor's performance scores for determining authorization of the Award Option(s) may differ from the Contractor's performance scores for overall contract performance.

4. Changes to the Contractor Assessment Report/Performance Indicators and Standards
Unilateral changes to the Contractor Assessment Report/Performance Indicators and Standards may be made if the Contractor is provided written notification by the Contracting Officer at least 30 days before the start of the upcoming evaluation period. Changes affecting the current evaluation period must be by mutual agreement of both parties.

5. Contractor Performance Assessment
The Contracting Officer Representative (COR), and other Government personnel as appropriate, will use the "Contractor Assessment Report/Performance Indicators and Standards" and the associated performance elements and standards to score contract performance for the Award Option determination. The Contracting Officer is responsible for making the final decision on the Contractor's score and for determining whether the Contractor has earned the Award Option.

6. Contractor Performance Evaluation
The COR and Contracting Officer will prepare reports required by FAR 42.15 and described in the POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE Article in SECTION G of this contract to determine the Contractor's overall contract performance. Unless specifically identified as a rating criterion in the "Contractor Assessment Report/Performance Indicators and Standards," this evaluation report will not be used in the Award Option determination.

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****(USE BELOW WHEN A CONTRACT REQUIRES A SUBCONTRACTING PLAN (All Contracts OVER $750,000 - OR $1.5 million for construction of Public Facilities) EXCEPT SMALL BUSINESS CONTRACTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **Last Paragraph:** Select appropriate contact from bracketed information within the paragraph; Insert e-mail address for the Government contact; and Select the appropriate title for the Government contact from the bracketed information.

ARTICLE H.56. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan**

1. In accordance with FAR 19.704 and FAR Clause 52.219-9, the submission of a subcontracting plan by other than small business offeror(s) is a requirement as a part of the proposal submission process and is to be submitted separately from the technical and cost proposals. An offeror's subcontracting plan must be determined to be acceptable, by the Contracting Officer, prior to the contract award.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled " Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the

remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. **Subcontracting Reports**

1. An offeror is to submit their respective subcontracting plan electronically using the U.S. Department of Health and Human Services (HHS) Small Business Customer Experience (SBCX) system at https://osdbu.hhs.gov . The offeror shall follow the instructions outlined in the SBCX Industry Guide at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j to successfully submit their subcontracting plan by the proposal submission deadline.
2. The official point of receipt for determining timely submission of an offeror's subcontracting plan is the SBCX system and/or email notification. Once the subcontracting plan is successfully submitted in the SBCX system the offeror should receive an email notification and confirmation message of completion upon submission.
3. If an offeror's subcontracting plan is not confirmed as received within the SBCX system by the proposal submission date specified in the solicitation, it will be considered late in accordance with subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offeror-Competition Acquisition. Disposition of late submittals of a subcontracting plan by an offeror via the SBCX system is at the discretion of the Contracting Officer.
4. Any technical questions regarding the use of the SBCX system may be submitted via email message to the SBCX help desk at client.support@apexlogic.com. The client support hours of operation are Monday - Friday, 6:00 a.m. - 8:00 p.m. Eastern Standard Time (EST). Note: help desk tickets can be submitted 24 hours a day / 7 days a week and a representative will respond within the presented client support hours of operation for assistance.
5. Individual Subcontract Reports (ISR)

   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

   April 30th
   October 30th
   Expiration Date of Contract

6. Summary Subcontract Report (SSR)
   Regardless of the effective date of this contract, the Summary Subcontract Report must be submitted annually on the following date for the entire life of this contract:

   October 30th

   For both the Individual and Summary Subcontract Reports, the [Contracting Officer/Contract Specialist/title of alternate designee] must be included as a contact for notification purposes at the following e- mail address:

   _____
   [Contracting Officer/Contract Specialist]

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****(USE BELOW IN ALL SBIR CONTRACTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

a. **For SBIR Phase I Contracts** : Select "two thirds" from the drop down box.
b. **For SBIR Phase II Contracts** : Select "one half" from the drop down box.
c. Choose the applicable language within the brackets and delete the language that is not appropriate. Awards made by the FY 2014 SBIR solicitation PHS 2014-1 should use "total labor hours." Awards made by the FY 2015 SBIR solicitation PHS 2015-1 should use "total contract costs less profit/fee." Prior to FY 2014, see the applicable SBIR solicitation for guidance.

ARTICLE H.57. LIMITATIONS ON SUBCONTRACTING - SBIR

The Contractor shall perform a minimum of [two-thirds/one-half] of the research and/or analytical effort [total labor hours/total contract costs less profit/fee] conducted under this contract. Any deviation from this requirement must be approved in writing by the Contracting Officer.

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****(The security and privacy requirements set forth herein apply to all new and existing information and IT solicitations and contracts, irrespective of dollar amount.) To determine the applicable language for each solicitation and contract, the requiring activity representative must confer with NIH Information System Security Officer (ISSO)/Chief Information Security Officer (CISO) and Privacy Officer/Senior Official for Privacy (SOP) to complete the "Information Security and Privacy Certification Checklists.")****

ARTICLE H.58. HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS

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****(USE BELOW HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS, IN ALL SOLICITATIONS AND CONTRACTS FOR PROCUREMENTS REQUIRING INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY.)****

NOTE: A procurement requires security if, as a result of the procurement, any Contractor (and/ or any subcontractor) employee:

- will develop, have the ability to access, use, or host and/ or maintain government information and/ or government information system(s), including instances of remote access to or physical removal of such information beyond agency premises or control; or
- will have regular or prolonged physical access to a " federally- controlled facility," as defined in FAR Subpart 2.1.

Physical and Logical Access refers to when contractor personnel (and/ or any subcontractor) are expected to have (1) routine physical access to an HHS- controlled facility; (2) logical access to an HHS- controlled information system; (3) access to government information, whether in an HHS- controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3) as per the HHSAR Subpart 304.13 - Personal Identity Verification and OMB M- 05- 24, Implementation of Homeland Security Presidential Directive (HSPD) 12 - Policy for a Common Identification Standard for Federal Employees and Contractors.

Additional guidance is located in for Position Sensitivity Designations. To determine the designation, the Position Designation Tool (PDT) discussion is found at: https://www.ors.od.nih.gov/ser/dpsac/resources/Pages/investigation-requirements-for-your-position.aspx and the link to access the tool is found at: https://pdt.nbis.mil/

General Resource Information for this Article:

- For more information, see HHS OCIO Policies at: https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/information-security-privacy-program/index.html.
- The Contract Specialist, Project Officer, I/ C Information Systems Security Officer (ISSO), and/ or Privacy Officer can assist the acquisition staff in tailoring the language in the below Article. If additional guidance is needed, contact NIH Office of the Chief Information Officer (OCIO) at nihisaopolicy@mail.nih.gov.

ARTICLE H.58.1. INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

A. Baseline Security Requirements

1. **Applicability.** The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:
   i. **Access (Physical or Logical) to Government Information:** A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.

ii. **Operate a Federal System Containing Information:** A Contractor (and/or any subcontractor) will operate a federal system and technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.

2. **Safeguarding Information and Information Systems.** All government information and information systems must be protected in accordance with HHS/NIH policies and level of risk. At a minimum, the Contractor (and/or any subcontractor) must:
   i. Protect the:
      - **Confidentiality,** which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;
      - **Integrity,** which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
      - **Availability,** which means ensuring timely and reliable access to and use of information.
   ii. Categorize all information owned and/or collected/managed on behalf of HHS/NIH and information systems that store, process, and/or transmit HHS information in accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800-60, Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories . Based on information provided by the ISSO, CISO, OpDiv SOP, or other representative, the impact level for each Security Objective (Confidentiality, Integrity, and Availability) and the Overall Impact Level, which is the highest watermark of the three factors of the information or information system are the following:
      - **Confidentiality:** [ ] Low [ ] Moderate [ ] High
      - **Integrity:** [ ] Low [ ] Moderate [ ] High
      - **Availability:** [ ] Low [ ] Moderate [ ] High
      - **Overall Risk Level:** [ ] Low [ ] Moderate [ ] High
   iii. Based on the agreed-upon level of impact, implement the necessary safeguards to protect all information systems and information collected and/or managed on behalf of HHS/NIH regardless of location or purpose.
   iv. Report any discovered or unanticipated threats or hazards by either the agency or contractor, or if existing safeguards have ceased to function immediately after discovery, **within one (1) hour or less,** to the government representative(s).
   v. Adopt and implement all applicable policies, procedures, controls, and standards required by the HHS/NIH Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain all applicable security and privacy policies by contacting the CO/COR or HHS/NIH security and/or privacy officials.

3. **Privacy Act.** Comply with the Privacy Act requirements (when applicable), and tailor FAR and HHSAR clauses as needed.
4. **Privacy Compliance.** Comply with the E-Government Act of 2002, NIST SP 800-53, and applicable HHS/OpDiv privacy policies, and complete all the requirements below:
    i. Per the Office of Management and Budget (OMB) Circular A-130, Personally Identifiable Information (PII), is "information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: Social Security number, date and place of birth, mother's maiden name, biometric records, etc.
    ii. Based on information provided by the ISSO, system/ data owner, or other security or privacy representative, it has been determined that this solicitation/ contract involves:

        [ ] No PII [ ] PII

    iii. The Contractor must support the agency with conducting a Privacy Threshold Analysis (PTA) for the information system and/ or information handled under this contract to determine whether or not a full Privacy Impact Assessment (PIA) needs to be completed.
        - If the results of the PTA show that a full PIA is needed, the Contractor must support the agency with completing a PIA for the system or information within **60 days** after completion of the PTA and in accordance with HHS policy and OMB M-03-22, *Guidance for Implementing the Privacy Provisions of the E- Government Act of 2002.*
        - The Contractor must support the agency in reviewing the PIA at least every **three years** throughout the system development lifecycle (SDLC)/information lifecycle, or when determined by the agency that a review is required based on a major change to the system, or when new types of PII are collected that introduces new or increased privacy risks, whichever comes first.
5. **Controlled Unclassified Information (CUI). Executive Order 13556 defines** CUI as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Contractor (and/or any subcontractor) must comply with *Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR, part 2002)* when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term " *handling* " refers to "…any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. The requirements below apply only to nonfederal systems that process, store, or transmit CUI, or that provide security protection for such components. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, must be:
    i. Marked appropriately;
    ii. Disclosed to authorized personnel on a Need-To-Know basis;
    iii. Protected in accordance with NIST SP 800-53, *Security and Privacy Controls for Information Systems and Organizations* applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, *Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations* if handled by internal Contractor system; and

iv. Returned to HHS control, destroyed when no longer needed, or held until otherwise directed. Information and/or data must be disposed of in accordance with NIST SP 800-88, *Guidelines for Media Sanitization* .

6. **Protection of Sensitive Information.** For security purposes, information is or may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) must protect all government information that is or may be sensitive by securing it with a solution that is validated with current FIPS 140 validation certificate from the NIST CMVP.
7. **Confidentiality and Nondisclosure of Information.** Any information provided to the contractor (and/or any subcontractor) by HHS or collected by the contractor on behalf of HHS must be used only for the purpose of carrying out the provisions of this contract and must not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and must ensure that all work performed by its employees and subcontractors must be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any HHS records may be made available or disclosed must be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

   The confidentiality, integrity, and availability of such information must be protected in accordance with HHS and NIH policies. Unauthorized disclosure of information will be subject to the HHS/NIH sanction policies and/or governed by the following laws and regulations:

   i. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
   ii. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and
   iii. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

8. **Internet Protocol Version 6 (IPv6).** All procurements using Internet Protocol must comply with OMB Memorandum M-05-22, *Transition Planning for Internet Protocol Version 6 (IPv6).*
9. **Information and Communications Technology (ICT).** ICT products and services from prohibited entities/sources must not be used/acquired in compliance with Public Law 115-232, Section 889 Parts A and B, FAR 4.21, FAR 52.204.23, FAR 52.204.24, and FAR 52.204.25. The contractor (and/or any subcontractor) must notify the government if they identify prohibited ICT products and/or services are used during the contract performance.
10. **Government Websites.** All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS must enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, HTTPS is not required, but it is highly recommended. Consult the *HHS Policy for Internet and Email Security* for additional information.
11. **Contract Documentation.** The Contractor must use provided templates, policies, forms and other agency documents. NIH will specify which documents/forms will be provided to comply with contract deliverables as appropriate.
12. **Standard for Encryption.** The Contractor (and/or any subcontractor) must:

i. Comply with the *HHS Standard for Encryption of Computing Devices and Information* to prevent unauthorized access to government information.
ii. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with encryption solution that is validated with current FIPS 140 validation certificate from the NIST CMVP.
iii. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and NIH-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).
iv. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with current FIPS 140 validation certificate from the NIST CMVP. The Contractor must provide a written copy of the validation documentation to the COR within **15 days** of the validation.
v. Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys http://csrc.nist.gov/publications/ . Encryption keys must be provided to the COR upon request and at the conclusion of the contract.

13. **Contractor Non-Disclosure Agreement (NDA).** Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract must complete the OpDiv non-disclosure agreement, https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf , as applicable. Contractors (and/or subcontractors) must submit a copy of each signed and witnessed NDA to the Contracting Officer (CO) and/or CO Representative (COR) prior to performing any work under this acquisition.

B. Training Requirements

1. **Mandatory Training for All Contractor Staff.** All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable HHS/NIH Contractor Information Security Awareness, Privacy, and Records Management training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, the employees shall complete NIH Information Security Awareness, Privacy, and Records Management training at least ***annually,*** during the life of this contract. All provided training shall be compliant with HHS training policies.
2. **Role-based Training.** All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training **annually** commensurate with their role and responsibilities in accordance with *HHS policy and the HHS Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Memorandum.* Read further guidance about the NIH Role-based Training at: https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/index.html .

3. **Training Records.** The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS policy. A copy of the training records shall be provided to the CO and/or COR within ***30 days*** after contract award and ***annually*** thereafter or upon request.

C. Rules of Behavior

1. The Contractor (and/or any subcontractor) must ensure that all employees performing on the contract comply with the *HHS Information Technology General Rules of Behavior, HHS Rules of Behavior for Privileged Users.*
2. All Contractor employees performing on the contract must read and adhere to the Rules of Behavior before accessing Department data or other information, systems, and/or networks that store/process government information, initially at the beginning of the contract and at least ***annually*** thereafter, which may be done as part of annual NIH Information Security Awareness Training. If the training is provided by the Contractor, the signed ROB must be provided as a separate deliverable to the CO and/or COR per defined timelines above.

D. Incident Response

1. The Contractor (and/or any subcontractor) must respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams **within 24 hours,** whether the response is positive or negative.

   FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. In accordance with OMB M-17-12, *Preparing for and Responding to a Breach of Personally Identifiable Information (PII)* , an incident is "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies" and a privacy breach is "the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose." For additional information on the HHS breach response process, please see the *HHS Policy and Plan for Preparing for and Responding to a Breach of Personally Identifiable Information (PII)."*
2. In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) must:
   i. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract, with encryption solution that is validated with current FIPS 140 validation certificate from the NIST CMVP.
   ii. NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor must send NIH approved notifications to affected individuals in accordance with

https://wiki.ocio.nih.gov/wiki/index.php/US-CERT_Federal_Incident_Notification_Guidelines

iii. Report all suspected and confirmed information security and privacy incidents and breaches to the OpDiv Incident Response Team (IRT) via email at IRT@mail.nih.gov , COR, CO, OpDiv SOP (or his or her designee), and other stakeholders, including breaches involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than **one (1) hour,** and consistent with the applicable OpDiv and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contact information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor must:
   - Cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
   - Not include any sensitive information in the subject or body of any reporting e-mail; and
   - Encrypt sensitive information in attachments to email, media, etc.

iv. Comply with OMB M-17-12, *Preparing for and Responding to a Breach of Personally Identifiable Information,* and HHS/NIH and NIH privacy breach response policies when handling PII breaches.

v. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation within an **hour** of discovery.

E. Position Sensitivity Designations

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/contract:

[ ] Tier 5: Critical Sensitive and Special Sensitive National Security, including Top Secret, SCI, and "Q" access eligibility.
[ ] Tier 5SR: Reinvestigation.

[ ] Tier 4: High Risk Public Trust (HRPT).
[ ] Tier 4SR: Reinvestigation.

[ ] Tier 3: Non-Critical Sensitive, National Security, including Secret and "L" access eligibility.
[ ] Tier 3SR: Reinvestigation.

[ ] Tier 2S with Subject Interview: Moderate Risk Public Trust (MRPT).
[ ] Tier 2SR: Reinvestigation.

[ ] Tier 1: Low Risk, Non-Sensitive, including HSPD-12 Credentialing.

F. Homeland Security Presidential Directive (HSPD)-12

The Contractor (and/or any subcontractor) and its employees must comply with Homeland Security Presidential Directive (HSPD)-12, *Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; OMB M-19-17; FIPS 201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; and Executive Order 13467, Part 1 §1.2.*
For additional information, see HSPD-12 policy at: https://www.dhs.gov/homeland-security-presidential-directive-12.

G. Roster

The Contractor (and/or any subcontractor) must submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster must be submitted to the COR and/or CO within **fourteen (14) calendar days** of the effective date of this contract. Any revisions to the roster as a result of staffing changes must be submitted within **seven (7) calendar days** of the change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j
If the employee is filling a new position, the Contractor must provide a position description and the Government will determine the appropriate suitability level. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

H. Contract Initiation and Expiration

1. **General Security Requirements.** The Contractor (and/or any subcontractor) must comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the Contractor must follow the HHS EPLC framework and methodology and in accordance with the HHS Contract Closeout Directive (2018) located at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HHS-Closeout-Directive-2018.pdf . HHS EA requirements are located at: https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-policy-for-enterprise-architecture.html and NIH EA requirements are located at: https://ocio.nih.gov/PM/Pages/EPLC.aspx .

2. **System Documentation.** Contractors (and/or any subcontractors) must follow and adhere to HHS System Development Life Cycle requirements, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.
3. **Sanitization of Government Files and Information.** As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) must provide all required documentation in accordance with the NIH Media Sanitization and Disposal Policy to the CO and/or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, *Guidelines for Media Sanitization.*
4. **Notification.** The Contractor (and/or any subcontractor) must notify the CO and/or COR and system ISSO within fifteen days before an employee stops working under this contract.
5. **Contractor Responsibilities upon Physical Completion of the Contract.** The Contractor (and/or any subcontractors) must return all government information and IT resources (i.e., government information in non-government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor must provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or NIH policies.
6. The Contractor (and/or any subcontractor) must perform and document the actions identified in the NIH Employee Separation Checklist https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf when an employee terminates work under this contract within 2 days of the employee's exit from the contract. All documentation must be available to the CO and/or COR upon request.

I. Records Management and Retention

1. The Contractor (and/or any subcontractor) must maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and *HHS Policy for Records Management* and NIH policies and must not dispose of any records unless authorized by HHS/NIH.
2. In the event that a Contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, he/she must document and report the incident in accordance with HHS/ NIH policies.

J. High Value Asset (HVA)

If a system is identified as HVA, the Contractor must comply with the HHS Policy for the High Value Asset (HVA) Program and the DHS HVA Control Overlay in addition to the above requirements.

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****(USE BELOW HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS, IN SOLICITATIONS, CONTRACTS AND ORDERS THAT REQUIRE THE DESIGN, DEVELOPMENT, OR OPERATION OF A SYSTEM OF RECORDS TO NOTIFY THE CONTRACTOR THAT IT AND ITS EMPLOYEES ARE SUBJECT TO CRIMINAL PENALTIES FOR VIOLATIONS OF THE PRIVACY ACT (5 U.S.C. 552A(I) TO THE SAME EXTENT AS HHS EMPLOYEES.)****
See HHSAR 324.105(a) for more information.

NOTE: This language does not alleviate the requirement to properly incorporate the three FAR and HHSAR clauses identified below in the applicable solicitation and resultant contract.

The following definitions and clauses are relevant to this section:
FAR Subpart 24.101- Definitions. Consult the definitions of " agency," " individual," " maintain," " operation of a system of records," " record," and " system of records on individuals" to determine if the Privacy Act applies. If the Privacy Act applies, the following three clauses must be incorporated.

1. FAR Clause 52.224-1 Privacy Act Notification.
2. FAR Clause 52.224-2 Privacy Act.
3. HHSAR Clause 352.224-70 Privacy Act.

NOTE: This clause requires inclusion of Language specifying the applicable system(s) of records or proposed system(s) of records, the design, development, or operation work the Contractor is to perform, and the records disposition instructions to be followed by the Contractor upon completion of contract performance.

ARTICLE H.58.2. PRIVACY ACT

It has been determined that this contract is subject to the Privacy Act of 1974, because this contract provides for the design, development, or operation of a system of records on individuals.
The System of Records Notice (SORN) that is applicable to this contract is: _____ [*Insert SORN number if one exists. If there is no SORN, indicate that a SORN will be developed*].
The design, development, or operation work the Contractor is to perform is: _____ [*Insert description of design, development, and/or operation work; see definitions in the FAR at 24.101 - Definitions*].
The SORN describing the types of information contained in the records, the legal authority for collecting and maintaining the records, how the records are used within HHS, and the purposes (referred to as "routine uses") for which HHS may disclose the records to non-HHS parties without the individual record subject's consent is found at: https://www.hhs.gov/foia/privacy/sorns/nih-sorns.html.
The Contractor and any Subcontractor must follow disposition to be made of the Privacy Act records upon completion of contract performance shall be in accordance with Section C of the contract, and by direction of the Contracting Officer/Contracting Officer Representative.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR GOVERNMENT INFORMATION PROCESSED ON GOCO OR COCO SYSTEMS.)****

In addition to definitions and clauses specified in clause "Procurement Requiring Information Security and/or Physical Access Security" and applicable definitions and clauses in "Requirements for Procurements Involving Privacy Act Records."

The following FAR references are relevant to this section:

1. FAR Part 52 including clauses 52.239-1 and 52.204-21 (Section 4.A.)
2. FAR Subpart 39.101(c) (Section 4.5)b.)

ARTICLE H.58.3. GOVERNMENT INFORMATION PROCESSED ON GOCO OR COCO SYSTEMS

A. SECURITY REQUIREMENTS FOR GOVERNMENT-OWNED/CONTRACTOR-OPERATED (GOCO)AND CONTRACTOR-OWNED/CONTRACTOR-OPERATED (COCO) RESOURCES

1. **Federal Policies-** The Contractor (and/or any subcontractor) shall comply with applicable federal laws that include, but are not limited to, the HHS Information Security and Privacy Policy (IS2P), Federal Information Security Modernization Act (FISMA) of 2014, (44 U.S.C. 101); National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53, Security and Privacy Controls for Federal Information Systems and Organizations; Office of Management and Budget (OMB) Circular A-130, Managing Information as a Strategic Resource; and other applicable federal laws, regulations, NIST guidance, and Departmental policies.
2. **Assessment and Authorization (A&A)-** A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) shall work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s) within three (3) months after contract award. The Contractor shall conduct the A&A requirements in accordance with HHS IS2P, NIST SP 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach (latest revision).

   For an existing ATO, Contracting Officer Representative must make a determination if the existing ATO provides appropriate safeguards or if an additional ATO is required for the performance of the contract and state as such.

   NIH acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the system security and privacy controls are implemented and operating effectively.

   i. **A&A Package Deliverables -** The Contractor (and/or any subcontractor) shall provide an A&A package within 30 days of contract award to the CO and/or COR. The following SA&A deliverables are required to complete the SA&A package. The NIH Assessment and Authorization Process is found at: https://wiki.ocio.nih.gov/wiki/index.php/NIH_Assessment_and_Authorization_(A%26A)_Process .

   - **System Security Plan (SSP)** - due within 30 days after contract award. The SSP shall comply with the NIST SP 800-18, Guide for Developing Security Plans for Federal Information Systems, the Federal Information Processing Standard (FIPS) 200,

Recommended Security Controls for Federal Information Systems, and NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline requirements, and other applicable NIST guidance as well as HHS and NIH policies and other guidance. The SSP shall be consistent with and detail the approach to IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The SSP shall provide an overview of the system environment and security requirements to protect the information system as well as describe all applicable security controls in place or planned for meeting those requirements. It should provide a structured process for planning adequate, cost-effective security protection for a system. The Contractor shall update the SSP at least annually thereafter.

- **Security Assessment Plan/Report (SAP/SAR)** - due 30 days after the contract award. The security assessment shall be conducted by the assessor and be consistent with NIST SP 800-53A, NIST SP 800-30, and HHS and NIH policies. The assessor will document the assessment results in the SAR.

  The NIH should determine which security control baseline applies and then make a determination on the appropriateness/necessity of obtaining an independent assessment. Assessments of controls can be performed by Contractor, government, or third parties, with third party verification considered the strongest. If independent assessment is required, include statement below.

  Thereafter, the Contractor, in coordination with the NIH shall conduct/assist in the assessment of the security controls and update the SAR at least annually.
- **Independent Assessment -** due 90 days after the contract award. The Contractor (and/or subcontractor) shall have an independent third-party validate the security and privacy controls in place for the system(s). The independent third party shall review and analyze the Security Authorization package, and report on technical, operational, and management level deficiencies as outlined in NIST SP 800-53. The Contractor shall address all "high" deficiencies before submitting the package to the Government for acceptance. All remaining deficiencies must be documented in a system Plan of Actions and Milestones (POA&M).
- **POA&M -** due 30 days after contract award. The POA&M shall be documented consistent with the HHS Standard for Plan of Action and Milestones and NIH policies. All findings/weaknesses shall be documented in the POA&M and remediated/mitigated from the date the weaknesses are formally identified and documented by the timelines below:

    - Critical within 30 days:
    - High within 60 days;
    - Medium within 1 year; and
    - Low within 1 year.

  The NIH will determine the risk rating of vulnerabilities. Identified risks stemming from deficiencies related to the security control baseline implementation, assessment, continuous monitoring, vulnerability scanning, and other security reviews and sources, as documented in the SAR, shall be documented and tracked by the Contractor for

mitigation in the POA&M document. Depending on the severity of the risks, NIH may require designated POAM weaknesses to be remediated before an ATO is issued. Thereafter, the POA&M shall be updated at least quarterly.

- **Contingency Plan and Contingency Plan Test** - due 60 days after contract award. The Contingency Plan must be developed in accordance with NIST SP 800-34, Contingency Planning Guide for Federal Information Systems, and be consistent with HHS and NIH policies. Upon acceptance by the System Owner, the Contractor, in coordination with the System Owner, shall test the Contingency Plan and prepare a Contingency Plan Test Report that includes the test results, lessons learned and any action items that need to be addressed. Thereafter, the Contractor shall update and test the Contingency Plan at least annually.
- **E-Authentication Questionnaire** - The Contractor (and/or any subcontractor) shall collaborate with government personnel to ensure that an E-Authentication Threshold Analysis (E-auth TA) is completed to determine if a full E-Authentication Risk Assessment (E-auth RA) is necessary. System documentation developed for a system using E-auth TA/E-auth RA methods shall follow OMB 04-04 and NIST SP 800-63, Rev. 2, Electronic Authentication Guidelines.

  Based on the level of assurance determined by the E-Auth, the Contractor (and/or subcontractor) must ensure appropriate authentication to the system, including remote authentication, is in-place in accordance with the assurance level determined by the E-Auth (when required) in accordance with HHS policies.

c. **Information Security Continuous Monitoring** - Upon the government issuance of an Authority to Operate (ATO), the Contractor (and/or subcontractor)-owned/operated systems that input, store, process, output, and/ or transmit government information, shall meet or exceed the Information Security Continuous Monitoring (ISCM) requirements in accordance with FISMA and NIST SP 800-137, *Information Security Continuous Monitoring (ISCM) for Federal Information Systems and Organizations* , and HHS IS2P. The following are the minimum requirements for ISCM:

   i. **Annual Assessment/ Penetration (Pen) Test** - Assess the system security and privacy controls (or ensure an assessment of the controls is conducted) every two (2) years on high-risk systems, to determine the implemented security and privacy controls are operating as intended and producing the desired results (this may involve penetration testing conducted by the agency or independent third-party. In addition, review all relevant A& A documentation (SSP, POA& M, Contingency Plan, etc.) and provide updates by specified due date provided by the Contracting Officer Representative.

   ii. **Asset Management -** Using any available Security Content Automation Protocol (SCAP)- compliant automated tools for active/passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing HHS- owned information/ data. It is anticipated that this inventory information will be required to be produced at least 60 days after contract award. IT asset inventory information shall include IP address, machine name, operating system level, security patch level, and SCAP-compliant format information. The Contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.

iii. **Configuration Management** - Use available SCAP- compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The Contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP- compliant automated tools.

iv. **Vulnerability Management** - Use SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process government information. Contractors shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS policy. Automated tools shall be compliant with NIST- specified SCAP standards for vulnerability identification and management. The Contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP- compliant automated tools and report to the agency at least within 30 days of the contract award.

v. **Patching and Vulnerability Remediation** - Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeframes.

vi. **Secure Coding** - Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.

vii. **Boundary Protection** - The Contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).

- **Government Access for Security Assessment -** In addition to the Inspection Clause in the contract, the Contractor (and/or any subcontractor) shall afford the Government access to the Contractor's facilities, installations, operations, documentation, information systems, and personnel used in performance of this contract to the extent required to carry out a program of security assessment (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the confidentiality, integrity, and availability of federal data or to the protection of information systems operated on behalf of HHS, including but are not limited to:

  i At any tier handling or accessing information, consent to and allow the Government, or an independent third party working at the Government's direction, without notice at any time during a weekday during regular business hours Contractor local time, to access Contractor and subcontractor installations, facilities, infrastructure, data centers, equipment (including but not limited to all

servers, computing devices, and portable media), operations, documentation (whether in electronic, paper, or other forms), databases, and personnel which are used in performance of the contract.

The Government includes but is not limited to the U.S. Department of Justice, U.S. Government Accountability Office, and the HHS Office of the Inspector General (OIG). The purpose of the access is to facilitate performance inspections and reviews, security and compliance audits, and law enforcement investigations. For security audits, the audit may include but not be limited to such items as buffer overflows, open ports, unnecessary services, lack of user input filtering, cross site scripting vulnerabilities, SQL injection vulnerabilities, and any other known vulnerabilities.

ii At any tier handling or accessing protected information, fully cooperate with all audits, inspections, investigations, forensic analysis, or other reviews or requirements needed to carry out requirements presented in applicable law or policy. Beyond providing access, full cooperation also includes, but is not limited to, disclosure to investigators of information sufficient to identify the nature and extent of any criminal or fraudulent activity and the individuals responsible for that activity. It includes timely and complete production of requested data, metadata, information, and records relevant to any inspection, audit, investigation, or review, and making employees of the Contractor available for interview by inspectors, auditors, and investigators upon request. Full cooperation also includes allowing the Government to make reproductions or copies of information and equipment, including, if necessary, collecting a machine or system image capture.

- Segregate Government protected information and metadata on the handling of Government protected information from other information. Commingling of information is prohibited. Inspectors, auditors, and investigators will not be precluded from having access to the sought information if sought information is commingled with other information.
- Cooperate with inspections, audits, investigations, and reviews.

4. **End of Life Compliance-** The Contractor (and/or any subcontractor) must use Commercial off the Shelf (COTS) software or other software that is supported by the manufacturer. In addition, the COTS/other software need to be within one major version of the current version; deviation from this requirement will only be allowed via the HHS waiver process (approved by HHS CISO). The Contractor shall retire and/or upgrade all software/systems that have reached end-of-life in accordance with HHS End-of-Life Operating Systems, Software, and Applications Policy.
5. **Desktops, Laptops, and Other Computing Devices Required for Use by the Contractor-** The Contractor (and/or any subcontractor) shall ensure that all IT equipment (e.g., laptops, desktops, servers, routers, mobile devices, peripheral devices, etc.) used to process information on behalf of HHS are deployed and operated in accordance with approved security configurations and meet the following minimum requirements:

i. Encrypt equipment and sensitive information stored and/or processed by such equipment in accordance with HHS and FIPS 140-3 encryption standards.
ii. Configure laptops and desktops in accordance with the latest applicable United States Government Configuration Baseline (USGCB), and HHS Minimum Security Configuration Standards;
iii. Maintain the latest operating system patch release and anti-virus software definitions within 15 days.
iv. Validate the configuration settings after hardware and software installation, operation, maintenance, update, and patching and ensure changes in hardware and software do not alter the approved configuration settings; and
v. Automate configuration settings and configuration management in accordance with HHS security policies, including but not limited to:
    - Configuring its systems to allow for periodic HHS vulnerability and security configuration assessment scanning; and
    - Using Security Content Automation Protocol (SCAP)-validated tools with USGCB Scanner capabilities to scan its systems at least on a monthly basis and report the results of these scans to the CO and/or COR, Project Officer, and any other applicable designated POC.

6. **Rights to Data.** All contracts that require data to be produced, furnished, acquired, or used in meeting contract performance requirements, must contain terms that delineate the respective rights and obligations of the Government and the contractor regarding the use, reproduction, and disclosure of that data. Data rights clauses do not specify the type, quantity or quality of data that is to be delivered, but only the respective rights of the Government and the contractor regarding the use, disclosure, or reproduction of the data. Accordingly, the contract must specify the data to be delivered.
7. **Information and Communications Technology (ICT) Cybersecurity Supply Chain Risk Management (C-SCRM) requirements.** The Contractor (and/or any subcontractor) must secure their ICT supply chain in compliance with *HHS Policy for Cyber Supply Chain Risk Management* and Public Law 115-232 § 889. At a minimum, they must implement the following:
    i. Develop rules for suppliers' development methods, techniques, or practices;
    ii. Use of secondary market components;
    iii. Prohibit counterfeit products;
    iv. Dispose and/or retain elements such as components, data, or intellectual property securely;
    v. Ensure adequate supply of components;
    vi. Require external providers handling federal information or operating systems on behalf of the federal government to meet the same security and privacy requirements as federal agencies;
    vii. Require external providers to express security and privacy requirements (including the controls for systems processing, storing, or transmitting federal information) in contracts or other formal agreements;
    viii. Establish Service Level Agreements (SLAs), patching vehicles and disclosure requirements in the case of a security incident or new vulnerability being discovered; and
    ix. Ensure that the supplier applies same contractual requirements to any sub-contractors/suppliers that they involve in the provision of the product or service to the customer; and

x. Prohibit the use of covered telecommunications and video surveillance equipment or services.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR PROCUREMENT INVOLVING CLOUD SERVICES.)****
In addition to the standard baseline language in Section "Procurement Requiring Information Security and/or Physical Access Security" and applicable language from clause "Requirements for Procurements Involving Privacy Act Records." and section for "Government Information Processed on GOCO/COCO Systems." These include: Infrastructure as a Service (IaaS), Platform as a Service (PaaS), Software as a Service (SaaS), and information systems moving to a cloud environment. The requiring activity representative must confer with the NIH's System Owner, ISSO or CISO, and the NIH Office of SOP to determine any additional security and privacy requirements applicable to the solicitation/contract that need to be included.

ARTICLE H.58.4. CLOUD SERVICES

A. **HHS FedRAMP (Federal Risk and Authorization Management Program) Privacy and Security Requirements**

The Contractor (and/or any subcontractor) shall be responsible for the following privacy and security requirements:

1. **FedRAMP Compliant ATO** . Comply with requirements and ensure the information system/service under this contract has a valid FedRAMP compliant (approved) authority to operate (ATO) in accordance with Federal Information Processing Standard (FIPS) Publication 199 defined security categorization. If a FedRAMP compliant ATO has not been granted, the Contractor must submit a plan to obtain a FedRAMP compliant ATO by 30 days of the contract award.
    i. Implement applicable FedRAMP baseline controls commensurate with the agency-defined security categorization and the applicable FedRAMP security control baseline (www.FedRAMP.gov).
    ii. A security control assessment must be conducted by a FedRAMP third-party assessment organization (3PAO) for the initial ATO and annually thereafter or whenever there is a significant change to the system's security posture in accordance with the FedRAMP Continuous Monitoring Plan.
2. **Data Jurisdiction** - The Contractor must store all information within the security authorization boundary, data at rest or data backup, within the continental United States (CONUS) if so required as stated in section C.
3. **Service Level Agreements** - Add when applicable/ Mark as Not Applicable _____ The Contractor must understand the terms of the service agreements that define the legal relationships between cloud customers and cloud providers and work with NIH to develop and maintain an SLA.
4. **Interconnection Agreements/ Memorandum of Agreements** - Add when applicable/ Mark as Not Applicable _____ The Contractor must establish and maintain Interconnection Agreements and or Memorandum of Agreements/ Understanding in accordance with HHS/ NIH policies.

B. **Protection of Information in a Cloud Environment**

1. If Contractor (and/or any subcontractor) personnel must remove any information from the primary work area, they shall protect it to the same extent they would the proprietary data and/ or company trade secrets and in accordance with HHS/ NIH policies.
2. HHS will retain unrestricted rights to federal data handled under this contract. Specifically, HHS retains ownership of any user created/ loaded data and applications collected, maintained, used, or operated on behalf of HHS and hosted on Contractor's infrastructure, as well as maintains the right to request full copies of these at any time. If requested, data must be available to HHS within one (1) business day from request date or within the timeframe specified otherwise. In addition, the data shall be provided at no additional cost to HHS.
3. The Contractor (and/or any subcontractor) must ensure that the facilities that house the network infrastructure are physically and logically secure in accordance with FedRAMP requirements and HHS policies.
4. The Contractor must support a system of records in accordance with NARA-approved records schedule(s) and protection requirements for federal agencies to manage their electronic records in accordance with 36 CFR § 1236.20 & 1236.22 (ref. a), including but not limited to the following:
    a. Maintenance of links between records and metadata, and
    b. Categorization of records to manage retention and disposal, either through transfer of permanent records to NARA or deletion of temporary records in accordance with NARA-approved retention schedules.
5. The disposition of all HHS data must be at the written direction of HHS/ NIH. This may include documents returned to HHS control; destroyed; or held as specified until otherwise directed. Items returned to the Government must be hand carried or sent by certified mail to the COR.

a. If the system involves the design, development, or operation of a system of records on individuals, the Contractor shall comply with the Privacy Act requirements.

3. **Assessment and Authorization (A&A) Process**

1. The Contractor (and/ or any subcontractor) must comply with HHS and FedRAMP requirements as mandated by federal laws, regulations, and HHS policies, including making available any documentation, physical access, and logical access needed to support the A& A requirement. The level of effort for the A& A is based on the system's FIPS 199 security categorization and HHS/ NIH security policies.
    a. In addition to the FedRAMP compliant ATO, the contractor shall complete and maintain an agency A& A package to obtain agency ATO prior to system deployment/ service implementation. The agency ATO must be approved by the NIH authorizing official (AO) prior to implementation of system and/ or service being acquired.
    b. CSP systems categorized as Federal Information Processing Standards (FIPS) 199 high must leverage a FedRAMP accredited third- party assessment organization (3PAO); moderate impact CSP systems must make a best effort to use a FedRAMP accredited 3PAO. CSP systems categorized as FIPS 199 low impact may leverage a non- accredited, independent assessor.
    c. For all acquired cloud services, the A& A package must contain the following documentation: SSP, SAR, POA&M, Authorization Letter, CP and CPT report, E- Authorization (if applicable), PTA/ PIA (if applicable), Interconnection/ Data Use Agreements (if applicable), Authorization Letter, Configuration Management Plan (if applicable), Configuration Baseline, Following the

initial ATO, the Contractor must review and maintain the ATO in accordance with HHS/ NIH policies.

2. HHS reserves the right to perform penetration testing (pen testing) on all systems operated on behalf of agency. If HHS exercises this right, the Contractor (and/or any subcontractor) must allow HHS employees (and/ or designated third parties) to conduct Security Assessment activities to include control reviews in accordance with HHS requirements. Review activities include, but are not limited to, scanning operating systems, web applications, wireless scanning; network device scanning to include routers, switches, and firewall, and IDS/IPS; databases and other applicable systems, including general support structure, that support the processing, transportation, storage, or security of Government information for vulnerabilities.
3. The Contractor must identify any gaps between required FedRAMP Security Control Baseline/Continuous Monitoring controls and the Contractor's implementation status as documented in the Security Assessment Report and related Continuous Monitoring artifacts. In addition, all gaps shall be documented and tracked by the contractor for mitigation in a Plan of Action and Milestones (POA&M) document. Depending on the severity of the risks, HHS may require remediation at the contractor's expense, before HHS issues an ATO.
4. The Contractor (and/or any subcontractor) must mitigate security risks for which they are responsible, including those identified during A& A and continuous monitoring activities. All vulnerabilities and other risk findings must be remediated by the prescribed timelines from discovery: (1) critical vulnerabilities no later than thirty (30) days and (2) high, medium and low vulnerabilities no later than sixty (60) days. In the event a vulnerability or other risk finding cannot be mitigated within the prescribed timelines above, they must be added to the designated POA& M and mitigated within the newly designated timelines 30 days. HHS will determine the risk rating of vulnerabilities using FedRAMP baselines.
5. Revocation of a Cloud Service. HHS/NIH staff division have the right to take action in response to the CSP's lack of compliance and/or increased level of risk. In the event the CSP fails to meet HHS and FedRAMP security and privacy requirements and/ or there is an incident involving sensitive information, HHS and/or NIH may suspend or revoke an existing agency ATO (either in part or in whole) and/ or cease operations. If an ATO is suspended or revoked in accordance with this provision, the CO and/or COR may direct the CSP to take additional security measures to secure sensitive information. These measures may include restricting access to sensitive information on the Contractor information system under this contract. Restricting access may include disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls.

4. **Reporting and Continuous Monitoring**

1. Following the initial ATOs, the Contractor (and/or any subcontractor) must perform the minimum ongoing continuous monitoring activities specified below, submit required deliverables by the specified due dates, and meet with the system/ service owner and other relevant stakeholders to discuss the ongoing continuous monitoring activities, findings, and other relevant matters. The CSP will work with the agency to schedule ongoing continuous monitoring activities.
2. At a minimum, the Contractor must provide the following artifacts/deliverables on a monthly basis as directed by the Contracting Officer/Contracting Officer Representative:
    i. Operating system, database, Web application, and network vulnerability scan results.

ii. Updated POA&Ms;
iii. Any updated authorization package documentation as required by the annual attestation/assessment/review or as requested by the NIH System Owner or AO; and
iv. Any configuration changes to the system and/or system components or CSP's cloud environment, that may impact HHS/NIH's security posture. Changes to the configuration of the system, its components, or environment that may impact the security posture of the system under this contract must be approved by the agency.

3. **Information Security Continuous Monitoring** - Upon the government issuance of an Authority to Operate (ATO), the Contractor (and/or subcontractor)-owned/operated systems that input, store, process, output, and/or transmit government information, shall meet or exceed the information security continuous monitoring (ISCM) requirements in accordance with FISMA and NIST SP 800-137, Information Security Continuous Monitoring (ISCM) for Federal Information Systems and Organizations, and HHS IS2P. The following are the minimum requirements for ISCM:
    i. **Annual Assessment/Pen Test** - Assess the system security and privacy controls (or ensure an assessment of the controls is conducted) at least annually to determine the implemented security and privacy controls are operating as intended and producing the desired results (this may involve penetration testing conducted by the agency or independent third-party. In addition, review all relevant A&A documentation (SSP, POA&M, Contingency Plan, etc.) and provide updates by specified due date provided by the Contracting Officer Representative.
    ii. **Asset Management** - Using any available Security Content Automation Protocol (SCAP)-compliant automated tools for active/passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing HHS-owned information/data. It is anticipated that this inventory information will be required to be produced at least 60 days after contract award. IT asset inventory information must include IP address, machine name, operating system level, security patch level, and SCAP-compliant format information. The Contractor must maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.
    iii. **Configuration Management** - Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The Contractor must maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.
    iv. **Vulnerability Management** - Use SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process government information. Contractors must actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS policy. Automated tools must be compliant with NIST-specified SCAP standards for vulnerability identification and management. The Contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP-

compliant automated tools and report to the agency at least within 30 days of the contract award.

v. **Patching and Vulnerability Remediation** - Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeframes.

vi. **Secure Coding** - Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.

vii. **Boundary Protection** - The Contractor must ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).

viii. A security control assessment must be conducted by a FedRAMP third-party assessment organization (3PAO) for the initial ATO and annually thereafter or whenever there is a significant change to the system's security posture in accordance with the FedRAMP Continuous Monitoring Plan.

5. **Configuration Baseline**

1. The Contractor must certify that applications are fully functional and operate correctly as intended on systems using the US Government Configuration Baseline (USGCB), DISA Security Technical Implementation Guides (STIGs), Center for Information Security (CIS) Security Benchmarks or any other HHS- identified configuration baseline. The standard installation, operation, maintenance, updates, and/ or patching of software must not alter the configuration settings from the approved HHS/NIH.
2. The Contractor must configure its computers that contain HHS data with the latest applicable United States Government Configuration Baseline (USGCB) and/ or other approved HHS IT Security Configurations. (See: https://usgcb.nist.gov/). Note: Approved security configurations include, but are not limited to, those published by the Department, the NIH, and the National Institute of Standards and Technology (NIST). NIH may have security configurations that are more stringent than the minimum baseline set by the Department or NIST. When incorporating such security configuration requirements in solicitations and contracts, the NIH CISO and/ or Information System Security Officer (ISSO) must be consulted to determine the appropriate configuration reference for a particular system or services acquisition.)
3. The Contractor must apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS and must adhere to all NIH configuration standards and policies (See: https://ocio.nih.gov/ITGovPolicy/Pages/spec_policy.aspx).
4. The Contractor must ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor must use Security Content Automation Protocol (SCAP) - validated tools with USGCB Scanner capability to ensure its products operate correctly with USGCB configurations and do not alter USCGB settings - (See: https://csrc.nist.gov/projects/scap-validation-program). The Contractor must test applicable product versions with all relevant and current updates and patches installed. The Contractor must ensure currently supported versions of information technology products met the latest USGCB major version and subsequent major versions.

5. The Contractor must ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.
6. The Contractor must ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.
7. The Contractor must (1) include Federal Information Processing Standard (FIPS) 201- compliant (See: https://csrc.nist.gov/csrc/media/publications/fips/201/1/archive/2006-06-26/documents/fips-201-1-chng1.pdf), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.
8. The Contractor must ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.
9. The Contractor must use Security Content Automation Protocol (SCAP) validated tools with configuration baseline scanner capability to certify their products operate correctly with HHS and NIST defined configurations and do not alter these settings.

6. **Incident Reporting**

1. The Contractor (and/or any subcontractor) must respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams within one (1) hour of the discovery of the loss/theft, whether the response is positive or negative. FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cyber security and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

   A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines a breach as "a suspected or confirmed incident involving PII" .

   In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) must:

   i. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-3 validated encryption.

   ii. NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send NIH approved notifications to affected individuals in accordance with https://wiki.ocio.nih.gov/wiki/index.php/US-CERT_Federal_Incident_Notification_Guidelines .

iii. Report all suspected and confirmed information security and privacy incidents and breaches to the NIH Incident Response Team (IRT) IRT@nih.gov , COR, CO, the NIH Office of the SOP (or his or her designee), and other stakeholders, including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour of the discovery of the loss/theft, and consistent with the applicable NIH and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contract information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor must:

- Cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
- Not include any sensitive information in the subject or body of any reporting e-mail; and
- Encrypt sensitive information in attachments to email, media, etc.

2. Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.
3. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to Contractor facilities during a breach/incident investigation.
4. The Contractor (and/or any subcontractor) must provide an Incident and Breach Response Plan (IRP) in accordance with HHS/NIH, OMB, and US-CERT requirements and obtain approval from the NIH. In addition, the Contractor must follow the incident response and US-CERT reporting guidance contained in the FedRAMP Incident Communications.
5. The Contractor (and/or any subcontractor) must implement a program of inspection to safeguard against threats and hazards to the security, confidentiality, integrity, and availability of federal data, afford HHS access to its facilities, installations, technical capabilities, operations, documentation, records, and databases within 72 hours of notification. The program of inspection must include, but is not limited to:
    a. Conduct authenticated and unauthenticated operating system/network/database/Web application vulnerability scans. Automated scans can be performed by HHS/NIH personnel, or agents acting on behalf of HHS/NIH, using agency-operated equipment and/or specified tools. The Contractor may choose to run its own automated scans or audits, provided the scanning tools and configuration settings are compliant with NIST Security Content Automation Protocol (SCAP) standards and have been approved by the agency. The agency may request the Contractor's scanning results and, at the agency discretion, accept those in lieu of agency performed vulnerability scans.
    b. In the event an incident involving sensitive information occurs, cooperate on all required activities determined by the agency to ensure an effective incident or breach response and provide all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. In addition, the Contractor must follow the agency reporting procedures and document the steps it takes to contain and eradicate the incident, recover

from the incident, and provide a post-incident report that includes at a minimum the following:

- Company and point of contact name;
- Contract information;
- Impact classifications/threat vector;
- Type of information compromised;
- A summary of lessons learned; and
- Explanation of the mitigation steps of exploited vulnerabilities to prevent similar incidents in the future.

7. **Media Transport**

1. The Contractor and its employees shall be accountable and document all activities associated with the transport of government information, devices, and media transported outside controlled areas and/or facilities. These include information stored on digital and non-digital media (e.g., CD-ROM, tapes, etc.), mobile/portable devices (e.g., USB flash drives, external hard drives, and SD cards).
2. All information, devices and media must be encrypted with HHS-approved encryption mechanisms to protect the confidentiality, integrity, and availability of all government information transported outside of controlled facilities.

8. **Boundary Protection: Trusted Internet Connections (TIC)**

1. The Contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities using cloud services is inspected by Trusted Internet Connection (TIC) processes.
2. The Contractor shall route all external connections through a TIC.
3. **Non-Repudiation** - The Contractor shall provide a system that implements encryption with current FIPS 140 validation certificate from the NIST CMVP that provides for origin authentication, data integrity, and signer non-repudiation.

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The following acquisition types are categories that are not covered by other clauses. These include hardware procurements, non-commercial/open source software procurements and procurements involving information technology (IT) design, development and support.
The Contracting Officer's shall adhere to OMB M-16-20 Category Management Policy 16-3: Improving the Acquisition and Management of Common Information Technology: Mobile Devices and Services when acquiring mobile devices.

ARTICLE H.58.5. OTHER IT PROCUREMENTS

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR PROCUREMENT INVOLVING HARDWARE.)****

NOTE: The Contracting Officer should confer with the System Owner, Information System Security Office (ISSO) and/or OpDiv Office of the Chief Information Security Officer (OCISO) when developing a contract involving other types of IT procurements to make sure all applicable security and privacy language is included.

The following clauses apply to this section:

1. FAR Part 12 (Section 6.A.1.)
2. FAR Subpart 4.13 (Section 6.A.1.)

ARTICLE H.58.5.1. HARDWARE PROCUREMENTS

1. **Card Readers-** The Contractor (and/or any subcontractor) must include Federal Information Processing Standard (FIPS) 201-compliant smart card readers (referred to as LACS Transparent Readers) with the purchase of servers, printers, desktops, and laptops.
2. **Mobile Devices-** The Contractor must follow NIST 800-124, Rev. 1, Guidelines for Managing the Security of Mobile Devices in the Enterprise and comply with Public Law 115-232 § 889, when purchasing mobile devices that process or store HHS data.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR PROCUREMENT INVOLVING NON-COMMERCIAL AND OPEN SOURCE COMPUTER SOFTWARE.)****

The use of non-commercial and open source computer software is in accordance with the HHS Guidance for Purchasing Noncommercial Computer Software and "Open Source" Licenses (2012),25 and OMB M-04-16, Software Acquisition26.

If HHS wants to be able to use or distribute the computer software, it is imperative that the computer software, including the source code if it is required by the procuring program, be included as a deliverable.

Noncommercial computer software means software that does not qualify as commercial in nature (e.g., commercial items and commercial off the shelf (COTS) items as defined in FAR 2.101). The following language should be used as appropriate in noncommercial computer software contracts. Each section includes an instruction providing where the information should be included in the contract.

(NOTE: If this procurement involves handling of sensitive information, include language from clause "Procurements Requiring Information Security and/or Physical Access Security.)

ARTICLE H.58.5.2. NON-COMMERCIAL AND OPEN SOURCE COMPUTER SOFTWARE PROCUREMENTS

The Contractor (and/or any subcontractor) must follow secure coding best practice requirements, as directed by the United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP) that will limit system software vulnerability exploits. The Contractor will be liable for malicious or defective code or failure to reduce risk.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR PROCUREMENT INVOLVING INFORMATION TECHNOLOGY APPLICATION DESIGN, DEVELOPMENT, OR SUPPORT.)****

This section refers to procurements including application design, development, or support. For the purposes of this document, "Computer software" means:

1. programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and
2. Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

"Computer software" does not include computer databases or computer software documentation.

ARTICLE H.58.5.3. INFORMATION TECHNOLOGY APPLICATION DESIGN, DEVELOPMENT, OR SUPPORT

a. The Contractor (and/or any subcontractor) must ensure IT applications designed and developed for end users (including mobile applications and software licenses) run in the standard user context without requiring elevated administrative privileges.
b. The Contractor (and/or any subcontractor) must follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
c. The Contractor (and/or any subcontractor) must ensure that computer software developed on behalf of HHS or tailored from an open-source product, is fully functional and operates correctly on systems configured in accordance with government policy and federal configuration standards. The contractor shall test applicable products and versions with all relevant and current updates and patches updated prior to installing in the HHS environment. No sensitive data must be used during software testing.
d. The Contractor (and/or any subcontractor) must protect information that is deemed sensitive from unauthorized disclosure to persons, organizations or subcontractors who do not have a need to know the information. Information which, either alone or when compared with other reasonably-available information, is deemed sensitive or proprietary by HHS shall be protected as instructed in accordance with the magnitude of the loss or harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the data. This language also applies to all subcontractors that are performing under this contract.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR PROCUREMENT INVOLVING PHYSICAL ACCESS TO GOVERNMENT CONTROLLED FACILITIES.)****

(NOTE: For procurements involving physical access to government facilities, selected language from "Procurement Requiring Information Security and/or Physical Access Security" may apply. This includes, but not limited to security awareness, incident response, and HSPD-12. Consult with the NIH Information Systems Security Officer (ISSO), the NIH Office of Senior Official for Privacy (SOP) and other relevant stakeholders to select applicable language.)

ARTICLE H.58.5.4. PHYSICAL ACCESS TO GOVERNMENT CONTROLLED FACILITIES

Refer to section H clause- Government Information and Physical Access Security.

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****(USE BELOW IN ALL CONTRACTS AND ORDERS)****

ARTICLE H.59. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-74 (December 2015).

a. Pursuant to Section 508 of the Rehabilitation Act of 1973(29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) supplies and services developed, acquired, or maintained under this contract or order must comply with the "Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 is available at https://www.hhs.gov/web/section-508/index.html. The complete text of Section 508 Final Provisions can be accessed at https://www.access-board.gov/ict.html.
b. The Section 508 accessibility standards applicable to this contract or order are identified in the Statement of Work or Specification or Performance Work Statement. The contractor must provide any necessary updates to the submitted HHS Product Assessment Template(s) at the end of each contract or order exceeding the simplified acquisition threshold (see FAR 2.101) when the contract or order duration is one year or less. If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.
c. The Section 508 accessibility standards applicable to this contract are: (Contract staff must list applicable standards)
d. In the event of a modification(s) to this contract or order, which adds new EIT supplies or services or revises the type of, or specifications for, supplies or services, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Web site: (https://www.hhs.gov/web/section-508/index.html). If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.
e. If this is an Indefinite Delivery contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include EIT supplies or services will define the specifications and accessibility standards for the order. In those cases, the Contractor may be required to provide a completed HHS Section 508 Product Assessment Template and any other additional information necessary to assist the Government in determining that the EIT supplies or services conform to Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at https://www.hhs.gov/web/section-508/index.html If it is determined by the Government that EIT supplies and services provided by the Contractor do not conform to the described accessibility

standards in the provided documentation, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(End of clause).

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****(USE IN ALL SOLICITATIONS)****

ARTICLE H.60. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY NOTICE HHSAR 352.239-73 (December 2015).

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.
b. Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at https://www.hhs.gov/web/section-508/index.html . The complete text of the Section 508 Final Provisions can be accessed at https://www.hhs.gov/web/section-508/index.html .
c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility. In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document-- in detail-- whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site https://www.hhs.gov/web/section-508/index.html . In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.
d. Respondents to this solicitation must identify any exception to Section 508 requirements. If an offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision).

The "HHS Section 508 Product Assessment Template (PAT)" updated to the "Voluntary Product Accessibility Template (VPAT)" is included in SECTION J - List of Attachments, of this solicitation.

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**** (USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE THE DEVELOPMENT, MAINTENANCE, AND/OR DISTRIBUTION OF NIH SPONSORED COMMUNICATION MATERIALS AND/OR SERVICES. THESE INCLUDE WEBSITES, PRINTED PRODUCTS, CAMPAIGN MATERIALS, AND PRODUCTS BEARING FEDERAL MARKS, TRADEMARKS, AND LOGOS.)****

Note to Contracting Officer and Contract Specialist: *Additional information about NIH Office of Communications and Public Liaison policy and procedures are contained in NIH Manual Chapters, which can be accessed at the following address:* https://policymanual.nih.gov/.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **Second paragraph:** Select all that contract requirements that apply.

ARTICLE H.61. COMMUNICATIONS MATERIALS AND SERVICES

To build and maintain public trust; promote credibility and consistency; minimize consistency and frustration; and contribute to efforts aimed at leveraging reduced resources and eliminating waste in Government, the Contractor shall ensure that all materials generated and/or services provided under this contract, comply with all applicable NIH policy and procedures published by the NIH Office of Management Assessment in conjunction with the NIH Office of Communications and Public Liaison as set forth below.

This acquisition requires the Contractor to:

[ ] Prepare, review, and/or distribute NIH Publications and Audiovisuals.

NIH Policy Manual Chapter 1184, " Preparation and Clearance of Scientific, Technical, and Public Information Presented by NIH Employees or Produced for Distribution by NIH ," is applicable to this contract. https://policymanual.nih.gov/1184

[ ] Use the NIH name and logo.

NIH Policy Manual Chapter 1186, "Use of NIH Names and Logos," is applicable to this contract. https://policymanual.nih.gov/1186

[ ] Create and/or Manage a Public Website which includes NIH hosted social media site(s), Web application(s) and mobile Web Site **(**s**).**

NIHPolicyManualChapter2804*, " Websites and Digital Services - Management Policy," is applicable to this contract. https://policymanual.nih.gov/2804

[ ] Create and/or Manage an NIH Website that maintains and disseminates personal information.

NIH Policy Manual Chapter 2805*, "NIH Web Privacy Policy," is applicable to this contract. https://policymanual.nih.gov/2805

[ ] Create and/or Manage an NIH hosted and/or funded social media site(s), Web application(s) and mobile Web site(s).

"NIH Social Media Guidelines," is applicable to this contract. https://employees.nih.gov/pages/social-media/

* NOTE: NIH Policy Manual Chapters found in the 2800 series are currently only available to NIH personnel. If unavailable, contact the Contracting Officer for a copy.

Additional Standards applicable to this contract are identified in the Statement of Work. If it is determined by the Government that products, services, and deliverables provided by the Contract or do not conform to standards described in these directives, remediation to an acceptable level of conformance shall be the responsibility of the Contractor at its own expense.

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****(USE BELOW WHEN THE CONTRACTOR WILL GENERATE MATERIALS UNDER THE CONTRACT FOR WHICH COMMERCIAL RECORDS STORAGE WILL BE REQUIRED.)****

Note: *This requirement may not be known at the time of initial award. If this is the case, this Article should be included in the contract, by modification, as soon as practicable, once the requirement need for commercial records storage has been determined .*

ARTICLE H.62. STORAGE FACILITY REQUIREMENTS AND CERTIFICATION

The Contractor shall ensure that all materials generated under this contract for which commercial records storage is required, shall be stored in a facility that meets National Archives and Records Administration (NARA) requirements for safe, secure and certified storage as required by 36 CFR 1228, subpart K.

The Contractor shall provide the Contracting Officer with the name(s) and location(s) of the commercial records storage facility used to store materials under this contract. In addition, the Contractor shall provide a copy of the "Records Storage Certification Statement," fount at: https://www.archives.gov/records-mgmt/storage-standards-toolkit/certification-statement.html self-certifying that the facility being used to store federal records meets established NARA standards. NARA Standards are available at: https://www.govinfo.gov/content/pkg/CFR-2013-title36-vol3/pdf/CFR-2013-title36-vol3-part1234.pdf

Sixty (60) days prior to contract end date, the Contractor shall submit to the Contracting Officer's Representative (COR) and Contracting Officer, an inventory of all materials stored. The disposition of these materials shall be determined no later than the expiration date of the contract.

Additional information about Records Storage Facility Standards can be found at: http://www.archives.gov/records-mgmt/storage-standards-toolkit/

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****(USE BELOW FOR SOLICITATIONS AND CONTRACTS WHERE THE POSSIBILITY EXISTS THAT THE CONTRACTOR WILL HAVE ACCESS TO NIH E-MAIL.)****

ARTICLE H.63. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as Contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the Contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each Contractor employee's computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT WILL:

- BE EITHER COST-REIMBURSEMENT OR FIXED-PRICE-INCENTIVE (Where the incentive is based on cost);
- HAVE AN EXPECTED VALUE, INCLUDING OPTIONS, EQUAL TO OR GREATER THAN $25 MILLION; AND,
- REQUIRE A CONTRACTOR TO USE FULL EVMS (See HHSAR 334.201)
- EVM IS APPLICABLE TO SOLICITATIONS AND CONTRACTS THAT USE DEVELOPMENT, MODERNIZATION AND ENHANCEMENT (DME) FUNDS.)****

Note: *Funds used to develop, Plan, Modernize, or Enhance an IT System are considered DME. DME does not include maintenance of existing IT systems (including technology refreshment hardware and software.*

For more information about EARNED VALUE MANAGEMENT (EVM) See: HHSAR 334.2.

ARTICLE H.64. FULL EARNED VALUE MANAGEMENT SYSTEM

1. The Contractor shall use an Earned Value Management System (EVMS) that has been validated and accepted by the Cognizant Federal Agency (CFA) as being compliant with the guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS has not been validated and accepted by the CFA at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.
2. If, at the time of award, the Contractor's EVM system has not bee validated and accepted by the CFA as complying with EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), the Contractor shall:

a. Apply the current system to the contract; and
b. Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

3. HHS requires the Contractor to obtain validation and acceptance of its EVM system by the CFA during the base period of performance of this contract. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action, which may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.
4. HHS will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post-award IBR will be conducted by HHS as early as practicable, but no later than ninety (90) days after contract award. The Contracting Officer may also require an IBR as part of the exercise of an option or the incorporation of a major modification.
5. Unless a waiver is granted by the CFA, Contractor-proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

6. The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the requirements referenced in paragraph (a) of this clause.
7. The Contractor shall require the subcontractors specified below to comply with the requirements of the clause: (Insert list of applicable subcontractors.)

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT WILL:

- BE EITHER COST-REIMBURSEMENT OR FIXED-PRICE-INCENTIVE (Where the incentive is based on cost);
- HAVE AN EXPECTED VALUE, INCLUDING OPTIONS, EQUAL TO OR GREATER THAN $10 MILLION BUT LESS THAN $25 MILLION; AND,
- REQUIRE A CONTRACTOR TO USE FULL EVMS (See HHSAR 334.201)
- EVM IS APPLICABLE TO SOLICITATIONS AND CONTRACTS THAT USE DEVELOPMENT, MODERNIZATION AND ENHANCEMENT (DME) FUNDS.)****

Note: *Funds used to develop, Plan, Modernize, or Enhance an IT System are considered DME. DME does not include maintenance of existing IT systems (including technology refreshment hardware and software.*

For more information about EARNED VALUE MANAGEMENT (EVM) See: HHSAR 334.2.

ARTICLE H.65. FULL EARNED VALUE MANAGEMENT SYSTEM

1. The Contractor shall use an Earned Value Management System (EVMS) that is compliant with the guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS is not compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.
2. If, at the time of award, the Contractor's EVM system is not in compliance with the EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), the Contractor shall:

a. Apply the current system to the contract; and
b. Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

3. HHS will not formally validate or accept the Contractor's EVMS with respect to this contract. The use of the Contractor's EVMS for this contract does not imply HHS acceptance of the Contractor's EVMS for application to future contracts. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action that may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.
4. HHS will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post-award IBR will be conducted by HHS as early as practicable, but no later than ninety (90) days after contract award. The Contracting Officer may also require an IBR as part of the exercise of an option or the incorporation of a major modification.
5. -Not Applicable-

6. The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the requirements referenced in paragraph (a) of this clause.
7. The Contractor shall require the subcontractors specified below to comply with the requirements of the clause: (Insert list of applicable subcontractors.)

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT WILL:

- BE EITHER FIRM-FIXED-PRICE, TIME AND MATERIALS, LABOR-HOURS OR TERM FORM CONTRACTS;
- HAVE AN EXPECTED VALUE, INCLUDING OPTIONS, EQUAL TO OR GREATER THAN $25 MILLION; AND,
- REQUIRE A CONTRACTOR TO USE PARTIAL EVMS (See HHSAR 334.201.)****

ARTICLE H.66. PARTIAL EARNED VALUE MANAGEMENT SYSTEM

1. The Contractor shall use an Earned Value Management System (EVMS) that has been validated and accepted by the Cognizant Federal Agency (CFA) as being compliant with the schedule-related guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS has not been validated and accepted by the CFA at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.
2. If, at the time of award, the Contractor's EVM system has not been validated and accepted by the CFA as complying with the schedule-related EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), the Contractor shall:

a. Apply the current system to the contract; and
b. Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

3. HHS requires the Contractor to obtain validation and acceptance of the schedule-related portions of its EVM system by the CFA during the base period of performance of this contract. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action, which may include, but is not limited to, suspension of or reduction in progress payments, or a reduction in fee.
4. HHS will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post-award IBR will be conducted by HHS as early as practicable, but no later than ninety (90) days after contract award. The Contracting Officer may also require an IBR as part of the exercise of an option or the incorporation of a major modification.
5. Unless a waiver is granted by the CFA, Contractor-proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

6. The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the requirements referenced in paragraph (a) of this clause.
7. The Contractor shall require the subcontractors specified below to comply with the requirements of the clause: (Insert list of applicable subcontractors.)

(End of clause).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT WILL:

- BE EITHER FIRM-FIXED-PRICE, TIME AND MATERIALS, LABOR-HOURS OR TERM FORM CONTRACTS;
- HAVE AN EXPECTED VALUE, INCLUDING OPTIONS, EQUAL TO OR GREATER THAN $10 MILLION BUT LESS THAN $25 MILLION; AND,
- REQUIRE A CONTRACTOR TO USE PARTIAL EVMS (See HHSAR 334.201.)****

ARTICLE H.67. PARTIAL EARNED VALUE MANAGEMENT SYSTEM

1. The Contractor shall use an Earned Value Management System (EVMS) that is compliant with the schedule-related guidelines in ANSI/EIA Standard-748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS is not compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit EVM reports in accordance with the requirements of this contract.
2. If, at the time of award, the Contractor's schedule-related EVM system is not in compliance with the schedule-related EVMS guidelines in ANSI/EIA Standard-748 (current version at time of award), or the Contractor does not have an existing schedule control system that is compliant with such guidelines, the Contractor shall:
    a. Apply the current system to the contract; and
    b. Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.
3. HHS will not formally validate or accept the Contractor's schedule-related EVMS with respect to this contract. The use of the Contractor's EVMS for this contract does not imply HHS acceptance of the Contractor's EVMS for application to future contracts. The Contracting Officer or designee will conduct a Compliance Review to assess the Contractor's compliance with its approved plan. If the Contractor does not follow the approved implementation schedule or correct all resulting system deficiencies noted during the Compliance Review within a reasonable time, the Contracting Officer may take remedial action that may include, but is not limited to, suspension of or reduction in progress payments, or a reduction.
4. HHS will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post-award IBR will be conducted by HHS as early as practicable, but no later than ninety (90) days after contract award. The Contracting Officer may also require an IBR as part of the exercise of an option or the incorporation of a major modification.
5. -Not Applicable-
6. The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to

ensure that the EVMS conforms, and continues to conform, with the requirements referenced in paragraph (a) of this clause.

7. The Contractor shall require the subcontractors specified below to comply with the requirements of the clause: (Insert list of applicable subcontractors.)

(End of clause).

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHEN THE CONTRACTOR WILL HAVE ACCESS TO LIBRARY RESOURCES AT NIH, e.g. when a Contractor is added to the NIH Enterprise Directory (NED) with the same privileges as NIH staff.)****

ARTICLE H.68. CONTRACTOR'S USE OF LIBRARY RESOURCES AT NIH

The Contractor is authorized to use library resources at NIH in the same manner as NIH staff. The Contractor's approved use of these resources is limited to performing the requirements of this contract. The Contractor shall not use library resources at NIH in a manner that exceeds the Fair Use limitations codified in 17 U.S.C. sec. 107 of the Copyright Act. Contractors shall not share access to library resources at NIH with, perform searches for, or provide results to, non-NIH users, i.e. collaborators at other universities or research centers.

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**** (THE FOLLOWING IS OPTIONAL. USE ONLY FOR PROPRIETARY INFORMATION, PERSONAL INFORMATION, OR INFORMATION WHICH MAY REQUIRE SPECIAL CONSIDERATION WITH REGARD TO THE TIMING OF DISCLOSURE. THE GOVERNMENT MUST IDENTIFY THE SPECIFIC INFORMATION TO BE COVERED BY THIS ARTICLE.)****

Note: *Before using this Article, the Contract Specialist/CO should review the Advance Understandings to determine if "Confidential Treatment of Sensitive Information" is more appropriate.*

ADDTIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- Insert the specific information applicable to this Article.

ARTICLE H.69. CONFIDENTIALITY OF INFORMATION

1. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
2. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
3. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

4. Confidential information, as defined in paragraph 1. of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
5. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
6. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.
7. The provisions of paragraph 4. of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

The following information is covered by this article:

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR R&D EXCEPT PHASE I SBIR/STTR AND CONTRACTS WITH FEDERAL AGENCIES.)****

ARTICLE H.70. RESPONSIBILITIES OF INSTITUTIONS REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: https://www.ecfr.gov/current/title-45/part-94.

As required by 45 CFR Part 94.4, **Responsibilities of Institutions regarding Investigator financial conflicts of interest,** each Institution shall:

a. Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this part, and make such policy available via a publicly accessible Web site. If the Institution does not have any current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request. If, however, the Institution acquires a presence on a publicly accessible Web site during the time of the NIH award, the requirement to post the information on that Web site will apply within 30 calendar days. If an Institution maintains a policy on financial conflicts of interest that includes standards that are more stringent than this part (e.g., that require a more extensive disclosure of financial interests), the Institution shall adhere to its policy and shall provide FCOI reports regarding identified financial conflicts of interest to the NIH Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by this part.
b. Inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to

engaging in research related to any NIH-funded contract and at least every four years, and immediately when any of the following circumstances apply:

1. The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
2. An Investigator is new to an Institution; or
3. An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

c. If the Institution carries out the NIH-funded research through a subrecipient (e.g., subcontractors, or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this part by Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.
    1. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this part. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;
    2. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the NIH as required by this part;
    3. Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this part.
    4. Providing FCOI reports to the NIH Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this part, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.
d. Designate an institutional official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the NIH-funded research.
e. Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than date of submission of the Institution's proposal for NIH-funded research
f. Require each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial

conflict of interest identified on a NIH-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

g. Require each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

h. Provide guidelines consistent with this part for the designated institutional official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to NIH-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: Could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the NIH-funded research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

i. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to § 94.5(a).

j. Provide initial and ongoing FCOI reports to the NIH as required pursuant to § 94.5(b) .

k. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest), and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date of final payment or, where applicable, for the time periods specified in 48 CFR part 4, subpart 4.7.

l. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

m. Certify, in each contract proposal to which this part applies, that the Institution:
    1. Has in effect at that Institution an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the NIH;
    2. Shall promote and enforce Investigator compliance with this part's requirements including those pertaining to disclosure of significant financial interests;
    3. Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the NIH Awarding Component consistent with this part;
    4. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and
    5. Shall fully comply with the requirements of this part.

n. As required by 45 CFR Part 94.5, Management and reporting of financial conflicts of interest:
    1. Management of financial conflicts of interest.

2. Prior to the Institution's expenditure of any funds under a NIH-funded research project, the designated official(s) of an Institution shall, consistent with § 94.4(f) : review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to NIH-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
    i Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
    ii For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
    iii Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, resulting from the financial conflict of interest;
    iv Modification of the research plan;
    v Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
    vi Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
    vii Severance of relationships that create financial conflicts.

o. Whenever, in the course of an ongoing NIH-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the designated official(s) of the Institution shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to NIH-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-funded research project between the date of disclosure and the completion of the Institution's review.

p. Whenever an Institution identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to NIH-funded research; determine whether a financial conflict of interest exists; and, if so:
    1. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
    2. (A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the

Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

B. The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:
    1. Project number;
    2. Project title;
    3. PD/PI or contact PD/PI if a multiple PD/PI model is used;
    4. Name of the Investigator with the FCOI;
    5. Name of the entity with which the Investigator has a financial conflict of interest;
    6. Reason(s) for the retrospective review;
    7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
    8. Findings of the review; and
    9. Conclusions of the review.

q. Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Institution is required to notify the NIH Awarding Component promptly and submit a mitigation report to the NIH Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in this part. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.
r. Whenever an Institution implements a management plan pursuant to this part, the Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the NIH-funded research project.
s. Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:
    1. The significant financial interest was disclosed and is still held by key personnel as defined in this part;

2. The Institution determines that the significant financial interest is related to the NIH-funded research; and
3. The Institution determines that the significant financial interest is a financial conflict of interest.

t. The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: The Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

u. If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the NIH-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the NIH-funded research project, if the Institution determines that the significant financial interest is related to the NIH-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

v. Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

w. In addition to the types of financial conflicts of interest as defined in this part that must be managed pursuant to this section, an Institution may require the management of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

2. Reporting of financial conflicts of interest.

a. Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution shall provide to the NIH Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this part. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of

NIH-awarded funds, the Institution shall not submit an FCOI report to the NIH Awarding Component.

b. For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing NIH-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the NIH Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this part. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also is required to complete a retrospective review to determine whether any NIH-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is found, the Institution is required to notify the NIH Awarding Component promptly and submit a mitigation report to the NIH Awarding Component.

c. Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section shall include sufficient information to enable the NIH Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:
    i. Project/Contract number;
    ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
    iii. Name of the Investigator with the financial conflict of interest;
    iv. Name of the entity with which the Investigator has a financial conflict of interest;
    v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
    vi. Value of the financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
    vii. A description of how the financial interest relates to the NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
    viii. A description of the key elements of the Institution's management plan, including:
        A. Role and principal duties of the conflicted Investigator in the research project;
        B. Conditions of the management plan;
        C. How the management plan is designed to safeguard objectivity in the research project;
        D. Confirmation of the Investigator's agreement to the management plan;
        E. How the management plan will be monitored to ensure Investigator compliance; and
        F. Other information as needed.

d. For any financial conflict of interest previously reported by the Institution with regard to an ongoing NIH-funded research project, the Institution shall provide to the NIH Awarding Component

an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the NIH-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Institution shall provide annual FCOI reports to the NIH Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the NIH Awarding Component.

e. In addition to the types of financial conflicts of interest as defined in this part that must be reported pursuant to this section, an Institution may require the reporting of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

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****(USE BELOW IN ALL R&D AND R&D SUPPORT SOLICITATIONS AND CONTRACTS. THIS MAY ALSO BE USED IN OTHER CONTRACTS AT THE DISCRETION OF THE CONTRACTING OFFICER.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **Second Paragraph (acknowledgment):** Insert the appropriate Institute/Center (I/C) and contract number in their respective text boxes.

ARTICLE H.71. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the _____ , National Institutes of Health, Department of Health and Human Services, under Contract No. _____ "

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****(FOR NIAID: INSERT BELOW IN ALL CONTRACTS THAT READS SUBSTANTIALLY AS FOLLOWS. NIAID Processes/Procedures Reviewed 9/22)****

a. **Advanced Copies of Press Releases**

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the Contracting Officer Representative (COR) has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

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****(NCI ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS. NCI Processes/Procedures Reviewed 9/22)****

b. **Advanced Copies of Press Releases**

Press releases shall be considered to include the public release of information to any medium,

excluding peer-reviewed scientific publications. The Contractor shall not publish a press release related to this contract without receiving prior concurrence from the Contracting Officer. The Contractor shall submit an advance copy of the press release to the Contracting Officer and Contracting Officer Representative (COR). Upon acknowledgment of receipt, the Contracting Officer will have five (5) working days to respond with concurrence or comments. In the event that the Contracting Officer does not communicate concurrence or comments to the Contractor within five (5) working days following acknowledgement of receipt of the press release advance copy, concurrence may be presumed.

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****(NHLBI: USE BELOW IN ALL NHLBI SOLICITATIONS AND CONTRACTS.
NHLBI Processes/Procedures Reviewed 9/22)****

ARTICLE H.72. REVIEW OF MANUSCRIPTS

In order to balance the oversight responsibility of the National Heart, Lung, and Blood Institute (NHLBI) with the authorization provided the Contractor by the Rights in Data clause of this contract, the NHLBI has established a process to review manuscripts produced under this contract. Please note that the NHLBI does not require contractors to seek the Institute's approval of manuscripts.

In order to have sufficient time to conduct a meaningful review, please provide to the Institute's Contracting Officer Representative (COR) and Contracting Officer advance notice of intent to submit a manuscript for publication at least 45 days prior to submission to the publisher. The advance notice should briefly describe the plans for publication of the manuscript. Concurrently or as soon as possible following this notice, provide a copy of the manuscript to the COR.

Any comments from the NHLBI will be provided in writing within 15 days after receipt of the manuscript by the COR. Comments expressed by the NHLBI about the manuscript shall not be a cause for action under the Disputes clause of the contract by either NHLBI or the Contractor, since the NHLBI does not approve manuscripts and draft manuscripts are not contract deliverables.

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****(USE BELOW IN SOLICITATIONS WHEN MULTIPLE-AWARD TASK ORDER OR DELIVERY ORDER CONTRACTS ARE ANTICIPATED.)****

ARTICLE H.73. TASK ORDER/DELIVERY ORDER CONTRACT OMBUDSMAN

In accordance with FAR 16.505(b)(8), the following individual has been designated as the NIH Ombudsman for task order and delivery order contracts.

[The appropriate individual will be included in the resultant contract as follows:]

For R&D Contracts:	For Non R&D Contracts:
Dr. Sheryl K. Brinings	Dr. Richard G. Wyatt
NIH Competition Advocate	NIH Competition Advocate
6705 Rockledge Drive, Room 707-A, MSC 7977	1 Center Drive, Room 160, MSC 0151
Bethesda, MD 20892-7977	Bethesda, MD 20892-0151
Phone: (301) 451-1763	Phone: (301) 496-4920
E-mail: brinings@mail.nih.gov	E-mail: WyattRG@mail.nih.gov

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****(NHLBI: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHEN THERE IS A REQUIREMENT FOR THE DELIVERY OF A DATA SET.
NHLBI Processes/Procedures - Data Sharing Policy - Reviewed 9/22)****

ARTICLE H.74. NHLBI POLICY FOR DATA SHARING FROM CLINICAL TRIALS AND EPIDEMIIOLOGICAL STUDIES

The National Heart, Lung, and Blood Institute (NHLBI) has supported data collection from participants in numerous clinical trials and epidemiologic studies. These data from well-characterized population samples constitute an important scientific resource. It is the view of the NHLBI that their full value can only be realized if they are made available, under appropriate terms and conditions consistent with the informed consent provided by individual participants, in a timely manner to the largest possible number of qualified investigators.

Data sets distributed under this policy include only data with personal identifiers and other variables that might enable individual participants to be identified, such as outliers, dates, and study sites, removed or otherwise modified. Because it may still be possible to combine the data with other publicly available data and thereby determine with reasonable certainty the identity of individual participants, these data sets are not truly anonymous. They are, therefore, only provided to investigators who agree in advance to adhere to established policies for distribution.

Investigators shall provide data sets in accordance with the NHLBI Data Set policy at https://www.nhlbi.nih.gov/grants-and-training/policies-and-guidelines/nhlbi-policy-for-data-sharing-from-clinical-trials-and-epidemiological-studies . All changes to the policy are hereby incorporated by reference without further amendment to the contract. Data sets are a deliverable under this contract for this trial or study, as described in Section C. Description/Specification/Work Statement and/or Section F. Deliveries or Performance of the contract.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

ARTICLE H.75. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: https://oig.hhs.gov/fraud/report-fraud/ and the mailing address is:

US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR A/E, CQM SERVICES, CONSTRUCTION, AND FACILITIES SERVICES.
ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.76. INSURANCE

a. The Contractor shall, at his own expense, procure and maintain, during the entire performance period of this contract, insurance of at least the kinds and amounts set forth below:

1. Worker's Compensation and Employer's Liability
   Contractors are required to comply with applicable Federal and State worker's compensation and occupational disease statutes. Employer's liability coverage of at least $100,000 shall be required except in states with exclusive or monopolistic funds that do not permit workers' compensation to be written by private carriers.

2. General Liability
   Contractors are required to have bodily injury liability insurance coverage written on the comprehensive form of policy of at least $2,000,000 per occurrence.

c. Automobile Liability Contractor
   The Contractor is required to have automobile liability insurance written on the comprehensive form of policy. The policy shall provide for bodily injury and property damage liability covering the operation of all automobiles used in connection with performing the contract. Policies covering automobiles operated in the United States shall provide coverage of at least $200,000 per person and $500,000 per occurrence for bodily injury and $20,000 per occurrence for property damage. The amount of liability coverage on other policies shall be commensurate with any legal requirements of the locality and sufficient to meet normal and customary claims.

b. At all times during performance, the Contractor shall maintain with the Contracting Officer a current Certificate of Insurance showing at least the insurance required by the Schedule, and providing for thirty (30) days written notice to the Contracting Officer by the insurance company prior to cancellation or material change in policy coverage.

c. Current certificates of insurance shall be furnished by the Contractor to the Contracting Officer before starting work under the contract.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, AND FACILITIES SERVICES.
ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **Last (4th) Paragraph:**
  1. **For Contracts:** Select the first sentence from the drop-down box.
  2. **For Solicitations:** Select the second sentence from the drop-down box.

ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77. HEALTH AND SAFETY PLAN

The Contractor is responsible for safety at the construction or work site. The contractor is also responsible for preparation of a safety plan and for carrying out the safety plan. The contractor staff shall maintain conformance to the health and safety plan throughout the course of construction.

Contractor inspectors shall consider safety a key element of their daily inspections.

The Contractor is required to cooperate with officials of other agencies (Federal and/or state) who are vested with authority to enforce requirements of the Occupational Safety and Health Act. If required, the contractor will assist the Government in preparing accident and fire reports.

[The Contractor shall comply with the following NIH Health and Safety Requirements./The resultant contract will require the contractor to comply with the following NIH Health and Safety Requirements.]

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, AND FACILITIES SERVICES.
ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.1. CONTRACTOR REQUIREMENTS

a. At a minimum, the Contractor shall comply with applicable Occupational Safety and Health Administration (OSHA) Regulations. Construction, renovation, alteration and maintenance services must adhere to the provisions of the US Army Corps of Engineers Safety and Health Manual 385-1-1 (EM 385-1-1). If there is a conflict between the two, the stricter regulation or provision will be adhered to.
b. Each contract employee is responsible for complying with applicable safety and occupational health requirements, wearing prescribed safety and health equipment, reporting unsafe conditions/activities, and avoiding actions and conditions that may result in an accident.
c. The Contractor will not commence services authorized under this contract without first submitting for review each deliverable specified in section "DELIVERABLES". Copies of each deliverable must be provided to the NIH Contracting Officer, NIH Contracting Officer's Representative, and the Division of Occupational Health and Safety (DOHS) Safety Officer (safety@nih.gov).
d. Prior to commencing contract services, the contractor's Project Manager, NIH Contracting Officer, Contracting Officer Representative, and DOHS Safety Officer shall meet to review and discuss the safety requirements of this contract. The Contractor's Project Manager is responsible for scheduling the meeting arrangement. The purpose of the meeting is to verify that project hazards have been identified and appropriately controlled. A sufficient substitution to this meeting is the completion of a pre-construction (kick-off) meeting.
e. The Contractor is responsible for ensuring that all of its subcontractors are compliant with all of the Contractor requirements outlined in this section.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, AND FACILITIES SERVICES **UNLESS** A WAIVER HAS BEEN GRANTED.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

Subparagraph b:

- **When No Waiver has been granted:** Include this subparagraph b. as is.
- **When a Waiver has been granted by the ORF Health & Safety Officer:** Delete this subparagraph b. and **ADD** a statement that a waiver has been granted and the date granted.

ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.2. WAIVER FROM NIH IMPOSED CONTRACTOR HEALTH AND SAFETY REQUIREMENTS

a. The Contractor may request a waiver from the requirements contained in the Contractor Health and Safety Requirements section. The waiver does not release the contractor, subcontractor, or any party associated with this contract from federal, state, and local health and safety requirements.

b. The following must be addressed used when requesting a waiver or a variance:
   i. The request must state the specific Contractor Health and Safety Requirement to be waived. State the period of time the requested waiver will cover.
   ii. Details as to why it is not possible or practical to comply with the requirement.
   iii. The request must explain the impact on the Contractor operations and services if this waiver is not approved.
   iv. Statement as to whether a waiver (total elimination of the requirement) or a variance (retaining the basic requirement but doing it differently) is being sought.
   v. Explanation of the method the Contractor suggests using in lieu of the existing requirement and how it provides protection equal to or greater than the requirement under waiver review. The burden of proof rests with the requesting Contractor.
   vi. The waiver request must be submitted to the NIH Contracting Officer, the NIH Contracting Officer Representative and DOHS Safety Officer (safety@nih.gov) prior to commencing services.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, AND FACILITIES SERVICES.

ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.3. NIH REQUIRED SAFETY TRAINING MANDATE

1. As a minimum all Contractor and subcontractor personnel working at NIH shall be certified as having successfully completed the OSHA 10-hour General Industry Outreach class or OSHA 10-hour Construction Industry Outreach class. The OSHA 30-hour course can be substituted for the 10-hour course.

2. Proof of completion may be demonstrated through either: 1) the presentation of a bona fide student course completion card issued by the federal OSHA Training Institute; 2) or the presentation of documentation provided to an employee by a trainer certified by the Institute pending the actual issuance of the completion card.

3. Any card with an issuance date more than five (5) years shall not constitute proof of compliance with this requirement.

4. Any employee required to complete the safety and health course required under this section who has not completed the course shall be subject to removal from the worksite if the employee does not provide documentation of having completed such course by the fifteenth day after the date the employee is found to be in noncompliance.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, AND FACILITIES SERVICES.
ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.4. NIH SAFETY PROFICIENCY REQUIREMENTS

1. Contractor Safety Program Assessment: The NIH is committed to providing a safe environment for its employees, guests, and patients. Safety, as demonstrated during previous contracts, may be used in the past performance evaluation of a Contractor. Contractors are required to enroll in the Contractor Safety Assessment Program (CSAP). The prime Contractor is responsible for ensuring that all subcontractors have completed the CSAP prior to beginning work at NIH. This program is used to assess Contractor's commitment to safety through a review of lagging and leading indicators. Contractors will be required to address program deficiencies prior to performing work. The assessment process requires the following items:
    i. Company Information
    ii. Insurance Experience Modification Rate (EMR)
    iii. General Liability Claims
    iv. OSHA Citation History (previous three years)
    v. Safety Program Elements

    To enroll in CSAP: create an account at https://www.highwire.com/ and enter the requested information. There is no fee to complete the assessment. Upon completion of the assessment a certification will be available to download. The certificate must be provided to the NIH Contracting Officer Representative and NIH Contracting Officer.

2. As a minimum requirement, all Contractor and subcontractor personnel working at NIH owned or leased property shall be certified as having successfully completed the OSHA 10-hour General Industry Outreach course or OSHA 10-hour Construction Industry Outreach course. The OSHA 510 Occupational Safety and Health Standards for Construction or the OSHA 511 Occupational Safety and Health Standards for General Industry course can be substituted for the 10-hour OSHA class.
    i. Proof of completion may be demonstrated through either: 1) the presentation of a bona fide student course completion card issued by an approved federal OSHA training provider; or 2) the presentation of documentation provided to an employee by a certified OSHA Outreach Instructor pending the actual issuance of the completion card.

ii. Employees shall be prepared to provide proof of training upon request.
iii. Any card with an issuance date more than five (5) years shall not constitute proof of compliance with this requirement.
iv. Any employee required to complete the safety and health course required under this section who has not completed the course shall be removed from the worksite until the required training is completed.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, AND FACILITIES SERVICES.
ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.5. CONTRACTOR SUPERVISOR ORIENTATION

1. Prior to commencing work, ensure that all Contractor and subcontractor site supervisors, at any tier, have completed the NIH Contractor Supervisor Orientation. The time expended and any associated costs to attend the orientation (such as travel time, parking, and other expenses) are to be borne by the Contractor.
2. It is the responsibility of the Contractor and subcontractor to contact the DOHS Safety Officer to register each supervisor for orientation. Orientation must be completed prior to commencing contract services or the date that the supervisor is assigned to NIH. Contact the ORF Safety Officer (safety@nih.gov) or by phone (301) 496-2960 for the orientation schedule.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, AND FACILITIES SERVICES.
ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.6. DELIVERABLES

1. The deliverables below must be affirmed and provided to the NIH Contracting Officer, NIH Contracting Officer Representative and DOHS Safety Officer (safety@nih.gov). All deliverables shall be submitted by email prior to the commencement of work activities. The deliverables must be in either MS Word or Adobe Acrobat format. Additional information is found at: https://ors.od.nih.gov/sr/dohs/YourRole/Pages/Contractor-Safety-Materials.aspx#top . Deliverables include:
    - The submission of a site-specific accident prevention plan completed in accordance with the Army Corps of Engineers Safety Manual Appendix A, EM 385- 1- 1 (including activity hazard analysis worksheets).
    - The submission of the Contractor Safety Assessment Program certification (https://www.highwire.com/) for the Contractor and each sub-contractor.
    - The submission of the curriculum vitae (a.k.a. resume) of the Contractors' assigned site safety and health officer to oversee the contract operations.
    - Verification of OSHA 10- hour training certification (i.e. general industry or construction) requirements for on- site personnel and other appropriate training (i.e. 1st Aid/ CPR, etc.).
    - The completed and submitted "Affirmation of NIH Contractor Safety Deliverables" form.
2. The DOHS Safety Officer will notify the Contractor (through the contract`s Contracting Officer Representative) once the deliverables have been accepted. Acceptance of the deliverables by the

NIH indicates only that the Government has received the item. Acceptance of a deliverable does not waive or lessen any contract requirements or the Contractor's obligation to meet all contract requirements and correct any later discovered deficiencies. Nor does acceptance by the Government imply that the deliverables or material contained within are adequate to prevent injury or illness.

3. Delays caused by failure to timely submit the required documentation shall not be considered a reason for extension of contract time or increase in costs to the Government.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, AND FACILITIES SERVICES.
ORF Processes/Procedures - Accident Prevention Plan Below - Reviewed 11/22)****

ARTICLE H.77.7. SITE SPECIFIC ACCIDENT PREVENTION PLAN

The Contractor shall submit a Site-Specific Accident Prevention Plan, to the NIH Contracting Officer Representative and the DOHS Safety Officer at safety@nih.gov , one week prior to the commencement of work for NIH's review and comment. The submittal shall contain the "Contract Number," Project "C" number (example C102XXX), "Project Name" in the subject line.

For construction, renovation, alteration, and maintenance services the contents of the Contractor's Site Specific Accident Prevention Plan will be in accordance with Appendix A, EM 385- 1- 1. See https://www.publications.usace.army.mil/Portals/76/Publications/EngineerManuals/EM_385-1-1.pdf .

Activity Hazard Analysis (AHA) shall be prepared for all field, laboratory, industrial, and maintenance activities. As outlined in Appendix A, EM 385- 1- 1, an AHA shall be completed for each major phase of work or service and included in the Site Specific Accident Prevention Plan.

Note: For LIMITED- SCOPE SERVICE, SUPPLY, AND R& D CONTRACTS, (e.g. painting, janitorial service, metering, TAB, etc.), the DOHS Safety Officer may allow an Abbreviated Accident Prevention Plan (see EM 385-1-1) and waive the more stringent elements of the comprehensive plan. The Contractor must make a written request to the DOHS Safety Officer safety@nih.gov and provide copy to the NIH Contracting Officer Representative.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, AND FACILITIES SERVICES.
ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.8. CONTRACTOR FULLY RESPONSIBLE FOR SITE SAFETY

1. The Contractor assumes full and sole responsibility for ensuring the safety of its personnel and sub-contractors.
   The Contractor shall comply with all laws, regulations ordinances, and governmental orders pertaining to employee worksite safety in the performance of this contract. Nothing the NIH may do, or fail to do, with respect to safety in the performance of the scope of work shall relieve the Contractor of this responsibility.

2. The Contractor shall be responsible for employing appropriate safety measures and taking all other actions reasonably necessary to protect the life, health, and safety of the public and to protect adjacent and NIH-owned property in connection with the performance of the scope of work. Personal protective equipment shall be selected for anticipated hazards and provided to the employee. Employees shall be instructed on the proper wear, maintenance, and limitations of the PPE.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, AND FACILITIES SERVICES.
ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.9. SELECTION OF CONTRACTOR SITE SAFETY AND HEALTH OFFICER

1. When the number of personnel on any shift is under 40 (including subcontractor employees), the Contractor's safety representative meeting the definition of "Collateral Duty Safety Officer" as defined in Section titled "SITE SAFETY AND HEALTH OFFICER" paragraph a) 2) CONTRACTOR SITE SAFETY AND HEALTH OFFICER shall be present on the project site.
2. For contractors with a total of 40 or more personnel (including subcontractor employees) on any shift, a Full-time Safety Professional as defined in Section titled "SITE SAFETY AND HEALTH OFFICER" paragraph a) 1) CONTRACTOR SITE SAFETY AND HEALTH OFFICER shall be present on the project site.
3. At the discretion of the NIH Contracting Officer Representative or DOHS Safety Officer, the requirements for the Contractor Safety and Health Officer can be reviewed and action taken to decrease or increase the number of onsite Contractor safety representatives. However, the need for a Contractor Safety and Health Officer is required and will not be waived.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, AND FACILITIES SERVICES.
ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.10. CONTRACTOR SITE SAFETY AND HEALTH OFFICER RESPONSIBILITIES

1. The responsibility for safety lies with the Contractor. Each Contractor shall appoint an individual(s) responsible for contract personnel safety. This individual(s) must be employed in a supervisory position, empowered by their employer to take corrective action; be present on the project while work is being performed; and spend the amount of time necessary to ensure the Contractor's compliance with safety requirements.
2. The Contractor Site Safety and Health Officer shall be primarily responsible for ensuring the safe work performed under this contract. Without limiting the generality of the foregoing, the Contractor Site Safety and Health Officer shall:

a. Review all subcontractor and sub-tier contractor's Site-Specific Accident Prevention Plan and Activity Hazard Analysis for compliance with applicable safety standards.
b. Perform or ensure that all Contractor, subcontractors and sub-tier contractors' employees have received a site-specific safety orientation prior to beginning work. Training will include discussion of the Site-Specific Accident Prevention Plan and Activity Hazard Analysis worksheets. This site-specific orientation is in addition to the NIH's Contractor Supervisor Safety Orientation course.

c. Regularly perform and document worksite inspections, assess hazards, and immediately correct any safety deficiencies, including those of any subcontractor. The Contractor shall specifically respond in writing to any substandard safety conditions or practices identified by the NIH. Inspection records shall be maintained at the project site and be made available upon request by the NIH Contracting Officer's Representative or DOHS Safety Officer.
d. Immediately report all personnel injuries, vehicle accidents, near miss incidents, and property damage to the Contracting Representative and DOHS Safety Officer (safety@nih.gov). Undertake a complete investigation of all accidents, injuries, illnesses, and near-misses (in the opinion of either the Contractor or NIH representatives) and implement corrective actions to prevent recurrence. Upon request, written findings shall be provided to NIH representatives.
e. Ensure appropriate safety meetings are held for all onsite employees, to include subcontractors. Safety meetings shall be conducted to review past activities, plan for new or changed operations, review pertinent aspects of appropriate Activity Hazard Analyses, establish safe working procedures for anticipated hazards, and provide pertinent safety and health training and motivation.
    1. Meetings shall be conducted at least once weekly for all workers.
    2. Meetings shall be documented, including the date, persons in attendance, subjects discussed, and names of individual(s) who conducted the meeting. Documentation shall be maintained and copies furnished to the NIH on request.
f. Be responsible for the control, availability, and use of necessary safety equipment, including personal protective equipment and apparel for the employees.
g. A Contractor Site Safety and Health Officer not performing his/her duties in accordance with the contract clauses, shall be replaced by the Contractor, or at the NIH's discretion.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.11. SITE SAFETY AND HEALTH OFFICER DEFINITIONS

1. ORF SAFETY OFFICER

   An employee of the NIH, or designated representative who is responsible for management of the Office of Research Facilities Development and Operations (ORF) Safety Program.

2. NIH CONTRACTING OFFICER REPRESENTATIVE (COR)

   An employee of the NIH or designated representative who conducts and monitors jobsite inspections and verifies contractor compliance with identified corrective actions.

3. CONTRACTOR

   The General Contractor contracted with NIH.

4. CONTRACTOR SITE SAFETY AND HEALTH OFFICER

The Contractor Site Safety and Health Officer(s) will be categorized as either a Full-time Safety Professional or a Collateral Duty Safety Officer based on the scope and size of the project.

1. Full-time Safety Professional qualifications include:
    - i The designated individual shall have no other duties.
    - ii An individual possessing a minimum of five years progressive experience managing safety programs on large projects comparable to this contract in scope and complexity.
    - iii Be knowledgeable concerning all federal, state, and local regulations applicable to construction and industrial safety.
    - iv Possess "Competent Person" certification in safety disciplines related to the work performed and possess verifiable training. This individual shall also be responsible for identifying "Competent Persons" required by state and federal safety standards for which they are not certified.
    - v Have successfully completed the OSHA 500 Trainer Course in OSHA Standards for Construction or OSHA 501 Trainer Course in OSHA Standards for General Industry. This requirement may be waived in lieu of an accredited safety and health degree or professional safety or industrial hygiene certification (i.e. CSP or CIH).
    - vi Be trained in and possess current certification for CPR and First Aid.
    - vii Be capable of performing accident investigations and developing a concise written report.
    - viii Is proficient in the development and presentation of "toolbox" meetings and safety training.

2. Collateral Duty Safety Officer qualifications include:

    - i An individual assigned to perform safety functions on any contract not requiring a Full-time Safety Professional. This can be a collateral duty position held by a supervisor.
    - ii Possess a minimum five (5) years progressive experience in their trade.
    - iii Be knowledgeable concerning all federal, state, and local regulations applicable to safety.
    - iv Have successfully completed the OSHA 30-Hour Course in OSHA Standards for Construction or OSHA 30-Hour Course in OSHA Standards for General Industry.
    - v Possess "Competent Person" certification in safety disciplines related to the work performed and possess verifiable training. This individual shall also be responsible for identifying "Competent Persons" required by state and federal safety standards for which they are not certified.
    - vi Be trained in, and possess current certification for CPR and First Aid.
    - vii Possess verifiable training and be capable of performing accident investigations and developing a concise written report.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.12. CONTRACTOR SAFETY AND HEALTH OFFICER QUALIFICATIONS

Prior to commencing services or assignment to the contract, the contractor shall submit a resume to the NIH Contracting Officer Representative and the DOHS Safety Officer (Safety@nih.gov) identifying the experience and qualifications for the proposed Contractor Safety and Health Officer(s). The NIH Contracting Officer's Representative or DOHS Safety Officer may reject individuals deemed "Not Qualified" if the proposed personnel does not meet the qualifications outlined in Section titled "SITE SAFETY AND HEALTH OFFICER".

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ARTICLE H.77.13. GENERAL OBLIGATIONS

The Contractor is responsible for accident prevention and worksite safety. This responsibility cannot be delegated to subcontractors, suppliers, the NIH, or other persons. To this end, the Contractor shall:

a. Promote a safe and healthy work environment.
b. Provide a Site Specific Accident Prevention Program.
c. Ensure subcontractors and employees are adequately trained in occupational safety and health topics relevant to the activities to be performed under this contract. This includes, but not limited communication and training of anticipated hazards (e.g. chemical, physical, biological, etc.). Maintain documentation of the employee training, to include the date and subject taught and be prepared to present upon request.
d. Instruct all employees of safe work methods and practices when assigning work.
e. Ensure that employees have, use, and understand the limitations of the proper protective equipment and equipment for the services performed under the contract.
f. Ensure that all heavy equipment operators (i.e. lasers, heavy equipment, etc.) are properly qualified and trained on the specific piece of equipment in use. Such verification shall be readily available upon request.
g. Cooperate fully with the NIH and its representatives in connection with all matters pertaining to safety.
h. Conduct a documented orientation training session for new employees that includes at a minimum, a review of:

1. The Site Specific Accident Prevention Plan
2. Potential hazards in assigned work areas
3. Proper wear of required personal protective equipment
4. Methods to mitigate anticipated hazards
5. Emergency response procedures

i. Ensure that all of its subcontractors, suppliers delivering materials or services to the worksite, etc., are provided with a copy of this specification and are informed of their obligations regarding worksite safety under this requirement. Ensure that provisions are documented and available upon request.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.14. ACCIDENT PREVENTION

a. The Contractor shall be responsible for correcting hazardous conditions and practices.
b. If it is determined there is an immediate threat of harm to anybody, the contractor shall:
1. Take immediate action to remove/safeguard personnel from the hazard and stabilize or stop work until corrective actions can be implemented to eliminate the hazard.
2. Immediately notify the NIH Contracting Officer's Representative and the DOHS Safety Officer via (safety@nih.gov) or by phone (301) 496-2960.

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ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **Subparagraph a:** Check to make sure contact information below is current and update as may be required.

ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.15. CONTRACTOR INJURIES AND ILLNESSES

1. Injury or illness resulting from work under this contract shall be reported to the NIH Contracting Officer Representative and DOHS Safety Officer (safety@nih.gov) within 24-hours of the incident.
2. For work conducted at remote locations where emergency medical service personnel are not capable of responding within 4-minutes, at least two persons shall be available at the work site at all times to render first aid and CPR. These personnel must have a valid certificate in first-aid and CPR from the U.S. Bureau of Mines, the American Red Cross, or equivalent verifiable training program. A minimum ratio of one such qualified person for every 25 employees shall be maintained throughout the project, but no less than 2 qualified persons at any time.
3. The Contractor is required to have and maintain at the worksite a first-aid treatment kit adequate for the anticipated hazards and number of personnel.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.16. NIH RIGHTS

1. INSPECTIONS/INVESTIGATIONS

a. The NIH Contracting Officer Representative may, in any reasonable manner, observe and inspect the Contractor's safety and accident prevention procedures for all activities and personnel. This specifically includes, but is not limited to, the right to attend all safety meetings.
b. Upon request, the NIH Contracting Officer Representative shall receive copies of any safety inspection reports completed by the Contractor or anyone performing work for, on behalf of, or under the Contractor.
c. The NIH Contracting Officer Representative may, in any reasonable manner, observe or participate in any accident investigation conducted by the Contractor or anyone performing work for, on behalf of or under the Contractor. The NIH may also, at its sole discretion and in any reasonable manner, undertake its own accident investigation.

2. CORRECTIVE ACTIONS/STOP-WORK
   a. The NIH Contracting Officer Representative shall have the right to direct the contractor to correct unsafe working conditions, including taking corrective action when unsafe working conditions are observed (i.e. lack of good housekeeping practices, use of equipment in obviously poor condition, failure to adhere to statutory OSHA regulations, etc.).
   b. The NIH Contracting Officer Representative shall have the right to require the removal, from the project, any person, property, or equipment that, in the NIH's opinion, is deemed unsafe.
   c. The NIH Contracting Officer Representative shall have the right to instruct the Contractor to immediately cease any action and/or stop work (or any action thereof) when any conditions exist that, in the NIH's opinion, constitutes an imminent danger or could result in serious harm.
   d. The NIH Contracting Officer Representative shall have the right to suspend the work pending the completion of any accident/incident investigation, whether undertaken by the Contractor, the NIH, or other parties of interest.
   e. The Contractor is responsible for costs, expenses, and other obligations paid or incurred, as a result of the Contractor or subcontractor's noncompliance with federal, state, or local safety regulations; or failure to comply with terms and conditions of this contract.

3. NIH'S ACTION/INACTION DOES NOT RELIEVE CONTRACTOR

   Nothing the NIH may do, or fail to do, with respect to safety in the performance of the work shall relieve the Contractor of its responsibility to comply strictly with this Contract and all standards referenced in this document.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.17. SPECIFIC SAFETY PROVISIONS

In addition to federal, state, and local regulations pertaining to operations and safety, the contractor shall adhere to the following NIH mandated safety requirements:

1. Asbestos: Many of NIH's buildings have asbestos-containing materials. It is the Contractor's responsibility to coordinate with the NIH Contracting Officer's Representative to ensure that a

survey for asbestos is conducted prior to commencing work. The Contractor shall ensure that all personnel who may disturb building materials have received and documented initial and annual Asbestos Awareness training prior to the start of work. If asbestos or other contaminants are found, the Contractor shall immediately notify the Contracting Officer and Contracting Officer Representative. NIH will address abatement of any asbestos and/or other contaminants.

2. Entry into Confined Spaces: The Contractor shall provide the NIH Contracting Officer Representative a copy of its Confined Space Entry Program as part of the Accident Prevention Plan and notify the Fire Department.
    a. Should the Contractor employ subcontractors to work in confined spaces, it shall be the Contractor responsibility to submit the required documentation for each subcontractor.
    b. Work shall not start in a confined space until the required submittals have been made and appropriate safety precautions have been taken by the Contractor or its subcontractors. In the event the Contractor does not comply with these regulations, ACCESS WILL BE DENIED.
    c. Personnel working in confined spaces must be trained in accordance with OSHA regulations.
3. Entry into mechanical spaces requires proper wear of head, eye, and hearing protection.
4. Wood and metal ladders are prohibited for personnel use. Fiberglass or ladders formed from non-conductive materials are appropriate.
5. Electrical - Safe Clearance Procedures
    a. Entry into High Voltage Areas: Work under this contract may require entry into High Voltage Areas.
    b. In the event entry is required, the Contractor is obligated to identify any High Voltage areas that may be involved in work under this contract. Before entry into a High Voltage work area, the Contractor shall notify the NIH Contracting Officer Representative.
    c. To prevent employee exposure or damage to electrical systems the contractor shall exhaust all options and means to de-energize live electrical parts in accordance with OSHA lock-out/tag-out requirements. Work around energized components requires appropriate safety training and PPE.
6. Fire Prevention: The Contractor shall ensure that the fire prevention measures on-site are in accordance with OSHA, NIH Division of Fire Protection policies, and the National Fire Protection Association standards.

    Approved safety cans (approved or listed by a nationally recognized testing laboratory) shall be used for flammable and combustible liquids. Fire extinguishers shall be provided by the Contractor where required.
    a. Open Flame Devices: Prohibit the use of unapproved fuel-burning types of lanterns, torches, flares or other open-flame devices on NIH property.
    b. Hot Work Permit: Open flame welding and spark producing equipment and tasks require the contractor to secure a "Hot Work Permit" from the NIH Fire Department. This can be obtained by calling the NIH Fire Marshall at (301) 496-0414.
7. Excavating and Trenching:
    a. Excavations and trenches shall be evaluated for confined spaces before entry.
    b. Ensure a Competent Person inspects the excavation or trench before work begins and as needed during the shift. When the Competent Person finds evidence of a hazardous condition, exposed employees shall be removed from the hazardous areas until the necessary precautions have been taken to ensure their safety.

c. All excavations, regardless of depth, shall be barricaded or covered. If barricades are utilized and are left they shall be equipped with appropriate lights or reflectors.
d. Walkways shall be provided where employees or equipment are required or permitted to cross over excavations. When walkways are utilized, a guardrail system shall be in place.

8. Activities that pose a potential risk of exposure to hazardous materials during remediation activities shall be supervised by personnel who have a current 40-hour Hazardous Waste Supervisor's certification and available upon request. These individuals shall be able to identify the potential need for upgrading the level of health and safety protection. All personnel working in direct contact with hazardous materials shall have a current 40-hour Hazardous Waste Operations certification and medical monitoring, in accordance with OSHA regulations. The Contractor is responsible for personnel monitoring to determine hazards and exposures to their employees.
9. Cranes and Hoisting Operations
   A written lift plan shall be submitted for all crane operations. The written lift plan will include as a minimum:
   i Make and model of the crane.
   ii Name of the crane operator, documentation of training and competent person responsible for the execution of the lift plan.
   iii A copy of the crane's most recent certificate of annual inspection.
   iv A copy of the crane`s maximum loads at various boom angles and radii.
   v Utilizing the crane boom angle and radius information identify all loads that will exceed 75% of the crane capability.
   vi Identify if two or more cranes are required.
   vii Provide a sketch or drawing of the anticipated boom angle, radius, center of gravity and crane placement.
   viii Provide a sketch or drawing of anticipated rigging methods to include:
      1. Number of slings
      2. Type of configuration
      3. Size and length of slings
      4. Rated capacity of slings
      5. Sling angle
      6. Size, number and rated capacity of shackles
   ix Identify number of ground handlers and location of ground handlers
   x Communication method between ground handlers and crane operator
   xi Location of material staging area
   xii Method of managing vehicle and pedestrian traffic
10. Chemical Exposure Plan: The contractor shall submit a Chemical Exposure Plan for any products containing isocyanates, methylene chloride, lead, silica, hydrofluoric acid and processes involving floor sealers, traffic coatings, terrazzo sealers, specialty paints or any other chemical which can produce nuisance odors. The plan shall include employee exposure control methods, isolation methods to prevent spread of chemicals and odors outside the work area and safeguarding of the NIH employees and public. Safety Data Sheets for each chemical must be maintained on site and available upon request.
11. Protection of the Public: The Contractor shall submit a plan for the protection of the public on or adjacent to construction and demolition operations.
12. Scaffolding:

a. Scaffolding must be erected in conformance with applicable regulatory policy.
b. Ensure a Competent Person inspects the scaffolding before work begins and daily, as required. When the Competent Person finds evidence of a hazardous condition, exposed employees shall be removed from the hazardous areas until the necessary precautions have been taken to ensure their safety.
c. Covered walkways in conformance to regulatory policy shall be provided at building entrances, egress, and other related areas when these cannot be secured.

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ARTICLE H.77.18. SAFETY PERFORMANCE

a. If the Contractor experiences repeated safety violations or fails to abate violations in a timely manner, the Contractor shall be subject to any of the following actions, at the Contracting Officer Representative or Contracting Officer's discretion:
    a. Removal and replacement of management personnel.
    b. Submitting a written safety recovery plan detailing what changes will be made to their safety program and a timeline as to when the changes will be implemented.
    c. Hiring an independent health and safety consultant who shall audit the contractor's procedures and operations. The consultant shall compile a plan detailing what changes the contractor shall implement. This report shall be submitted to the NIH Contracting Officer's Representative.
    d. Conduct a "Safety Stand Down" (suspend all work or any action thereof).
    e. Issue a cure notice notifying that the Contractor has failed to comply with a contract requirement and directing that the deficiency be "cured" within a specified time period.

b. Costs incurred by the Contractor to abate hazards or to respond to actions noted in this Safety Performance Section shall not be considered a reason for extension of contract time or increase in costs to the Government.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.77.19. HEALTH AND SAFETY REQUIREMENTS

The Contractor is responsible for safety at the construction or work site. The Contractor is also responsible for preparation of a safety plan and for carrying out the safety plan. The Contractor staff shall maintain conformance to the health and safety plan throughout the course of construction.

Contractor inspectors shall consider safety a key element of their daily inspections.

The Contractor is required to cooperate with officials of other agencies (Federal and/or state) who are vested with authority to enforce requirements of the Occupational Safety and Health Act (last updated June 12, 2002) at: https://www.osha.gov/laws-regs/oshact/completeoshact. If required, the Contractor will assist the Government in preparing accident and fire reports.

The Contractor shall comply with the NIH Health and Safety Requirements as applicable to the work being performed.

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ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **Subparagraph C:** Select the Contracting Officer or the Contracting Officer Representative (COR) from the drop-down box as appropriate. Note: If another individual will be designated for notification, delete the drop-down box and enter the Name and/or Title of the appropriate individual.

ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.78. SECURITY

GENERAL

1. The Contractor and all subcontractor's personnel will observe and adhere to all National Institutes of Health (NIH) security regulations and requirements at: https://security.nih.gov/pages/home.aspx when using or providing services on the NIH property. The Contractor shall be responsible for subcontractor compliance and include specific provisions in all subcontracts that these regulations be accepted.

2. The Contractor shall be accountable for compliance with the provisions of this Section by all individuals and entities employed by or under contract to the Contractor.

3. Notification: Notify the [Contracting Officer (CO)/Contracting Officer Representative (COR)] or a designated representative, not less than 48 hours prior to performing work in a restricted-access area as defined by the NIH. Include the following:
    a. Companies: Name of each company performing the work.
    b. Personnel: Name, social security number, date and place of birth, citizenship and, where applicable, visa status of each individual who is to work.
    c. Time: The exact time, date, and hours of work.
    d. Areas: Specific areas of the building in which work is to be performed.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.78.1. CONTRACTOR RESPONSIBILITY

1. Contractors shall be responsible for security of their property and material from theft and vandalism.
2. The Government does not accept responsibility for loss or damage to any property or work it has not accepted.
3. Contractors shall be responsible for excluding all but authorized persons from their work sites.

4. Contractors and their employees shall immediately report any known violations of law or regulations, or the discovery of unaccountable property, either private or Government-owned, to the Contracting Officer Representative (COR).
5. Conduct on Federal Property: Contractors are advised that operating a motor vehicle when entering upon or while on NIH property by a person under the influence of alcoholic beverages, narcotic drugs, including hallucinogens, marijuana, barbiturates or amphetamines, is prohibited. Entering upon the property, or while on the property, under the influence of, or using, or possessing any narcotic drug is prohibited. Such prohibition shall not apply in cases where the drug has been prescribed by a physician. Entering upon the property, or being on the property, under the influence of alcoholic beverages is prohibited. The use or possession of alcoholic beverages on NIH property is prohibited unless, upon occasions and at specific locations which the Director, NIH, or his delegated official has for appropriate official uses, granted an exemption in writing.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.78.2. CONTRACTOR SECURITY PLAN

1. Upon award of contract for this requirement, the Contractor shall develop and submit for approval a Contract specific Contractor Security Plan. The Contractor Security Plan shall encompass all administrative, physical, and operational security requirements noted in this specification section for all persons and subcontractors under this Contract.
2. The Contractor shall, within 10 days receive Contractor Security Plans from each subcontractor or other entity to be engaged under the Contract and shall furnish evidence satisfactory to the Contracting Officer Representative (COR) that this has been done.
3. All persons employed within the boundaries of the property or restricted-access areas therein, and all persons permitted to enter such property and areas shall comply with the security regulations and procedures that have been established for this Contract.
4. The Contractor Security Plan shall include provisions to address various Security Alert Levels as determined by the Department of Homeland Security.
5. The Contractor Security Plan shall include provisions to address an approach to overall security that is consistent with the goals contained in existing NIH Security Policies, Guidelines and Regulations at: https://security.nih.gov/pages/home.aspx.

   The Contract specific Contractor Security Plan seeks to achieve the following security goals:
   a. Screen Contractor workforce consistent with NIH policies and procedures.
   b. Safeguard NIH employees and assets from events or persons who could cause harm.
   c. Limit project information distribution and ensure compliance with the National Institutes of Health Confidentiality Non-Disclosure Certification, a copy of which is included as an attachment to authorized persons and entities to the greatest extent that is practical, and as directed by the Associate Director for Security and Emergency Response (ADSER).

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ORF Processes/Procedures - NCIC Link Below - Reviewed 11/22)****

ARTICLE H.78.3. CONTRACTOR PERSONNEL

Upon award of Contract the following security procedures will apply:

1. The Contractor shall provide information about all Contractor and subcontractor personnel and others who require continued access to the site, before access is required and when access ceases.
2. No interviews of prospective Contractor employees shall be conducted on the project site or NIH property. The Contractor and subcontractors will be required to maintain a field office, outside the project site or NIH property, for all public contacts. Applicants for employment and other persons not entitled to access to the project site shall be required to contact the Contractor or subcontractor at these offices.
3. Within 10 calendar days after the award of the Contract, the Contractor shall submit a list of all employees, subcontractors and their employees, and others who will perform work or otherwise require access to the site. Personnel shall be listed in alphabetical order by company. The list shall include the full name, social security number, date and place of birth, citizenship and, where applicable, visa status for each individual.
4. Name of any employee added later to the original list shall be submitted with the same information on the Contractor's letterhead at least 8 calendar days in advance of the date of access by the employee.
5. The Contractor shall notify the Government in writing when personnel are no longer employed by the Contractor or a subcontractor. The written notification shall include the individual's name, social security number and date and place of birth, citizenship, visa status and the company who employed the individual, if applicable.
6. Each company or entity with personnel assigned to this Project shall ensure that all personnel undergo a personnel security screening to determine their suitability for access to NIH facilities, information and data.
    a. The Contractor Security Plan establishes two levels of contractor personnel involvement: those involved in sensitive duties; and those not involved in sensitive duties. The NIH will provide two different screening processes accordingly.
    b. Completion of a background questionnaire and assorted forms (Standard Form 85P - "Long Form Screening") as well as a credit check is required for the following sensitive duties:
        1. Contractor personnel with direct senior level management responsibilities on the Contract.
        2. Contractor personnel with direct management responsibilities on the Contract and requiring access to "Law Enforcement Sensitive" or other NIH-designated sensitive information.
        3. Contractor personnel with direct in-depth knowledge or installation responsibilities of access control systems, closed circuit television (CCTV), and/or intrusion, motion or other detection devices on the Contract and requiring access to "Law Enforcement Sensitive" or other NIH-designated sensitive information.
    c. A police check provided by the NIH Police through the National Crime Information Center (NCIC) (NCIC "Short Form" screening) is required for all other Contractor personnel working

on the project involving non-sensitive duties. Information found at: https://irp.fas.org/agency/doj/fbi/is/ncic.htm.

d. In addition to other disqualifying factors as determined by the NIH, the following shall apply:
    i Conviction for tax evasion may disqualify contractor personnel being considered for sensitive positions.
    ii A history of acts of violence, arrests for firearms or explosives violations, illegal alien status, or any felony convictions will disqualify Contractor personnel from working on this Contract.

7. The Contractor shall notify the NIH Division of Police through the Contracting Officer, or a designated representative, of any change in personnel assigned to the project site, including changes in employee status such as terminations of employment, civil or criminal charges, visa status, if applicable.
8. The NIH reserves the right to require the removal of any Contractor employee from the project site if the employee is deemed a security risk by the Director for Security and Emergency Response (ADSER).
9. In order to permit the NIH Division of Police to supply NIH ID Badges for on-site personnel, the Contractor shall cause each individual to complete a personnel identification form. These forms will be provided by the NIH to the Contractor at the pre-construction conference. Processing of the forms and issuance of NIH ID Badges will be performed by the NIH at NIH expense.
10. At a time designated by the Contracting Officer or when an individual reports to the site for work the first time, of at least 2 hours will be required for security processing, including review of identification forms and fabrication of a permanent badge. Personnel will then be permitted to go to work without further processing of identification forms by the Government. Time will be required each day for signing in with security to obtain access to the site.
11. The permanent NIH ID Badge furnished by the NIH to each Contractor employee or other person granted access to the site will serve to authorize the wearer to enter and leave the project area. The NIH ID Badge must be worn so as to be clearly visible at all times when at the work site.
12. Access to other parts of the NIH property will be subject to the screening procedures applicable to visitors under the Alert Level in effect as determined by the Department of Homeland Security.
13. The NIH ID Badge will be retained by the individual as long as continued admittance to the site is required. The Contractor will arrange for immediate return of the badge to NIH when such need ceases. Temporary or visitor ID Badges will be provided for persons who are identified as having an infrequent or temporary legitimate business need for access to the site.
14. Security Manager
    a. A Security Manager (SM) shall be designated by the Contractor for the duration of the project. The SM must report directly to an officer of the firm and not to the site superintendent and must be provided the authority in writing to implement the designated security plan, policies, procedures and directives for the project as provided by the NIH Division of Police.
    b. The individual must be familiar with the requirements of the Department of Homeland Security threat levels. NIH Division of Police will define the NIH responses to the various threat levels to the successful contractor.
    c. The individual must be fluent in speaking and writing English.

d. The individual must undergo and pass a U.S. Government Background Investigation prior to receiving security sensitive information from the NIH Police.
e. The individual must be capable of understanding potential security problems, exploring issues and developing efficient and effective solutions.
f. The individual must possess good interpersonal skills and be capable of working with a variety of organizations, including the NIH, other federal agencies, local law enforcement, and the private sector.
g. In addition to implementing and managing the construction security program for the project, the construction security manager may perform other management-level duties within the firm.
h. The only duties and responsibilities of the construction security manager are to manage and implement the construction security program on this contract.

15. All personnel engaged on the Contract will be required to execute a Contractor Non-Disclosure Agreement (NDA) found at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf.

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ORF Processes/Procedures - Security Link Below - Reviewed 11/22)****

ARTICLE H.78.4. SECURITY PROCEDURES

Upon commencement of the work under this contract, the NIH Security Policies, Guidelines and Regulations at: https://security.nih.gov/pages/home.aspx shall apply to the Contractor and all subcontractors.

1. Contractor personnel shall not enter the NIH campus without appropriate NIH ID Badge.

2. For work outside "normal work hours" as defined in the Contract, the Contractor shall give the Contracting Officer or his designated representative at least three (3) calendar days` notice. This notice is required so that security arrangements may be provided and is separate and distinct from any notices required for utility shutdown or other outages.

3. The NIH reserves the right to restrict photography of the project or other areas of the NIH premises.
   - Cameras are not permitted without written permission from the Contracting Officer or his designated representative. If approved, permission will be granted in writing and will provide additional guidelines.

4. Personnel may be subject to inspection of their personal effects when entering and leaving the project site. In addition, unscheduled inspections of personnel may be made while on site.

5. The NIH reserves the right to alter security procedures based on the Security Alert Level in effect as determined by the Department of Homeland Security, for as long as the Security Alert Level change exists.

6. The NIH reserves the right to close down the project site and order Contractor personnel off the premises in the event of a national emergency or a shut-down, for as long as the national emergency or shut down exists. The Contractor may only return to the site with written approval from the Contracting Officer or authorized representative.

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Note: *This item is a heading only.*

ARTICLE H.79. OTHER ON-SITE

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ARTICLE H.79.1. NON-INTERRUPTION OF GOVERNMENT ACTIVITIES

All work areas must be separated from the remainder of the building with smoke tight partitions constructed with non-combustible or fire-retardant materials. Barriers must be in place prior to and during all stages of renovation work.

Interruption or interference with the conduct of government business in other building areas outside the contract area, or damage to existing equipment within the contract area, will not be permitted. To protect government property and to isolate his work, the Contractor shall provide, at no additional expense to the government, drop cloths, plastic film draping, taping, barriers, weatherproof closures and/or coverings, and temporary dust-proof enclosures and partitions, etc. Temporary dust-proof enclosures and partitions shall be provided wherever demolition or construction operations will produce dust or dirt subject to spreading via tracking or air currents beyond the immediate area of work. Such enclosures shall be erected structurally sound and shall be maintained dust proof so as to keep surrounding areas clean and free of dust. Where practical, dust-producing activities shall be kept dampened with water, so as to reduce the generation of dust.

Temporary dust-proof enclosures will always be required to separate sterile or germ-free areas from the contractor's work area. Materials shall be conveyed inside buildings in and on rubber-tired vehicles provided by the contractor. Use of NIH equipment is prohibited. The use of equipment which produces substantial noise or vibration in buildings, such as pneumatic hammers, etc., is prohibited except in those cases where it is approved by the Contracting Officer Representative (COR) because no other method is available. If use of such equipment is approved, work will be restricted to non-NIH work hours, 6:00 P.M. through 6:00 A.M. Monday through Friday or weekends.

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ARTICLE H.79.2. UTILITY SHUTDOWNS

All outages or modifications to the fire protection systems must be scheduled and approved by the Contracting Officer or his/her representative(s). Contractors shall not cut, disconnect, switch, open, or alter position of valves, or otherwise interrupt any utility systems, piping systems, electric services, etc. without prior approval of the Contracting Officer Representative (COR). Shutdown of any utility service which will affect service to any areas other than those in the contract area, must be requested in writing a minimum of fifteen (15) working days in advance, and requires written confirmation/approval prior to service interruption. This work shall be accomplished outside normal NIH working hours, at no additional cost to the Government.

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ARTICLE H.79.3. USE OF GOVERNMENT BUILDING FACILITIES

General

Where the term "NIH Reservation" appears herein, it shall be defined as also including all "off reservation" facilities.

1. Contractors (including subcontractors), their officials, employees, and all other persons visiting or conducting business on the NIH Reservation, NIH Animal Center, Federal Building and future construction sites pertaining to NIH facilities in connection with contract work shall conform to these requirements.

   The Contractor shall be responsible for the enforcement of these requirements by his subcontractors.

2. Before work is started, the Contractor shall furnish to the NIH Contracting Officer Representative (COR), the name of the principle responsible official for the contract plus at least one alternate, with their home addresses and phone numbers, who may be contacted in case of emergencies occurring outside the regular hours of work. Similar information shall be furnished concerning all subcontractors.

3. The COR shall act as the liaison between the Contractor and NIH activities to provide or obtain:
   1. Truck routes for delivery of supplies and equipment.
   2. Storage areas for Contractor's materials and equipment (generally limited to the Contractor's site).
   3. Staging areas for Contractor's trucks, cranes, etc., within limits of space available as outlined in Section H, Motor Vehicles and Parking Regulations.
   4. Approvals, clearances, permits, and inspections by NIH activities.
   5. Notification to affected NIH activities regarding interruptions of services and blasting operations.
   6. Compliance of the Contractor with general and specific requirements listed here.

4. Contractors shall comply with all orders and directives of NIH Police and Fireman or local jurisdiction for off "reservation" projects.

   Building freight elevators may be use by the Contractor to transport materials only at times when such use does not interfere with normal NIH operations. Elevator use shall be arranged through the COR. The Contractor is responsible for protecting elevator cab interiors from damage.
   Construction Contractors and subcontractors working at NIH facilities shall not use NIH toilet facilities. The Contractor shall make arrangements for portable toilet facilities.

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ARTICLE H.79.4. MATERIAL DELIVERY, STORAGE AREAS AND DEBRIS REMOVAL

1. Material Delivery -- Contractors shall arrange for the deliveries of supplies or material and equipment to the work site or designated storage areas via previously approved routes. Wherever practicable, deliveries shall be made during the regular NIH working hours and only when the Contractor's representative is available to receive them. If a Contractor's representative cannot be located, the NIH Police Force has standing instructions not to allow the material to be unloaded at the construction site. When deliveries are to be made outside normal NIH work hours, they must be scheduled for a pre-designated time in advance through the Contracting Officer Representative (COR) or Construction Manager so that the NIH Police can arrange to open (and secure) doors to the building and area. This requirement is necessary to maintain building security.

2. Storage of Materials -- There is no space available in NIH buildings for the storage of materials and equipment. The Contractor shall be responsible for storing all of the long-lead-time materials and equipment, as designated within the project's specifications and drawings. Corridors and other public areas must be kept clear at all times. Materials stored at locations not authorized by the COR or Construction Manager are subject to being hauled away by the government or having the Contractor's progress payments delayed.

   Contractor shall provide and maintain proper storage for all hazardous materials and/or wastes and maintain copies of all relevant Material Safety Data Sheets (MSDS) paperwork on-site for NIH review.

3. Debris Removal -- Removed materials, which are designated in the specifications or drawings as contractor's property, or debris shall be promptly removed from the job site and the NIH Reservation. Storage and/or collection of debris inside or outside buildings will not be permitted. Contractors shall remove all debris and other material from the job site and Reservation with their own carts, containers, and/or refuse disposal facilities. Government facilities may not be used for this purpose. All interior areas of existing buildings shall be left clean on a daily basis. When debris must be removed from buildings outside normal NIH work hours, it must be scheduled for a designated time in advance (the same as for material deliveries).
   Projects in Building 10 shall dispose of construction debris and trash in the B-2 level loading dock dumpsters. Dispose of debris and trash in the appropriate dumpsters according to the type of

refuse.

4. Combustible debris and trash must be removed from the work site daily.

5. No corridor or stairwell can be locked, blocked, closed or used for storage without the written permission of the COR.

6. Keep passage through all corridors clear and without obstructions at all times. Do not block the emergency egress with construction supplies, equipment or debris. Written permission must be obtained from the COR for temporary storage of supplies.

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ARTICLE H.79.5. CONSTRUCTION DEBRIS

The ORF Division of Environmental Protection (DEP) at: https://orf.od.nih.gov/EnvironmentalProtection/Pages/default.aspx provides construction dumpsters for all construction and renovation projects on the Bethesda Campus at no cost. The dumpster rental, transportation, and disposal costs of all collected materials are covered by DEP. Before the dumpster will be delivered, the Contracting Officer Representative (COR) must submit a Site Selection Request and obtain approval. For additional information, view the DEP Construction Dumpster Program, the COR's Guide, and Construction Debris Waste Management and Recycling Plan at the DEP section of the ORF website. Contact DEP staff at 301-496-7990 with questions about this service.

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ARTICLE H.79.6. FIRE PREVENTION

1. Contractors shall instruct their employees to immediately report any fire to the NIH Fire Department, (dial 116 if the phone is on an NIH exchange or 496-9913 if the phone is not on an NIH exchange) even if it has been extinguished. In addition, the NIH Fire Department shall be immediately notified on any hazardous material spill, ambulance or rescue emergency.

2. Contractors are responsible for promptly replacing/recharging any self-owned fire extinguisher that has been discharged. If the fire extinguisher is NIH owned, the NIH Fire Department shall be promptly notified for a replacement (dial 496-2372). Portable NIH-owned fire protection equipment shall not be moved unless approved by the NIH Fire Department.

3. All construction trailers shall not be moved into place or erected on the NIH reservation without prior approval by the NIH Fire Prevention Section as to location, type and method of heating and

lighting. They must be located within the Contractor's assigned area and are generally restricted by a minimum separation distance of 40 feet to an adjacent trailer or an occupied building. In cases where this separation distance is not feasible, additional fire protection features will be required dependent on the maximum separation distance which can be attained. The Fire Prevention Section shall be consulted to determine the additional fire protection features which must be incorporated.

4. The installation of aboveground tanks for fueling the Contractor's equipment must be approved by the NIH Fire Prevention Section. Contractor shall provide secondary containment equipment for all fuel and/or chemical storage containers/tanks that meets Maryland Department of the Environment regulatory requirements.

5. Contractor shall not use water from fire hydrants to standpipe risers without prior approval from the NIH Fire Department. In the event of actual emergencies, the fire department may discontinue the use of water from fire hydrants and or standpipe risers without advance notice.

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ARTICLE H.79.7. RECYCLING OF CONSTRUCTION MATERIALS

The only construction debris material that should not be placed into debris dumpsters is ceiling titles. Contractors are to separate and stack these on the loading docks. The ORF Division of Environmental Protection (DEP) recycling contractor will collect them for consolidation and recycling. Ceiling titles must be palletized on the loading dock to allow for removal. Broken ceiling titles will not be accepted. Cardboard generated from any projects should also not be placed in the dumpsters. Cardboard is to be flattened and left on the loading document for collection by the DEP on-site Contractor who collects loading dock cardboard at each dock in the mornings and afternoons.

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ARTICLE H.79.8. ENVIRONMENTAL

1. The Contractor shall strictly follow all the conditions and requirements in the Maryland Department of the Environment (MDE)-approved drawings.

2. Inspect all the erosion and sediment control measures daily and perform necessary repairs.

3. Maintain a log of the site erosion control measures' condition. At the minimum, the log shall contain information such as date and time of the inspection, weather, deficiencies found, and any corrective measures (repairs, in/outside of the site cleaning) performed.

4. Make the above inspection log available upon request by NIH-Division of Environmental Protection (DEP) representative and/or MDE inspector.

5. Completely cover any dirt/stockpiles with plastic tarp at the end of every business day regardless of the weather condition.

6. Clean/sweep the road as well as adjacent areas of the site of any debris that may have expelled from the site. The debris includes dirt, sand, gravel, and any other material related to the construction project.

7. Notify NIH-DEP of any utility line (pipes, plumbing, etc.) cleaning, flushing and/or testing at least one week in advance. The Contractor's procedure must be prepared and provided to NIH-DEP for approval.

8. Notify NIH-DEP as the project nears its completion and coordinate for a final site inspection by MDE. The Contractor shall be responsible for the site condition and the contract shall not be closed however until the site is inspected and approved by NIH-DEP.

9. The address for NIH-DEP is NIH, Division of Environmental Protection, 9000 Rockville Pike, Bldg. 13, Room 2S11, MSC 5746, Bethesda, Maryland 20892-5746. The phone number is (301)496-7775.

10. As-built drawings of the stormwater management features shall be provided to DEP upon completion.

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ARTICLE H.79.9. INTERIM LIFE SAFETY MEASURES (ILSM)

a. Interim Life Safety Measures (ILSM)

The Contractor shall comply with the ILSM established by the NIH Division of the Fire Marshal or the Clinical Center. These measures shall be implemented for all construction, renovation and alteration work and periods when the work compromises the fire protection systems such that the facility does not meet applicable provisions of the Life Safety Code®.

1. All contract employees shall abide by the no smoking policy when working in or around the perimeter of the facility.
2. All corridors and stairs required for emergency egress shall remain clear and unobstructed at all times.
3. Access to emergency services and for fire, police, and other emergency forces shall remain free and unobstructed at all times.

4. When normal access or exiting paths need to be changed or modified in any way, this action shall be done only with prior written approval by the authority having jurisdiction (AHJ). The AHJ will keep the NIH Fire Department and relevant occupants notified of all route changes.
5. Existing fire alarm, detection, and suppression systems shall remain in good working order. All modifications or planned shutdowns of the fire protection systems must be scheduled and approved by Maintenance Engineering. It is the responsibility of Maintenance Engineering to notify the AHJ and the NIH Fire Department of all modifications in these systems and to ensure that temporary, but equivalent, fire safety measures are in place when the operation of any fire system is impaired. Temporary and equivalent systems must be tested monthly.
6. All work areas will be separated from the remaining portion of the building with smoke-tight partitions constructed with noncombustible or fire-retardant materials. All barriers shall have clean, smooth surfaces and provide a contiguous seal to minimize the migration of construction dust as well as smoke.
7. Because the building's air pressure is negative relative to the outdoors, work that involves a break in an exterior wall shall be protected with two parallel noncombustible or fire-retardant partitions to minimize energy loss, property damage, and occupants' discomfort or exposure to chemical vapors and bioaerosols.
8. Penetrations in fire and smoke walls contiguous with occupied areas will be properly sealed at the end of each work shift.
9. All individuals must obtain a NIH Hazardous Work Permit from the NIH Division of the Fire Marshal by calling 301-496-0414 prior to the start of any welding, cutting, or use of an open flame.
10. Fire safety measures as required by the NIH Hazardous Work Permit shall be conspicuously posted at the work site and accessible at all times. Measures may include fire extinguishers, blankets, and other suppression methods designated by the AHJ or NIH Fire Department.
11. Commensurate with the fire hazard potential, the NIH Fire Department may provide employees and Contractors who perform work requiring an NIH Hazardous Work Permit training in the use of portable fire extinguishers.
12. Prior to use, the Contracting Officer Representative (COR), with the CC safety officer and CC Office of Facility Management will assess the risks associated with the flammables, oxidizers, irritants, and other potentially hazardous chemicals proposed for use in the work area.
13. The Contractor will provide the Material Safety Data Sheets (MSDS) for chemicals used on the site in accordance with provisions of the OSHA Hazard Communication Act. The contractor must keep a binder containing all MSDS for chemicals approved for use at the worksite---where it is readily available for employees and emergency responders at NIH.
14. Flammable and oxidizing chemicals on the jobsite shall be limited to a one-day supply. Additional supplies shall not be stored in a building unless an approved storage area is designated by the AHJ.
15. Flammable compressed gas cylinders shall be limited to a one-day supply. Additional cylinders shall not be stored in a building unless an approved storage area is designated by the AHJ.
16. Compressed gas cylinders shall be securely stored in an approved cart.
17. Wastes shall be removed from the worksite at the end of each work shift or as needed.
18. Until completion of the construction project, all combustible storage on the jobsite shall be kept at the minimum level acceptable to the AHJ for daily operations.
19. The NIH Division of the Fire Marshal [the fire safety "authority having jurisdiction" (AHJ)], as well as the CORs will monitor renovation and construction areas for compliance with the ILSM.

20. The NIH AHJ shall approve all completed work for compliance with provisions of the National Fire Codes prior to acceptance and beneficial occupancy of the space.
21. Daily Inspections:
    a. The Contractor's Project Manager or Superintendent shall monitor compliance with the ILSM on a daily basis.
    b. Contractor shall address ILSM requirements in their daily report that shall be provided to the COR.
    c. Noncompliance with checklist is sufficient cause for a "Stop Work Order".

2. Building 10 Complex - Construction Risk Assessment (CRA).

The Contractor shall comply with Construction Risk Measures that identify and address hazards that could potentially compromise patient care, treatment, and services in occupied areas of the Building 10 complex (e.g. Buildings 10, 10B (ACRF), CRC, and NMR imaging center). Hazards include air quality requirements, infection control measures, utility requirements, noise, vibration, and emergency procedures. Construction Risk Measures must be implemented prior to the project execution phase and be maintained through demolition, construction, or renovation till the completion of the project. The Contractor shall complete the Construction Risk Assessment (CRA) to identify, develop and implement control measures required for the TYPE, GROUP and CLASS of area in which work will be performed (using the Patient Risk Group Drawings) and for adjacent areas that may be affected by the work. The Contractor shall complete the information included in the CRA procedure, distribute this information to the COR and other persons designated by the COR and receive approval from the government prior to starting work. This construction risk assessment process shall be repeated each time when the location or character of work changes. Construction risk measures include scheduled times and thresholds for vibration and noise; barriers to contain particulates including sticky carpet mats, smoke-tight wall boards, air pressure differentials, and filtration devices; redundant or comparable safeguards to maintain effective odor removal, air conditioning, humidification, heating, critical air quality and clinical parameters required for patient care and the safety of all occupants, and emergency procedures. The TYPE, GROUP and LOCATION of the work determines when and to what extent construction risk measures applies to the work performed by the Contractor.

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ARTICLE H.79.10. MOTOR VEHICLE AND PARKING REGULATIONS

1. All persons driving motor vehicles on the NIH Reservation in connection with Contractor business, including the driving of employees' personal vehicles, shall abide by the Conduct of Persons and Traffic on Certain Federal Enclaves, dated July 21, 1980, as a condition of being permitted to enter the Reservation and as part of the contract.
2. When Contractor trucks are to be parked for loading or unloading materials for a period longer than just a routine delivery, approval must be obtained from the Contracting Officer Representative (COR) who will notify the NIH Police Section. During the course of a construction job, as space needed for truck parking changes, the Contractor shall inform the COR who will clear the need through the NIH Police Section.

3. Vehicles operated over reservation roads in connection with contract work shall be loaded so as to minimize spillage of dirt, gravel, and other debris. The Contractor shall remove inadvertent spillage of nails, construction materials, scrap, etc., immediately. Dirt and gravel spillages or accumulations shall be removed as soon as practicable and as satisfactory to the COR, but in every case, it shall be removed no later than the end of each workday.
4. The driver of any vehicle involved in an accident on the NIH Reservation shall stop and render aid as required. The accident shall be reported as soon as possible in person or by telephone to the NIH Police Section. Drivers of the vehicles involved shall remain until released, and shall furnish such reports of the accident as required.
5. When closing of roads or lots is necessary for a Contractor to perform work, notify the COR at least fourteen (14) calendar days in advance, so that the action may be cleared through the NIH Police Section. Once approval is granted, Contractors shall provide their own barricades and cones and block off the area.

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ARTICLE H.79.11. PARKING REGULATIONS

A. **Policy for Construction Personnel and Miscellaneous Contract Service Vehicles at the National Institutes of Health (NIH) Bethesda, Maryland Campus.**

a. The purpose of this clause is to establish clear directives for parking of Construction/Contract service vehicles and their personnel.
b. Construction/Contract service categories have been established to identify policies specific to individual user groups.

Category 1 - General Labor

All Category 1 parking will be located off-site

The NIH shall require that Contractors for projects in excess of $10 million (construction contract award amount) provide off-site parking and shuttle service for their workers for the duration of their project. This cost shall be borne by the Contractor.

Construction workers are strictly prohibited from parking their personal vehicles on the NIH campus including visitor parking areas between the hours of 7:00 a.m. and 7:00 p.m. Construction workers may park in the general employee parking:

i) outside this time period,
ii) during federal holidays, and
iii) on weekends.

Category 2 - Specialty Contractors

Includes smaller job Contractors who work out of their vehicles for projects of short duration and no staging area is provided. (This would include elevator Contractors, plumbing Contractors, etc.).

Specialty Contractors shall use paid visitor lots. This cost shall be borne by the Contractor.

When it is essential that the specialty Contractor's vehicle be in close proximity to the work area, the Contractor may request special exception through the Contracting Officer Representative (COR). The COR will notify the Division of Public Safety for specific instructions.

Category 3 - Contractors with Approved Staging Areas

Includes Contractors with approved staging areas. This would include general Contractors as well as their subcontractors.

Properly marked company vehicles and equipment required in the performance of their project shall be permitted to park within their approved staging areas. Personal vehicles are prohibited from parking within the staging areas.

Category 4 - Full Time CQM/A&E/Consultants for Design and Construction Activity

Properly marked company vehicles required as part of their work shall be permitted to park within their approved staging areas. Personal vehicles are prohibited from parking within the staging areas.

Personnel in a continuing role on construction sites may be provided parking permits in accordance with NIH parking policies by request through their COR.

Off-site CQM/consultant personnel shall use paid visitor parking areas.

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ARTICLE H.79.12. PARKING MITIGATION PLAN

PROJECT TRAFFIC / PARKING REQUIREMENTS

PART 1 - GENERAL

1.1 RELATED DOCUMENTS

A. Drawings and general provisions of the Contract, including General and Supplementary Conditions and other Division 1 Specification Sections, apply to this Section.

1.2 SUMMARY

A. This Section defines parking requirements and responsibilities for all parties involved in the performance of the work, and includes the following types of provisions:
   1. On Campus parking
   2. Project Site parking
   3. Satellite parking
   4. Shuttle service to the NIH campus
   5. Parking monitoring/enforcement

B. This Section includes the requirements for providing the following documentation as part of the Project Traffic / Parking Mitigation Plan:
   1. List of all management personnel working full time on site for the Prime Contractor.
   2. Site Plan identifying available parking on the Project Site and staging areas for construction vehicles and materials.

3. Number of workers requiring parking; not including personnel identified in item B.1.
4. Identification of Satellite Parking facilities.
5. Identification of means to transport workers to project site.
6. Identification of enforcement procedures.

C. Related Sections: This specification section is related to any and all specification sections with explicit or implicit reference to construction progress documentation. Specific submittal requirements of these related specification sections are not included in this section. Related sections include but are not limited to the following specification sections:
1. Section 00700 General Conditions - AIA document A201-1997
2. Section 00800 Supplemental Conditions
3. Division 1 Section "Submittal Procedures"
4. Division 1 Section "Reference Standards and Definitions"
5. Division 1 Section "Temporary Facilities and Controls"

1.3 DEFINITIONS

A. NIH Campus: NIH main campus in Bethesda, Maryland (boundaries to be determined, is it applicable to other campuses…Poolesville, RML, etc.)

B. NIH Parking Policy: All full time, management staff of the Prime Contractor shall be provided either On Campus Parking or Project Site Parking at no cost to the Prime Contractor. All Subcontractors must park in Satellite Parking facilities as provided by the Prime Contractor. Costs for providing the Satellite Parking, shuttle service, enforcement, management and evaluation of the parking plan shall be included in cost of the work.

C. On Campus Parking: Parking located on the NIH Campus, either in NIH parking lots/structured parking facilities or on the Project Site.

D. Owner: Either the NIH and/or NIH's Contractor (General Contractor, Construction Quality Manager, Architect/Engineer, etc.).

E. Prime Contractor: The entity that has executed the contract with the owner.

F. Project Site Parking: Parking located within the Limits of Disturbance as defined by the approved Site Plan or MDE Soil Erosion, Sediment Control Plan.

G. Satellite Parking: Parking not located within the NIH Campus or in neighborhoods adjoining the NIH Campus.

H. Shuttle Service: Transportation service provided by responsible contractor from Satellite Parking to the Project Site. Examples include bus service and public transportation.

I. Public Transportation: Any mode of transportation service offered by local and state authorities. (Examples: WMATA, Montgomery County Bus Service)

J. Subcontractor: Any Contractor that is not a Prime Contractor.

PART 2 - PRODUCTS

2.1 PROJECT TRAFFIC / PARKING MITIGATION PLAN

A. Prime Contractor shall prepare and submit to the Contracting Officer Representative (COR) for approval a Parking Plan showing the measures to control and manage parking of its personnel including but not limited to management personnel, construction labor and subcontractor personnel during the performance of the work. The Parking Plan shall contain the information and be presented in the format shown in Attachment 1 at the end of this section.
    1. Be in the form of a written report.
    2. Identify all management personnel working full time on site for the Prime Contractor.
    3. Identify the number of subcontractor vehicles requiring parking. The description shall provide the maximum number of parking spaces required for each six month period for the project duration.
    4. Identify Satellite parking locations, their distance from the NIH Campus and time required to travel to the NIH Campus.
    5. Identify if the Satellite parking facility requires additional fees for parking after hours, weekends or holidays. Such costs shall be included in cost of the work.
    6. Identify the Shuttle service to be used along with the means to transport subcontractors to their vehicles in the case of weekend/holiday work, personal emergencies, a project emergency or unscheduled overtime to maintain project schedule and project quality. The Plan shall also include the time frames the shuttle service will be regularly operating as well as for atypical occurrences.
    7. Identify the means the Prime Contractor shall use to monitor/enforce the Subcontractors commitment to utilizing Satellite Parking.
    8. Identify the number of subcontractors utilizing public transportation.
    9. Provide a means for evaluating the Plan at the end of each project. Such evaluation shall be provided to the NIH with the Project Close-out documents.
    10. Identify means to communicate the Plan to Subcontractors: Contracts, training, handouts, etc.
    11. Identify total cost of parking for the contract duration.

PART 3 - EXECUTION

3.1 PROJECT TRAFFIC / PARKING MITIGATION PLAN

A. Parking Officer: Designated member of Prime Contractors team that will be responsible for writing and implementing Parking Plan.
    1. Submission of the plan: The plan shall be submitted and approved prior to site mobilization. On campus parking permits will not be provided until plan is approved in its entirety.
    2. Meetings: The Parking Officer shall provide a parking update at the regularly scheduled Project Meeting.
B. Contractor's Parking Plan update: At six-month intervals, Prime Contractor shall update Parking Plan to reflect the actual number of subcontractors using satellite parking, public transportation as well as report occurrences of parking not consistent with the Parking Plan.
C. Distribution: Distribute copies of the Parking Plan to the Contracting Officer Representative.
    1. When revisions are made, distribute updated plans to the same party.

3.2 COORDINATION

A. Coordinate Project Traffic / Parking Mitigation Plan with information provided by Owner.
B. Coordinate Project Traffic / Parking Mitigation Plan with the project Site logistics plan and the project Site Selection Plan.

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ARTICLE H.79.13. DESIGNATED CONSTRUCTION TRAFFIC ROUTE

The designated construction traffic truck route for this contract will be determined on a task order basis.

The requirement for truck inspection stations will be addressed on a task order basis.

The NIH will provide the truck inspection security guards.

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ARTICLE H.79.14. SANITATION AND FOOD SERVICES

1. Contractors shall maintain their working areas free from food debris and wrappers. Contractors shall provide covered trash containers in the number and type approved by the NIH Sanitarian and shall be responsible for the sanitary collection and prompt removal of trash in these containers from the NIH grounds.
2. All temporary toilets used by the Contractor must be approved as to number, location, and construction by the NIH Sanitarian. The Contractor will make arrangements to secure this approval with the Contracting Officer Representative (COR).
3. The NIH Sanitarian will periodically inspect the site for the presence of insects and rodents. If a significant problem related to Contractor activities is found, NIH authorities will institute action to eradicate the infestation, back charging the Contractor for this service.
4. No food or drinks are allowed within the building.
5. Contractor's food service facilities must meet all local food service ordinances and be approved by the NIH Sanitarian before operating. The facilities must be open for inspection by the NIH Sanitarian at all times. The Contractor shall arrange for approval through the COR.
6. The government will provide catered food services under a separate contract. General contractor is to coordinate locations and time schedules.
7. The project construction site will not permit construction Contractor personnel overall access to the campus, but to the assigned work area only. The construction Contractor personnel assigned to this project will not be permitted access to NIH cafeterias.
   The Office of Research Services, Division of Amenities and Transportation Services (DATS), will provide the name and associated contact information regarding the qualified mobile food vendor

that will be permitted access to the construction site that can be used by the CMc or General Contractor to provide mobile food vending to the project site.

The construction Contractor is not permitted to use the mobile food services of any other company other than that provided to DATS by the Maryland Business Enterprise Program for the Blind (MBEPB) as a result of the associated requirements within the Randolph-Sheppard Act as promulgated.

The Contractor shall establish the times that the mobile food vendor is to be on-site and coordinate and provide the locations on site; directly with the vendor from MBEPB.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.79.15. DOCUMENT CONTROL

The Contractor shall assume responsibility for and maintain records of distribution of all drawings, specifications and other project information. Such information shall be distributed only to those specifically with a need for them to accomplish the Work.

Certain documents may be marked as "Sensitive Unclassified - For Official Use Only" or "Law Enforcement Sensitive", hereinafter called "sensitive" information which may include drawings, sketches, digital photographs, exposed negatives, video, written descriptions of work requirements, and similar information. Return such information promptly to Contracting Officer Representative (COR) upon request, including any copies.

Store all Project Information in file cabinets locked during non-business hours. Store "Sensitive" documents in separate containers with access restricted to those with a specific need for use of the information.

Reproduction of documents shall be kept at the minimum needed to accomplish the Work, and all copies shall be numbered and recipients recorded. "Sensitive" documents shall be returned to the NIH COR when no longer needed, and the NIH will arrange for their proper disposal.

Limit dissemination of sensitive information on need-to-know basis.

Any proposed deviations from these requirements must be submitted to the Contracting Officer (CO) and COR for review. Approval may or may not be granted. Do not allow removal/transmission of such information from Project Site without prior written approval by the CO and COR.

"Sensitive" documents shall be transmitted using U.S. Postal Service or any commercial services that permit delivery only after receiving signature.

All paper waste and electronic media such as diskettes and CDS of "Sensitive" documents shall be shredded or otherwise destroyed in a manner acceptable to the NIH.

Notification and Reporting: Notify both the COR and the Construction Security Manager immediately when known or suspected loss/compromise of "sensitive" information or other documents, notes, drawings, sketches, reports, photographs, exposed films, or similar information has occurred which may affect the security interests of the NIH. Extend this requirement to employees and other personnel working on behalf of Contractor and expand the responsibility to include prompt reporting

of security issues, including observed efforts by unauthorized persons to gain access to sensitive information.

The Contractor and each sub-contractor or other entity involved in the Contract shall submit an electronic security memorandum describing the approach to meeting the above goals and maintaining confidentiality of Contract files The memorandum shall describe security within the Project, including any intrusion prevention and detection methodology.

The Contractor shall not proceed without NIH's written approval of the memorandum.

Any requests for exceptions from these requirements shall be submitted in writing to the COR for review. No entity or person shall proceed with such exception without written approval by the NIH.

Electronic Document Security

All Electronic files shall be stored in specified location following NIH standards and procedures using an Engineering Document Management Software (EDMS).

Each Project shall have a registry file, listing the project team with their contact information, drawing list, and Revision index stored in the same location of the other project documents.

Security, access and maintenance of all project engineering drawings and related documents, both scanned and electronic, shall be performed and tracked through the EDMS system.

All documents shall be distributed among team members, including A/E, DM, CM, and their sub-contractors with approval and knowledge of the NIH COR.

Three principles shall always be followed in providing information:

1. Only give the information to those that have a need to know
2. Keep records of who received the information
3. Safeguard the information during use.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.79.16. COMMUNICATIONS

Use of telephone or facsimile for communications will not be restricted except that these means shall not be used for "Sensitive" information.

"Sensitive" information, including drawings and other documents may be attached to electronic mail. However, the commercially available encryption software must be approved in advance for use by the NIH and must be compatible with Microsoft Outlook.

If computer area networks are used for performing administrative or technical work, electronic partitions must be installed to limit access by unauthorized personnel Contract to electronic files. Electronic files shall be organized to allow complete purging of Contract files at the conclusion of the Work.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.80. WORK BY THE GOVERNMENT

The Government reserves the right to undertake performance by Government forces or other Contractors, the same type or similar work as contracted for herein, as the Government deems necessary or desirable, and to do so will not breach or otherwise violate this contract.

1. General. The Government has awarded and will award other contracts for specialized work, which is outside the scope of this contract or outside the scope of awarded options. These contracts will involve additional work at or near the site of the work under this contract. The contractor shall carefully adapt its schedule and performance of work under this contract to accommodate the work of the Other Government Contractors (OGC's) and shall take coordinating direction from the Contracting Officer. The OGCs will be placed under similar contracting conditions regarding coordination. The Contractor shall make every reasonable effort to avoid interference with the performance of work by the OGCs, as scheduled by the OGCs or by the Government.

2. Critical Path Method (CPM) Schedule Inclusion. The Contractor's CPM Schedule shall include all OGC activities as indicated by the Contracting Officer.

3. Notification of Defective Work. If any part of the Contractor's work is dependent upon the completion of work by OGCs, the Contractor shall inspect such work and promptly report to the Contracting Officer in writing any apparent defects or deficiencies in such work that would render it unacceptable or prevent the Contractor from fulfilling his requirements to deliver a quality product in compliance with the Contractor's CPM schedule. Failure to perform such inspection of dependent OGC work, prior to Contractor commencement or continuance of Contractor follow upon work would constitute an acceptance by the Contractor of work by other Contractors, as being fit and proper for integration with work under this contract, except for those defects and deficiencies in the work by other Contractors which are latent or otherwise were not discoverable by reasonable inspection.

4. Notification of Obstructive conditions. If any part of the Contractor's work is impeded by unscheduled occupation or obstruction of Contractor work areas by OGCs, the Contractor shall promptly report such conditions in writing to the Contracting Officer and Contracting Officer Representative.

5. Preparation of and access to OGC Worksites. The Contractor shall be responsible to make ready applicable areas to allow for scheduled activities by each of the OGCs in accordance with the project schedule.

6. Notification of Scheduling Conflicts. If the Contractor becomes aware of potential scheduling conflicts with activities by OGCs, the Contractor shall promptly notify the Contracting Officer in writing.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.80.1. SUPPORT OF NIH REPLACED, RENOVATED, IMPROVED EQUIPMENT OR FACILITIES

Within the term of this contract, NIH may replace, renovate, or improve equipment, systems, facilities, components, and fixtures by means not associated with this contract. The Contractor shall provide maintenance support for replaced, renovated, improved, and repaired systems facilities, components, and fixtures in the same manner as would be performed for existing systems, facilities, components, and fixtures.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.80.2. EQUIPMENT DEVIATIONS

Equipment deviations of greater or larger power, dimensions, capacity, and ratings may be furnished provided such proposed equipment is approved in writing by the Contracting Officer; and, feeders, circuit breakers, conduit, motors, bases, structural support, and equipment spaces are increased by the contractor and other adjustments required to accommodate proper installment and use are made by the Contractor at no additional cost to the Government.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.81. PERFORMANCE REQUIREMENTS

Personnel operating heavy equipment shall have appropriate training and experience with the specific equipment they operate and shall operate the equipment in a proper and safe manner. Personnel shall be certificated and/or licensed for equipment operation where required by applicable State Statutes.

Every Contractor employee entering the NIHAC Poolesville Monkey Field Habitat shall have a TB Certificate indicating a TB test with a negative result was conducted on the individual within the previous twelve (12) months. No Contractor employee shall enter the Monkey Habitat without an active certificate or with an expired certificate.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.81.1. EQUIPMENT AND FIXTURE REPLACEMENT REQUIREMENT

When the Contractor completes work on a facility, system, or piece of equipment, that facility, or equipment shall be free of missing components or defects that would prevent it from functioning as originally intended and/or designed.

Corrective or repair and/or replacement work shall include operational checks and cleanup of the job site. When equipment and/or fixtures are replaced or repaired the contractor shall perform specific

inspections, procedures, and preservation required by the manufacturer and shall verify all systems and components are operating as designed. Except where approved by the Contracting Officer, replacements shall match the existing in dimensions, finish, color, and design.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.81.2. COMPLYING WITH STANDARDS

The Contractor shall meet workmanship standards specified herein and shall perform work in accordance with approved and accepted industry standards; equipment manufacturers' standards; local, state, and federal standards; and applicable building and safety standards. The Contractor shall perform work in a neat and workmanlike manner readily and easily accessible for operation, maintenance, and repair. The Contractor shall perform work and install equipment in accordance with manufacturer's instructions and recommendations. The Contractor shall provide necessary access panels in walls and ceilings for access to equipment.

Applicable standards include, but not limited to:

- American Institutes of Architects (AIA)
- American National Standards Institute (ANSI)
- American Society of Heating, Refrigerating and Air Conditioning Engineers (ASHRAE)
- American Society of Mechanical Engineers (ASME)
- American Society of Safety Engineers (ASSE)
- American Society for Testing and Materials (ASTM)
- American Water Works Association (AWWA)
- Americans with Disabilities Act (ADA)
- Association for Assessment and Accreditation of Laboratory Animal Care (AALAC)
- Illumination Engineering Society (IES)
- Institute of Electrical and Electronic Engineers (IEEE)
- International Electrical Testing Association (NETA)
- Joint Commission for the Accreditation of Healthcare Organizations (JCAHO)
- National Electrical Manufacturers Association

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, AND FACILITIES SERVICES.)****
Note: *This item is a heading only.*

ARTICLE H.82. CONTRACTOR FURNISHED ITEMS

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.82.1. CONTRACTOR MACHINERY AND STORAGE

1. The Contractor shall have sufficient (quantity and type) machinery, and tools to perform the work specified herein. All machinery, equipment, and tools shall be in good, safe, and efficient working order.
2. Any equipment allowed by the Contracting Officer Representative (COR) to be stored or to remain overnight on NIH property shall be kept only in designated areas and shall be the Contractor's total responsibility. The Government will not accept responsibility for loss or damage to any property of the Contractor.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, DESIGN-BUILD, AND FACILITIES SERVICES.
ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.82.2. VEHICLES

All Contractor and Sub-contractor vehicles including but not limited to trucks, tractors, and trailers shall be well maintained, and shall clearly display the company name, address, telephone number.

1. Motor vehicles and trailers shall have and display valid license plates.
2. There are no fueling facilities on either campus. Bulk gasoline storage containers over five (5) gallons are not permitted.
3. Under no circumstances shall Contractor employees work, service, or clean their private or work vehicles on either the NIH or NIHAC campuses.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.82.3. FURNISHED PARTS AND INDUSTRIAL CODES

The Contractor shall provide new or factory reconditioned parts and components when providing maintenance, repair, and alteration services as described herein. Lack of availability of parts, material, or equipment will not relieve the Contractor from the requirement to complete work within the time limits and quality standards stated herein. All replacement units, parts, components, and materials to be used in the maintenance, repair, and alteration of facilities and equipment shall be compatible with the existing equipment on which it is to be used, shall be of equal or better quality than original equipment specifications, shall comply with all applicable Government, commercial, or industrial standards and regulations.

All parts shall be used in accordance with original design and manufacture intent and shall be of acceptable industrial grade and quality. If the original manufacturer has updated the quality of parts for current production, parts supplied under this contract shall equal to or exceed the updated quality.

The Contractor shall provide copies of all applicable manufacturer operation and maintenance (O&M) manuals, pamphlets, and any other documentation related to the products provided.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.82.4. CARE AND PROTECTION OF MATERIALS AND EQUIPMENT

The Contractor shall protect and store material and equipment in such a manner as to effectively prevent damage from climatic and work conditions. The Contractor shall cover the ends of all ducts and pipes during work. The Contractor shall coordinate storage locations with the Contracting Officer Representative (COR).

If the Contractor is unsure as to the disposition of any portion of the materials, with regards to the Task Order, the Contractor must request clarification from the COR prior to removal. In the event the contractor removes material and equipment not intended for removal, the Contractor shall replace those materials and equipment in a similar condition prior to removal at no cost to NIH.

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ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.83. PARTNERING

1. The NIH encourages a partnering relationship with the Contractor and its Subcontractors. This relationship will draw on the strengths of each organization to identify and achieve common goals and objectives of efficient and effective contract performance and to facilitate on-time, within budget completion of projects in accordance with contract plans and specifications.

   The guiding principles of partnering are:

   Identification and Elimination of Barriers
   Continuous Process Improvement
   Mutual Respect
   Open Communications

   An integral part of the partnering concept is resolution of disputes in a timely, professional and non-adversarial manner. Alternative Dispute Resolution (ADR) methodologies are encouraged in place of more formal dispute resolution procedures.

2. In order to effectively accomplish this project, a partnering provision is included for implementation with the selected Contractor. Partnering is a concept of contract execution and management, which strives to draw on the strengths of both the NIH and the Contractor in an effort to achieve:
   i. A quality project done right the first time.
   ii. Budget control and on-time scheduling in accordance with plans and specifications.

The NIH intends that its relationship with the Contractor will be one of mutual cooperation and benefit. To implement this partnership initiative, the Contractor's key project staff and NIH representatives may be required to attend a one to two-day partnership development and team-building workshop within thirty calendar days after the Contractor has mobilized its workforce on site at NIH. The Contractor and the NIH will hold follow-up workshops periodically throughout the duration of the contract as agreed upon.

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ADDITIONAL INFORMATION ABOUT THIS ITEM:

- Replace or Edit this item IF other quality control systems are required other than what is indicated below.

ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.84. CONTRACTOR QUALITY CONTROL (CQC) PROGRAM

1. The Contractor shall establish and maintain a CQC Program that supports the intent of the ISO 9001 standards and the ORF/AECCB Quality System Manual. The Contractor will incorporate these quality system components in its CQC Program to the maximum extent possible to ensure that annual audits of ORF/AECCB Quality Systems by ISO9001 auditors result in re-certification status.
2. A general description of the Contractor's CQC Program shall be available for NIH review during the pre-award survey. Two copies of the complete CQC Program shall be provided to the Contracting Officer for review and approval within thirty days after award of master contract and as changes are made thereafter. The program shall include:
    i. A quality control inspection system covering all contract services. It must specify areas to be inspected on either a scheduled or unscheduled basis and how inspections are to be conducted.
    ii. The name(s) and qualifications of the individual(s) tasked to perform the quality control inspections, and the extent of their authority.
    iii. A method for identifying deficiencies in the quality of services performed and taking corrective action before the level of performance becomes mandatory.
3. A file of all Quality Control Inspections, Inspection results, and corrective actions required, shall be maintained by the Contractor throughout the term of this contract. This file shall be the property of the NIH and shall be made available to the Contracting Officer within one hour of request. The file shall be turned over to the Contracting Officer within five days after completion and prior to final payment.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR DESIGN-BUILD REQUIREMENTS ONLY.

ORF Processes/Procedures Reviewed 11/22)****

ARTICLE H.85. DESIGN BUILD CONTRACT - ORDER OF PRECEDENCE

1. The contract includes the standard contract clauses and schedules current at the time of award. It also entails: (1) the solicitation in its entirety, including all drawings, cuts and illustrations, and any

amendments during proposal evaluation and selection, and (2) the successful Offeror's accepted proposal. The contract constitutes and defines the entire agreement between the Contractor and the Government. No documentation shall be omitted which in any ways bears upon the terms and conditions of that agreement.

2. In the event of conflict or inconsistency between any of the provisions of the various portions of this contract, precedence shall be given in the following order:
    i. Betterments: Any portions of the Offeror's proposal which both meet and exceed the provisions of the solicitation.
    ii. The provisions of the solicitation. (See also FAR Clause 52.236-21, Specifications and Drawings for Construction.)
    iii. All other provisions of the accepted proposal.
    iv. Any design products, including but not limited to plans, specifications, engineering studies and analyses, shop drawings, equipment installation drawings, etc. These are "deliverables" under the contract and are not part of the contract itself. Design products must conform to all provisions of the contract, in the order of precedence herein.

RESPONSIBILITY OF THE CONTRACTOR FOR DESIGN

1. The Contractor shall be responsible for the professional quality, technical accuracy, and the coordination of all designs, drawings, specifications, and other non-construction services furnished by the Contractor under this contract. The Contractor shall, without additional compensation, correct or revise any errors or deficiency in its designs, drawings, specifications, and other non-construction services and perform any necessary rework or modifications, including any damage to real or personal property, resulting from the design error or omission.

2. Neither the Government's review, approval or acceptance of, nor payment for, the services required under this contract shall be construed to operate as a waiver of any rights under this contract or of any cause of action arising out of the performance of this contract. The Contractor shall be and remain liable to the Government in accordance with applicable law for all damages to the Government caused by the Contractor's negligent performance of any of these services furnished under this contract.

3. The rights and remedies of the Government provided for under this contract are in addition to any other rights and remedies provided by law.

4. If the Contractor is comprised of more than one legal entity shall be jointly and severally liable there under.

SEQUENCE OF DESIGN-CONSTRUCTION

1. After receipt of the Contract Award the Contractor shall initiate design, comply with all design submission requirements and obtain Government review of each submission. No construction may be started, until the Government reviews the Final Design submission and determines it satisfactory for purposes of beginning construction. The Contracting Officer will notify the

Contractor when the design is cleared for construction. The Government will not grant any time extension for any design resubmittal required when, in the opinion of the Contracting Officer, the initial submission failed to meet the minimum quality requirements as set forth in the Contract.

2. If the Government allows the Contractor to proceed with limited construction based on pending minor revisions to the reviewed Final Design submission, no payment will be made for any in-place construction related to the pending revisions until they are completed, resubmitted and are satisfactory to the Government.

3. No payment will be made for any in-place construction until all required submittals have been made, reviewed and are satisfactory to the Government.

SEQUENCE OF DESIGN - CONSTRUCTION (FAST TRACK)

1. After receipt of the Contract Award the Contractor shall initiate design, comply with all design submissions requirements and obtain Government review of each submission. The Contractor may begin construction on portions of the work for which the Government has reviewed the final design submission and has determined satisfactory for purposes of beginning construction. The Contracting Officer will notify the Contractor when the design is cleared for construction. The Government will not grant any time extension for any design resubmittal required when, in the opinion of the Contracting Officer, the initial submission failed to meet the minimum quality requirements as set forth in the Contract.

2. If the Government allows the Contractor to proceed with the construction based on pending minor revisions to the reviewed Final Design submission, no payment will be made for any in-place construction related to the pending revisions until they are completed, resubmitted and are satisfactory to the Government.

3. No payment will be made for any in-place construction until all required submittals have been made, reviewed and are satisfactory to the Government.

CONSTRUCTOR'S ROLE DURING DESIGN

The Contractor's construction management key personnel shall be actively involved during the design process to effectively integrate the design and construction requirements of this contract. In addition to the typical required construction activities, the constructor's involvement includes, but is not limited to actions such as: integrating the design schedule into the Master Schedule to maximize the effectiveness of fast-tracking design and construction (within the limits allowed in the contract), ensuring constructability and economy of the design, integrating the shop drawing and installation drawing process into the design, executing the material and equipment acquisition programs to meet critical schedules, effectively interfacing the construction QC program with the design QC program, and maintaining and providing the design team with accurate, up-to-date redline and as-built documentation. The Contractor shall require and manage the active involvement of key trade subcontractors in the above activities.

PAYMENT FOR DESIGN UNDER FIXED-PRICE DESIGN-BUILD CONTRACTS

1. The Contracting Officer may approve progress payments for work performed during the project design phase up to the maximum amount of four (4) percent of the contract price.

2. Contractor invoices for payment must be accompanied by satisfactory documentation supporting the amounts for which payments are requested. Progress payments approved by the Contracting Officer during the project design phase in no way constitute an acceptance of functional and aesthetic design elements nor acceptance of a final settlement amount in the event of a buy-out nor a waiver of any contractual requirements.

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**** (NCI APPROVED PROVISION: USE TO PROTECT INTELLECTUAL PROPERTY FOR ALL SOLICITATIONS AND CONTRACTS INVOLVING THE RAPID ACCESS TO INTERVENTION DEVELOPMENT (RAID) PROGRAM.

Note: *This must be in place prior to filing an IND.*

NCI Processes/Procedures Reviewed 9/22)****

ARTICLE H.86. INTELLECTUAL PROPERTY OPTION TO COLLABORATOR

NCI may collaborate with an outside investigator who has proprietary rights to compounds which may be assigned under this contract. This collaborator will be identified by the Contracting Officer Representative (COR) at the time of assignment and in this case, the following option regarding Intellectual Property Rights will be applicable.

Contractor agrees to promptly notify the NCI and "Collaborator" in writing of any inventions, discoveries or innovations made by the Contractor's principal investigator or any other employees or agents of the Contractor, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of this study using Collaborator's Study Agent (hereinafter "Contractor Inventions").

Contractor agrees to grant to Collaborator: (1) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (2) a time-limited first option to negotiate an exclusive world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all Contractor Inventions on terms to be negotiated in good faith by Collaborator and Contractor. Collaborator shall notify Contractor, in writing, of its interest in obtaining an exclusive license to any Contractor Invention within six (6) months of Collaborator's receipt of notice of such Contractor Invention(s). In the event that Collaborator fails to so notify Contractor or elects not to obtain an exclusive license, then Collaborator's option shall expire with respect to that Contractor Invention, and Contractor will be free to dispose of its interests in such Contractor Invention in accordance with its own policies. If Contractor and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Contractor may agree) on the terms for an exclusive license for a particular Contractor Invention, then for a period of six (6) months thereafter, Contractor shall not offer to license the Contractor Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator shall have a period of thirty (30) days in which to accept or reject the offer.

Contractor agrees that notwithstanding anything herein to the contrary, any inventions, discoveries or innovations, whether patentable or not, which are not Subject Inventions as defined in 35 U.S.C. 201(e),* arising out of any unauthorized use of the Collaborator's Study Agent shall be the property of the Collaborator (hereinafter "Collaborator Inventions"). Contractor will promptly notify the Collaborator in writing of any such Collaborator Inventions and, at Collaborator's request and expense, Contractor will cause to be assigned to Collaborator all right, title and interest in an to any such Collaborator Inventions and provide Collaborator with reasonable assistance to obtain patents (including causing the execution of any invention assignment or other documents). Contractor may also be conducting other more basic research using Study Agent under the authority of a separate Material Transfer Agreement (MTA), or other such agreement with the Collaborator. Inventions arising thereunder shall be subject to the terms of the MTA, and not to this clause.

*35 U.S.C. 201(e): The term "subject invention" means any invention of the Contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, that in the case of a variety of plant, the date of determination (as defined in section 41(d)(FOOTNOTE 1) of the Plant Variety Protection Act (7 U.S.C. 2401(d)) must also occur during the period of contract performance.

Protection of Proprietary Data

Data generated using an investigational agent proprietary to a Collaborator will be kept confidential and shared only with the NCI and the Collaborator. The Contractor retains the right to publish research results subject to the terms of this contract.

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****(USE BELOW IN R&D AND NON-R&D SOLICITATIONS AND CONTRACTS THAT INVOLVE BIOMEDICAL RESOURCES SUCH AS A REPOSITORY, STORAGE FACILITY OF MATERIALS, OR TRANSFER OF HUMAN MATERIALS. Guidance at link below.)****

ARTICLE H.87. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf is intended to help Contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools", "research materials", and "research resources" are used interchangeably and have the same meaning.

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****(ADD THE FOLLOWING PARAGRAPH BELOW FOR CONTRACTS THAT INVOLVE BIOMEDICAL RESEARCH OF MODEL ORGANISMS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- Select the sentence to be used in the contract within the brackets below. Make sure to delete the sentence you will not be using.

a. Sharing of Model Organisms for Biomedical Research

[The plan for sharing model organisms submitted by the Contractor is acceptable/The Contractor's plan for sharing model organisms, dated _____, is hereby incorporated by reference.] The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan

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****(FOR NCI USE: ADD THE FOLLOWING PARAGRAPH BELOW FOR CONTRACTS THAT INVOLVE THE TRANSFER OF HUMAN MATERIALS FROM INTRAMURAL LABORATORIES FOR RESEARCH. NCI Processes/Procedures - Guidance at link below - Reviewed 9/22)****

b. Transfer of Human Materials

All human materials transferred to the Contractor under this contract for the purposes of research shall be accomplished in accordance with the Policy entitled, "Policy for the Transfer of Materials from NIH Intramural Laboratories,"
located at: https://www.ott.nih.gov/sites/default/files/documents/policy/pdfs/500-A-Policy_12042014.pdf.

The Contractor shall coordinate with the **NCI Technology Transfer Center** (see https://techtransfer.cancer.gov/) [or the Contracting Officer will insert name and contact information of the appropriate TDC] to determine the specific terms and conditions for the human materials to be transferred. Generally, the Government and Contractor will enter into Material Transfer Agreement which stipulates the specific terms and conditions relating to the materials being transferred.

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****(USE BELOW FOR ALL CONTRACTS THAT REQUIRE A "DATA MANAGEMENT AND SHARING PLAN" FOR THE MANAGEMENT AND SHARING OF FINAL RESEARCH DATA. IN ACCORDANCE WITH "FINAL NIH POLICY FOR DATA MANAGEMENT AND SHARING," NOTICE NOT-OD-21-013 WITH A RELEASE DATE OF 29 OCTOBER 2020 AND AN EFFECTIVE DATE OF 25 JANUARY 2023, INCLUDE THE FOLLOWING IN ALL SOLICITATIONS RELEASED AFTER 01 JULY 2022 WITH AN ORIGINAL PROPOSAL RECEIPT DATE OF 25 JANUARY 2023 OR LATER, AND ANY CONTRACTS RESULTING FROM THESE SOLICITATIONS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **First Paragraph:** Select the appropriate sentence within (" **[…]** ") the brackets below. Make sure to delete the sentence you will not be using.

ARTICLE H.88. SHARING RESEARCH DATA

[The Data Management and Sharing Plan submitted by the Contractor is acceptable/The Contractor's Data Management and Sharing Plan, dated _____ , is hereby incorporated by reference herein.] The Contractor agrees to adhere to its Data Management and Sharing Plan and shall request the prior written approval of the Contracting Officer for any changes in its Data Management and Sharing Plan.

NIH encourages, to the maximum extent practicable, the sharing of final research data to serve public health for the common good and this contract is expected to generate research data that must be shared with the public and other researchers. NIH's Data Management and Sharing policies may be found at the following websites:

- NOT-OD-14-124 - NIH Genomic Data Sharing Policy;
- NOT-OD-21-013 - Final NIH Policy for Data Management and Sharing;
- NOT-OD-21-014 - Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan;
- NOT-OD-21-015 - Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing; and
- NOT-OD-21-016 - Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research.

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including but not limited to the Privacy Act of 1974 (2020 Edition), the Privacy Rule (see HHS-published documentation on the Privacy Rule at https://www.hhs.gov/ocr/index.html), the Health Insurance Portability & Accountability Act of 1996 (HIPAA), and the Health IT for Economic & Clinical Health (HITECH) Act, which was enacted as part of the American Recovery & Reinvestment Act of 2009 (ARRA).

As per NIH Notice NOD-OD-21-013, "Final NIH Policy for Data Management and Sharing," respect for participant autonomy and maintenance of participant privacy and confidentiality can be consiste nt with data sharing. The rights and privacy of people who participate in NIH-funded research shall be protected at all times and Contractors shall anonymize and aggregate (or otherwise fully protect from release) any personally identifiable information (PII), HIPAA-protected personal health information (PHI), and/or HITECH-protected electronic health information which they receive, use, and/or reference; thus, data intended for broader use should be free of any and all personal identifiers that would permit linkages to individual research participants and/or variables that could lead to any disclosure of the identity of individual subjects, direct or deductive, for which the Government shall have no liability whatsoever.

295

****(USE BELOW WHEN CONTRACT PERFORMANCE WILL INVOLVE POSSESSION, USE OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS.

Note: *At this time, may only be applicable to NIAID projects* .

NIAID Processes/Procedures Reviewed 9/22)****

ARTICLE H.89. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

The work being conducted under this contract may involve the possession, use, or transfer of a select agent or toxin. The Contractor shall not conduct work involving a Select Agent or Toxin under this contract until it and any associated subcontractor(s) comply with the following:

For prime or subcontract awards to ***domestic institutions*** that possess, use, and/or transfer a Select Agent or Toxin under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (https://ors.od.nih.gov/sr/dohs/safety/laboratory/BioSafety/Pages/select_agents.aspx) as required, before using NIH funds for work involving a *Select Agent or Toxin* . **No NIH funds can be used for research involving a *Select Agent or Toxin* at a domestic institution without a valid registration certificate.**

For prime or subcontract awards to ***foreign institutions*** that possess, use, and/or transfer a *Select Agent or Toxin* , before using NIH funds for any work directly involving a *Select Agent or Toxin* , the foreign institution must provide information satisfactory to the NIAID that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 are in place and will be administered on behalf of all *Select Agent or Toxin* work supported by these funds. The process for making this determination includes a site visit to the foreign laboratory facility by an NIAID representative. During this visit, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agent or Toxin and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents or Toxins under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. Site visits to foreign laboratories are conducted every three years after the initial review. **No NIH funds can be used for work involving a *Select Agent or Toxin* at a foreign institution without written approval from the Contracting Officer.**

Prior to conducting a restricted experiment with a Select Agent or Toxin under this contract or any associated subcontract, the contractor must discuss the experiment with the Contracting Officer's Representative (COR) and request and obtain written approval from the Contracting Officer. **Domestic institutions** must submit to the Contracting Officer written approval from the CDC to perform the proposed restricted experiment. **Foreign institutions** require review by a NIAID representative. The prime contractor must contact the COR and the NIAID Office of International Extramural Activities (OIEA) at niaidforeignawards@niaid.nih.gov for guidance on the process used by NIAID to review proposed restricted experiments. The NIAID website provides an overview of the review process at https://www.niaid.nih.gov/grants-contracts/foreign-manual-of-operations . The Contracting Officer

will notify the prime Contractor when the process is complete. **No NIH funds can be used for a restricted experiment with a Select Agent or Toxin at either a domestic or foreign institution without written approval from the Contracting Officer.**

Listings of HHS and USDA select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at https://www.selectagents.gov/

For foreign institutions, see the NIAID Select Agent Award information: (https://www.niaid.nih.gov/grants-contracts/sa-grants-include-foreign-institutions).

296

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN CONTRACT PERFORMANCE WILL INVOLVE POSSESSION, USE OR TRANSFER OF A HIGHLY PATHOGENIC AGENT.

Note: *At this time, may only be applicable to NIAID projects .*

NIAID Processes/Procedures Reviewed 9/22)****

ARTICLE H.90. HIGHLY PATHOGENIC AGENTS

The work being conducted under this contract may involve a Highly Pathogenic Agent (HPA). The NIAID defines an HPA as a pathogen that, under any circumstances, warrants a biocontainment safety level of BSL3 or higher according to either:

a. The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)(https://ors.od.nih.gov/sr/dohs/Documents/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2020-P.PDF);
b. The Contractor's Institutional Biosafety Committee (IBC) or equivalent body; or
c. The Contractor's appropriate designated institutional biosafety official.

If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an IBC or equivalent body, or institutional biosafety official, the highest recommended containment level must be used.

297

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS IN WHICH THE POSSIBILITY OF A FEDERALLY FUNDED, IN WHOLE OR IN PART, MEETING, CONVENTION, CONFERENCE OR TRAINING SEMINAR EXISTS.)****

ARTICLE H.91. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: https://apps.usfa.fema.gov/hotel/.

298

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FUNDED WITH APPROPRIATED BIO-DEFENSE FUNDS.

Note: *At this time, may only be applicable to NIAID projects .*

NIAID Processes/Procedures Reviewed 9/22)****

ARTICLE H.92. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

299

****(THE FOLLOWING ITEM IS FOR NIEHS USE ONLY. TO BE USED AT THE CONTRACTING OFFICER'S DISCRETION.

Note : *The purpose of this clause is to adequately define the Government's level of control over records and data that are produced by the Contractor under the contract, but are defined as a deliverable under the terms of the contract, or are not yet in the Government's physical possession as defined as a deliverable under the terms of the contract.*

NIEHS Processes/Procedures Reviewed 9/22)****

ARTICLE H.93. GOVERNMENT CONTROL OVER UNDELIVERED AND/OR UNPUBLISHED RECORDS AND DATA

1. As used in this clause, "records and data" means: (1) any handwritten, typed, or printed documents (including, but not limited to, memoranda, letters, writings, books, brochures, transcripts, minutes, electronic transmissions, study findings, laboratory note books, chromatograms, spectra, and maps); (2) documentary material in other forms (such as punch cards, magnetic or paper tapes, instrumentation cards, computer discs, electronically stored information, audio or video recordings, motion pictures, photographs, slides, microfilm, and microfiche); and, (3) biological samples and pathology materials (pathology slides, paraffin blocks, and wet tissues). Records and data may or may not constitute a specific deliverable defined under the terms of the contract.
2. The purpose of this clause is to define the Government's control over records and data that are produced by the Contractor under this contract, but are not defined as a deliverable under the terms of the contract, or are not yet in the Government's physical possession if a deliverable under the terms of the contract. This clause is designed to serve public policy by limiting the disclosure of certain records and data if disclosure is made at a time when such records and data remain unvalidated and unreliable (i.e. may not have undergone a quality control nor subsequent audit and inspection as part of a quality assurance process) and could thereby lead to erroneous conclusions which might threaten public health or safety.
3. The Government shall be deemed as having no control over, or direct ownership of records and data created or produced by the Contractor in the performance of this contract until such time as the records and data have been: (1) subjected to an acceptable method of quality control and quality assurance; (2) delivered to the Government or obtained by the Government under the

terms of this contract; (3) published in accordance with the terms of this contract; or (4) used by the Federal Government in developing an agency action that has the force and effect of law.

4. In the event of a contract termination, this clause does not relieve the Contractor of its obligations set forth elsewhere in this contract to transfer title and deliver to the Government work in process, completed work, supplies, and other material produced or acquired for the work terminated, or, the completed or partially completed plans, drawings, information, and other property that, if the contract had been completed, would be required to be furnished to the Government.
5. This clause shall have no effect on the Government's rights during the performance of the contract as specified elsewhere herein, including the Governments rights and abilities to request access to or be provided with such records and data for the purpose of conducting any inspections, examinations or audits as set forth in the contract.

300

****(USE BELOW IN ALL RFPs AND CONTRACTS WITH EDUCATIONAL INSTITUTIONS.) ****

ARTICLE H.94. CONSTITUTION DAY

Each educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.

301

****(INCLUDE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT INVOLVE LOGISTICAL SUPPORT SERVICES; OR ANY CONTRACT THAT INCLUDES THE CONDUCT OF A CONFERENCE OR MEETING, EVEN IF INCIDENTAL TO THE PERFORMANCE OF THE CONTRACT.)****

IMPORTANT INFORMATION ABOUT THIS ARTICLE:

1. The Contracting Officer shall not authorize the Contractor to conduct any conferences or meetings until the appropriate conference approval/waiver has been approved by the ICEO, NIH Director or HHS Deputy Secretary as applicable in accordance with the NIH Policy on Use of Appropriated Funds for Conferences and Associated Expenses found at: https://oamp.od.nih.gov/sites/default/files/ContractToolbox/confpolrewrite20151101_508rev.pdf and HHS Policy on Promoting Efficiency Spending dated January 23, 2015 found at: https://www.hhs.gov/grants/contracts/contract-policies-regulations/efficient-spending/index.html

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **3rd Paragraph:**
  1. Complete the information in the Table for any conferences or meetings that have been approved at the time of award.
  2. Remove this paragraph, including the Table, if conferences and/ or meetings have not been approved at the time of award.

ARTICLE H.95. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD

The Contractor shall not use contract funds (direct or indirect) to conduct meetings or conferences in performance of this contract without prior written Contracting Officer approval.

In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.

The following conferences and/or meetings have been approved by the Contracting Officer and are hereby authorized under this contract:

Conference or Meeting Title	Conference or Meeting Location	Federal/NonFederal Space	Date of Conference	Not to Exceed Estimate Cost
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		

302

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS IN WHICH A NON-FEDERAL ENTITY IS COSPONSORING WITH AN INSTITUTE/CENTER (IC) A SCIENTIFIC MEETING, CONFERENCE OR WORKSHOP AND REGISTRATION FEES ARE CHARGED AND COLLECTED.)****

See Manual Chapter 6031, "Conference Support/Collection and Retention of Registration Fees," for additional information.

ARTICLE H.96. REGISTRATION FEES FOR CONFERENCES, WORKSHOPS AND MEETINGS

A Non-Federal entity co-sponsoring a conference with an Institute/Center (IC) under a contract may charge and collect a registration fee from all participants for the purpose of defraying its portion of the expenses of the conference. Under these circumstances, the Contractor shall document that the registration fees associated with the event are being charged, collected and used solely by the co-sponsor.

Whenever possible, the Contracting Officer, prior to each conference, shall provide the Contractor with uniform assumptions of the government's estimate of the registration fee offset to include in the costs estimate for the conference. This offset should be deducted by the Contractor from the total cost of the conference.

In addition, prior to each conference, the Contractor shall provide the following information and documentation to the Contracting Officer Representative (COR) and Contracting Officer:

1. Co-sponsor's name
2. Conference name, location, dates, times
3. Copy of the agenda
4. A completed "Contractor Pre-Conference Expense Offset Worksheet" (Attachment provided in SECTION J).
5. After the conference is held, the Contractor shall submit a completed "Post-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the COR and Contracting Officer.

The Contractor shall collect and maintain current and accurate accounting of collected conference fees and conference expenses. The Contractor shall immediately notify the COR and Contracting Officer, in writing, if it appears the total registration fees collected will exceed the estimated total cost of the conference. If the registration fees collected are in excess of the total actual conference expenditures, the Contractor shall return the excess funds to the Contracting Officer to be deposited as miscellaneous receipts into the U.S. Treasury. If the registration fees collected are in excess of the uniform assumptions provided by the Contracting Officer, the Contracting Officer, shall, as necessary, modify the contract price to reflect the decrease in conference costs. If the registration fees collected are less than the uniform assumptions provided by the Contracting Officer, the Contracting Officer shall, as necessary, modify the contract price to reflect the increase in conference costs.
Although Contractors may bill for allowable conference costs as they are incurred, they may not submit a final invoice for the total costs of the conference until the "Post-Conference Expense Offset Worksheet" has been approved by the COR.

303

****(USE THE FOLLOWING IN ALL SOLICITATIONS AND CONTRACTS FOR NIH SPONSORED SCIENTIFIC, EDUCATIONAL AND RESEARCH-RELATED CONFERENCES IN WHICH REGISTRATION FEES ARE CHARGED AND COLLECTED FOR THE PURPOSE OF DEFRAYING THE COSTS OF THE CONFERENCE.)****

See Manual Chapter 6031, "Conference Support/Collection and Retention of Registration Fees" for additional information.

ARTICLE H.97. REGISTRATION FEES FOR NIH SPONSORED SCIENTIFIC, EDUCATIONAL, AND RESEARCH-RELATED CONFERENCES

In accordance with the NIH Reform Act of 2006, P.L. 109-482, the NIH may authorize a Contractor procured to assist in the development and implementation of a scientific, educational or research-related conference to collect and retain registration fees from Non-HHS Federal and Non-Federal participants to defray the costs of the contract.

Whenever possible, the Contracting Officer, prior to each conference, shall provide the Contractor with uniform assumptions of the government's estimate of the registration fee offset to include in the costs estimate for the conference. This offset should be deducted from the total cost of the conference.

Prior to each conference, the Contractor shall submit a completed "Contractor Pre-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the Contracting Officer's Representative (COR) and Contracting Officer. After the conference is held, the Contractor shall submit a completed "Post-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the COR and Contracting Officer.

The Contractor shall collect and maintain current and accurate accounting of collected conference fees and conference expenses. The Contractor shall immediately notify the COR and Contracting Officer, in writing, if it appears the total registration fees collected will exceed the estimated total cost of the conference. If the registration fees collected are in excess of the total actual conference expenditures, the contractor shall return the excess funds to the Contracting Officer to be deposited as miscellaneous receipts into the U.S. Treasury.

If the registration fees collected are in excess of the uniform assumptions provided by the Contracting Officer, the Contracting Officer, shall, as necessary, modify the contract price to reflect the decrease in conference costs. If the registration fees collected are less than the uniform assumptions provided by the Contracting Officer, the Contracting Officer shall, as necessary, modify the contract price to reflect the increase in conference costs.

Although Contractors may bill for allowable conference costs as they are incurred, they may not submit a final invoice for the total costs of the conference until the "Post-Conference Expense Offset Worksheet" has been approved by the COR.

304

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT MAY CONDUCT DOMESTIC AND/OR INTERNATIONAL SCIENTIFIC MEETINGS SPONSORED BY AND/OR RECEIVING SUPPORT FROM THE NIH.)****

ARTICLE H.98. GUIDELINES FOR INCLUSION OF WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES IN NIH-SUPPORTED CONFERENCES

Pursuant to the NIH Revitalization Act (P.L. 103-43, Section 206), which adds Section 402(b) to the Public Health Service Act, it is required that NIH, "in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research." In addition, Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990 require reasonable accommodations to be provided to individuals with disabilities.

It is NIH policy that organizers of scientific meetings should make a concerted effort to achieve appropriate representation of women, racial/ethnic minorities, and persons with disabilities, and other individuals who have been traditionally underrepresented in science, in all NIH sponsored and/or supported scientific meetings.

Therefore, it is the contractor's responsibility to ensure the inclusion of women, minorities, and persons with disabilities in all events when recruiting speakers and/or participants for meetings or conferences funded by this contract.

See the policy announcement for additional details and definitions at:
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-053.html

305

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHERE THE POSSIBILITY EXISTS THAT THE CONTRACTOR WILL PROVIDE OR PURCHASE PROMOTIONAL ITEMS.)****

ARTICLE H.99. USE OF FUNDS FOR PROMOTIONAL ITEMS

The Contractor shall not use contract funds to purchase promotional items. Promotional items include, but are not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees,

grantees, or conference attendees. This includes items or tokens given to individuals as these are considered personal gifts for which contract funds may not be expended.

306

****(USE BELOW IF NONE OF THE ABOVE CLAUSES ARE APPLICABLE.)****

THERE ARE NO ARTICLES CONTAINED IN THIS SECTION.

307

**** (USE THE FOLLOWING IN ALL RFP's AND CONTRACTS.) ****

PART II - CONTRACT CLAUSES

308

**** (USE THE FOLLOWING IN ALL RFP's AND CONTRACTS.) ****

SECTION I - CONTRACT CLAUSES

309

****(USE THE FOLLOWING IN ALL SOLICITATIONS.

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- Select only those General Clause Listing(s) that are applicable to your RFP from the Drop Down List..)****

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at:
https://oamp.od.nih.gov/DGS/reference-material-prospective-offerors-and-contractors

310

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE ARCHITECT-ENGINEER CONTRACT

311

ARTICLE I.1. GENERAL CLAUSES FOR A FIXED-PRICE CONSTRUCTION CONTRACT

312

ARTICLE I.1. GENERAL CLAUSES FOR A FIXED-PRICE RESEARCH AND DEVELOPMENT SBIR PHASE I CONTRACT

313

ARTICLE I.1. GENERAL CLAUSES FOR A FIXED-PRICE RESEARCH AND DEVELOPMENT SBIR PHASE II CONTRACT

314

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SBIR PHASE II CONTRACT

315

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS

316

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT CONTRACT WITH NON-PROFIT ORGANIZATIONS OTHER THAN EDUCATIONAL INSTITUTIONS

317

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT

318

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT

319

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SUPPLY CONTRACT

320

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE RESEARCH AND DEVELOPMENT CONTRACT

321

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE SERVICE CONTRACT

322

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE SUPPLY CONTRACT

323

ARTICLE I.1. GENERAL CLAUSES FOR A SEALED BID CONSTRUCTION CONTRACT

324

ARTICLE I.1. GENERAL CLAUSES FOR A SEALED BID SERVICE CONTRACT

325

ARTICLE I.1. GENERAL CLAUSES FOR A SEALED BID SUPPLY CONTRACT

326

ARTICLE I.1. GENERAL CLAUSES FOR A TIME AND MATERIAL OR A LABOR HOUR CONTRACT

327

****(USE BELOW IN ALL SOLICITATIONS.)****

328

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

329

****(USE BELOW WHEN THE CONTRACTOR IS NOT REQUIRED TO REGISTER IN THE SAM BASED ON ONE OF THE EXCEPTIONS LISTED AT FAR 4.1102(a).)****

Note: *This item consists of two substitutions.*

a. FAR Clause **52.204-13, System for Award Management Maintenance** (Oct 2018) is deleted in its entirety and FAR Clause **52.204-12, Unique Entity Identifier Maintenance** (Oct 2018) is substituted therefor.

FAR Clause **52.232-33, Payment By Electronic Funds Transfer--System for Award Management** (Jul 2013) is deleted in its entirety and FAR Clause **52.232-34, Payment by Electronic Funds Transfer--Other Than System for Award Management** (Jul 2013) is substituted therefor.

330

****(USE BELOW WHEN CONTRACTING BY SEALED BIDDING, IN ALL SOLICITATIONS AND CONTRACTS, IF THE ACQUISITION WILL USE RECOVERY ACT FUNDS.)****

b. **Alternate I** (Mar 2009) of FAR **Clause 52.214-26, Audit and Records--Sealed Bidding** (Oct 2010) is added.

331

****(USE BELOW WHEN CONTRACTING BY NEGOTIATION, IN ALL SOLICITATIONS AND CONTRACTS, IF THE ACQUISITION WILL USE RECOVERY ACT FUNDS.)****

c. **Alternate I** (Mar 2009) of FAR Clause **52.215-2, Audit and Records--Negotiation** (Jun 2020) is added.

332

****(USE BELOW FOR COST REIMBURSEMENT CONTRACTS OVER THE SIMPLIFIED ACQUISITION THRESHOLD WHEN THE CONTRACT IS WITH A STATE AND LOCAL GOVERNMENT, EDUCATIONAL INSTITUTIONS AND OTHER NONPROFIT ORGANIZATIONS.)****

d. **Alternate II** (Aug 2016) of FAR Clause **52.215-2, Audit and Records--Negotiation** (Jun 2020) is added.

333

****(USE BELOW WHEN THE CONTRACT IS OVER THE SIMPLIFIED ACQUISITION THRESHOLD **AND** IS BEING AWARDED WITHOUT ADEQUATE PRICE COMPETITION **UNLESS** 52.215-14 IS NOT APPLICABLE IN ACCORDANCE WITH FAR 15.408(f).)****

e. **Alternate I** (Oct 1997) of FAR Clause **52.215-14, Integrity of Unit Prices** (Nov 2021) is added.

334

****(USE BELOW IN NEGOTIATED SOLICITATIONS AND CONTRACTS WHERE CERTIFIED COST OR PRICING DATA WILL **NOT** BE REQUIRED, **AND** FOR WHICH ANY PREAWARD OR POSTAWARD COST DETERMINATION WILL **NOT** BE SUBJECT TO FAR SUBPART 31.)****

f. FAR Clauses **52.215-15, Pension Adjustments and Asset Reversions** (Oct 2010); **52.215-18, Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions** (Jul 2005); and, **52.215-19** , **Notification of Ownership Changes** (Oct 1997), are deleted in their entirety.

335

****(USE BELOW IN COST-REIMBURSEMENT CONTRACTS VALUED OVER THE SIMPLIFIED ACQUISITION THRESHOLD.)****
Note: *May be used when the contracting officer determines that inclusion of the clause is appropriate. For further information, see FAR 15.408(n).*

g. FAR Clause **52.215-23, Limitations on Pass-Through Charges** (Jun 2020), is added.

336

****(USE BELOW WHEN CERTIFIED COST OR PRICING DATA ARE NOT EXPECTED TO BE REQUIRED BECAUSE AN EXCEPTION MAY APPLY, BUT THE CONTRACTING OFFICER DETERMINES THAT DATA OTHER THAN CERTIFIED COST OR PRICING DATA WILL BE REQUIRED AS DESCRIBED IN FAR 15.403-3.)****

h. **Alternate IV** (Oct 2010) of FAR Clause **52.215-21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data--Modifications** (Nov 2021) is added.

337

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN A COST-PLUS-INCENTIVE-FEE IS CONTEMPLATED.)****

i. FAR Clause **52.216-8, Fixed Fee** (Jun 2011) is deleted in its entirety and FAR Clause **52.216-10, Incentive Fee** (Jun 2011) is substituted therefor.

338

****(USE BELOW WHEN THE ACQUISITION:
1. Has been Set-Aside for Small Business (except for contracts awarded under the SBIR Program); OR,
2. Is an 8(a) Acquisition; OR,
3. Is LESS THAN $700,000 [$1.5 million FOR CONSTRUCTION OF PUBLIC FACILITY]; OR,
4. When FAR 19.705-2 Applies.)****

j. FAR Clauses **52.219-9, Small Business Subcontracting Plan** (Oct 2022), and **52.219-16, Liquidated Damages--Subcontracting Plan** (Jan 1999) are deleted in their entirety.

339

****(USE BELOW IN SOLICITATIONS THAT REQUIRE SUBMISSION OF THE SUBCONTRACTING PLAN WITH THE INITIAL PROPOSAL IN ACCORDANCE WITH FAR 19.705-2(d).)****
Note: *Include this item if using the basic FAR Clause 52.215-1, i.e. award without discussions.*

k. **Alternate II** (Nov 2016) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (Oct 2022) is added.

340

****(USE BELOW WHEN THE CONTRACT ACTION WILL NOT BE REPORTED IN THE FEDERAL PROCUREMENT DATA SYSTEM (FPDS) PURSUANT TO FAR SUBPART 4.606(c)(5), e.g., reporting of the information would compromise national security.)****

l. **Alternate III** (Jun 2020) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (Oct 2022) is added.

341

****(USE BELOW IN SOLICITATIONS AND CONTRACTS UNDER THE SIMPLIFIED ACQUISITION THRESHOLD; WHEN CONTRACT WORK WILL BE PERFORMED EXCLUSIVELY OUTSIDE OF THE UNITED STATES; OR WHEN THE ACQUISITION WILL BE COVERED (IN ITS ENTIRETY) BY AN EXEMPTION GRANTED BY THE SECRETARY.)****
See FAR 22.1603(b) for more information.

m. FAR Clause **52.222-40, Notification of Employee Rights Under the National Labor Relations Act** (Dec 2010) is deleted in its entirety.

342

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR:

- Awards NOT expected to exceed $150,000; **or**
- Work performed outside the United States; **or**
- A Period of Performance of less than 120 days; **or**
- Commercially available off-the-shelf (COTS) items; items that would be COTS items, but for minor modifications; or items that would be COTS items if they were not bulk cargo; **or**
- Commercial Services that are: Part of the purchase of a COTS item; performed by the COTS provider; and are normally provided for that COTS item.)****

For additional information about this item see FAR 22.1803.

n. FAR Clause **52.222-54, Employment Eligibility Verification** (May 2022) is deleted in its entirety.

343

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR SUPPLIES OR SERVICES INVOLVING THE FURNISHING OF SUPPLIES WITH A COST EXCEEDING $25,000 BUT LESS THAN $202,000, **EXCEPT,** FOR SMALL BUSINESSES.)****

Note: *See FAR 25.401 for a complete list of exemptions.*

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. If the contract value is $25,000 or more but less than $50,000 you MUST include this clause WITH its Alternate I.
2. If the contract is $50,000 or more but less than $77,494 you MUST include this clause WITH its Alternate II.
3. If the contract value is $77,494 or more but is less than $100,000 use this clause WITH its Alternate III.

o. FAR Clause **52.225-1, Buy American--Supplies** (Nov 2021) is deleted in its entirety and FAR Clause **52.225-3, Buy American--Free Trade Agreements--Israeli Trade Act** (Nov 2021) is substituted therefor.

Alternate I (Jan 2021) [is/is not] applicable to this contract.

Alternate II (Jan 2021) [is/is not] applicable to this contract.

Alternate III (Jan 2021) [is/is not] applicable to this contract.

344

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR SUPPLIES OR SERVICES INVOLVING THE FURNISHING OF SUPPLIES WITH A COST VALUED AT $202,000 OR MORE, **IF** , THE TRADE AGREEMENTS ACT APPLIES. **Note:** *See FAR 25.401 and 25.403 for exception and applicability criteria* .)****

p. FAR Clause **52.225-1, Buy American--Supplies** (Nov 2021) is deleted in its entirety and FAR Clause **52.225-5, Trade Agreements** (Oct 2019) is substituted therefor.

345

****(USE BELOW IN **NON-R&D** CONTRACTS WITH EDUCATIONAL INSTITUTIONS AND/OR NONPROFIT ORGANIZATIONS. **Note:** *Selection of this item deletes three Alternates and one clause since FAR prescribes their use for R&D requirements* .)****

q. **Alternate I** (Apr 1984), of FAR Clause **52.227-1, Authorization and Consent** (Jun 2020) is deleted in its entirety.

FAR Clause **52.227-11, Patent Rights--Ownership by the Contractor** (May 2014) is deleted in its entirety.

Alternate IV (Dec 2007), of FAR Clause **52.227-14, Rights in Data--General** (May 2014) is deleted in its entirety.

Alternate II (Apr 2012), of FAR Clause **52.245-1, Government Property** (Jan 2017) is deleted in its entirety.

346

****(USE BELOW WHEN BOTH COMPLETE CONTRACT PERFORMANCE AND DELIVERY ARE OUTSIDE OF THE UNITED STATES.)****

r. FAR Clause **52.227-1, Authorization and Consent** (Jun 2020), and

FAR Clause **52.227-2, Notice and Assistance Regarding Patent and Copyright Infringement** (Jun 2020) are deleted in their entirety.

347

****(USE BELOW WHEN THE CLAUSE AT 52.227-14 Rights in Data - General is included in the applicable General Clause Listing AND the contract is:

- For the acquisition of existing data, commercial, computer software, or other existing data as described in 27.405-2 through 27.405-4, (also see 27.409(f) & (g)); or
- To be performed outside the United States; or
- For the management, operation, design, or construction of a Government-owned facility to perform research, development, or production work (also see 27.409 (i)(3));
- Involving cosponsored research and development in which a clause providing for less than unlimited rights has been authorized (See 27.408); or
- For A & E services or Construction work.)****

s. FAR Clause **52.227-14, Rights in Data-General** (May 2014) is deleted in its entirety.

348

****(USE BELOW IN ALL SBIR PHASE I CONTRACTS OVER THE SIMPLIFIED ACQUISTION THRESHOLD.)****

t. The following clause(s) are added to this contract:

- FAR Clause **52.203-3, Gratuities** (Apr 1984)

- FAR Clause **52.203-5, Covenant Against Contingent Fees** (May 2014)
- FAR Clause **52.203-6, Restrictions on Subcontractor Sales to the Government** (Jun 2020)
- FAR Clause **52.203-7, Anti-Kickback Procedures** (Jun 2020)
- FAR Clause **52.203-8, Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity** (May 2014)
- FAR Clause **52.203-10, Price or Fee Adjustment for Illegal or Improper Activity** (May 2014)
- FAR Clause **52.204-4, Printed or copied Double-Sided on Postconsumer Fiber Content Paper** (May 2011)
- FAR Clause **52.215-2, Audit and Records Negotiation** (Jun 2020)
- FAR Clause **52.215-14, Integrity of Unit Prices** (Nov 2021)
- FAR Clause **52.219-8, Utilization of Small Business Concerns** (Oct 2022)
- FAR Clause **52.219-14, Limitations on Subcontracting** (Oct 2022)
- FAR Clause **52.222-40, Notification of Employee Rights Under the National Labor Relations Act** (Dec 2010)
- FAR Clause **52.229-3, Federal, State and Local Taxes** (Feb 2013)
- FAR Clause **52.232-2, Payments under Fixed-Price Research and Development Contracts** (Apr 1984)
- FAR Clause **52.232-17, Interest** (May 2014)
- FAR Clause **52.242-13, Bankruptcy** (Jul 1995)
- FAR Clause **52.244-5, Competition in Subcontracting** (Dec 1996)

The following clause(s) is substituted as follows:

- FAR Clause **52.249-1, Termination for the Convenience of the Government (Fixed-Price)(Short Form)** (Apr 1984) is deleted in its entirety and **FAR Clause 52.249-2, Termination for the Convenience of the Government (Fixed Price)** (Apr 2012) is substituted therefor.

349

****(USE BELOW FOR NONCOMPETITIVE FIXED-PRICE SBIR PHASE II SOLICITATIONS AND CONTRACTS, OVER THE SIMPLIFIED ACQUISITION THRESHOLD, TO BE PERFORMED WHOLLY OR PARTLY WITHIN THE UNITED STATES, ITS POSSESSIONS OR PUERTO RICO, IF THE PRICE WOULD OTHERWISE INCLUDE AN INAPPROPRIATE CONTINGENCY FOR POTENTIAL POST-AWARD CHANGES IN STATE OR LOCAL TAXES.)****

u. FAR Clause **52.229-4, Federal, State and Local Taxes (State and Local Adjustments)** (Feb 2013) is added in its entirety.

350

****(USE BELOW FOR NONCOMPETITIVE FIXED-PRICE SOLICITATIONS AND CONTRACTS, OVER THE SIMPLIFIED ACQUISITION THRESHOLD, TO BE PERFORMED WHOLLY OR PARTLY WITHIN THE UNITED STATES, ITS POSSESSIONS OR PUERTO RICO, IF THE PRICE WOULD OTHERWISE INCLUDE AN INAPPROPRIATE CONTINGENCY FOR POTENTIAL POST-AWARD CHANGES IN STATE OR LOCAL TAXES.)****

v. FAR Clause **52.229-3, Federal, State and Local Taxes** (Feb 2013) is deleted in its entirety, and FAR Clause **52.229-4, Federal, State and Local Taxes (State and Local Adjustments)** (Feb 2013) is substituted therefor.

351

****(USE BELOW IN FIXED PRICE SOLICITATIONS AND CONTRACTS WHEN THE CONTRACT IS TO BE PERFORMED WHOLLY OR PARTLY IN A FOREIGN COUNTRY, UNLESS THE CONTRACT WILL BE WITH A FOREIGN GOVERNMENT.)****

w. FAR Clause **52.229-3, Federal, State and Local Taxes** (Feb 2013), is deleted in its entirety, and FAR Clause **52.229-6, Taxes--Foreign Fixed-Price Contracts** (Feb 2013) is substituted therefor.

352

****(USE BELOW IN FIXED PRICE SOLICITATIONS AND CONTRACTS WITH FOREIGN GOVERNMENTS.)****

x. FAR Clause **52.229-3, Federal, State and Local Taxes** (Feb 2013) is deleted in its entirety, and FAR Clause **52.229-7, Taxes--Fixed-Price Contracts with Foreign Governments** (Feb 2013) is substituted therefor.

353

****(USE BELOW AT THE DESCRETION OF THE CONTRACTING OFFICER, IN SOLICITATIONS AND CONTRACTS that are:

1. AT OR BELOW THE SIMPLIFIED ACQUISTION THRESHOLD; AND/OR,
2. WITHOUT ANY PROVISION FOR PROFIT OR FEE WITH A NONPROFIT ORGANIZATION.)****

See FAR Parts 32.608 and 32.611 for additional information.

y. FAR Clause **52.232-17, Interest** (May 2014) is applicable to this contract.

354

****(USE BELOW FOR SOLICITATIONS AND CONTRACTS WITH STATE OR LOCAL GOVERNMENTS, FOREIGN GOVERNMENTS, CONTRACTS FOR PAID ADVERTISING, OR CONTRACTS WITHOUT ANY PROVISION FOR FEE OR PROFIT AT THE DISCRETION OF THE CONTRACTING OFFICER.)****

z. FAR Clause **52.232-17, Interest** (May 2014) is deleted.

355

****(USE BELOW IN ALL COST REIMBURSEMENT INCREMENTALLY FUNDED SOLICITATIONS AND CONTRACTS)****

aa. FAR Clause **52.232-20, Limitation of Cost** (Apr 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation of Funds** (Apr 1984) is substituted therefor. **[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

356

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS OTHER THAN COST-REIMBURSEMENT SERVICES.)****

bb. **Alternate I** (Feb 2002), of FAR Clause **52.232-25, Prompt Payment** (Jan 2017)

357

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN PAYMENT UNDER CONTRACT WILL BE MADE EXCLUSIVELY THROUGH USE OF THE GOVERNMENTWIDE COMMERCIAL PURCHASE CARD OR OTHER THIRD PARTY PAYMENT ARRANGEMENT.)****

Note: *Payment by a purchase card may also be made under a contract that does not contain the clause below to the extent the Contractor agrees to accept that method of payment, see FAR 32.1108 and 32.1110(d) for further information.*

cc. FAR Clause **52.232-33, Payment by Electronic Funds Transfer--System for Award Management** (Oct 2018), is deleted in its entirety and FAR Clause **52.232-36, Payment by Third Party** (May 2014) is substituted therefor.

358

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN THE CO DETERMINES THAT THE GOVERNMENT'S INTEREST WOULD BE BETTER SERVED BY USE OF PARAGRAPH (i) IN ALTERNATE I AND HAS RECEIVED WRITTEN APPROVAL FOR ITS USE BY THE CHIEF OF THE CONTRACTING OFFICE.)****

See HHSAR 333.213 for additional information.

dd. **Alternate I,** (Dec 1991), of FAR Clause **52.233-1, Disputes** (May 2014) is added.

359

****(USE BELOW IN SOLLICITATIONS AND CONTRACTS FOR FIXED PRICE CONSTRUCTION, OR DISMANTLING, DEMOLITION, OR REMOVAL OF IMPROVEMENTS WHEN THE CONTRACT WILL INVOLVE WORK OF A LONG DURATION OR HAZARDOUS NATURE.)****

ee. **Alternate I** (Nov 1991) of FAR Clause **52.236-13, Accident Prevention** (Nov 1991), is added.

360

****(FOR BELOW, USE ANY OF THE FOLLOWING CLAUSES IN CONSTRUCTION CONTRACTS AT OR BELOW THE SIMPLIFIED ACQUISITION THRESHOLD AT THE DISCRETION OF THE CONTRACTING OFFICER.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **FAR Clause 52.236-21, Specifications** . Use the dropdown boxes below to identify the applicability of Alternates as follows:
  - **Use with Alternate I:** if reproducible shop drawings are needed;
  - **Use with Alternate II:** if reproducible shop drawings are NOT needed.

ff. FAR Clause **52.236-2, Differing Site Conditions** (Apr 1984) is applicable to this contract.

FAR Clause **52.236-3, Site Investigations and Conditions Affecting the Work** (Apr 1984) is applicable to this contract.

FAR Clause **52.236-6, Superintendence by the Contractor** (Apr 1984) is applicable to this contract.

FAR Clause **52.236-8, Other Contracts** (Apr 1984) is applicable to this contract.

FAR Clause **52.236-9, Protection of Existing Vegetation, Structures, Equipment, Utilities and Improvements** (Apr 1984) is applicable to this contract.

FAR Clause **52.236-10, Operations and Storage Areas** (Apr 1984) is applicable to this contract.

FAR Clause **52.236.11, Use and Possession Prior to Completion** (Apr 1984) is applicable to this contract.

FAR Clause **52.236-12, Cleaning Up** (Apr 1984) is applicable to this contract.

FAR Clause **52.236-13, Accident Prevention** (Nov 1991) is applicable to this contract.

FAR Clause **52.236-21, Specifications** (Feb 1997)

Alternate I (Apr 1984) [is not/is] applicable to this contract.

Alternate II (Apr 1984) [is not/is] applicable to this contract.

361

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR FIXED-PRICE REQUIREMENTS WHEN SERVICES **AND** SUPPLIES ARE TO BE FURNISHED.)****

gg. **Alternate I** (Apr 1984) of FAR Clause **52.243-1, Changes, Fixed Price** (Aug 1987), is hereby deleted in its entirety and **Alternate II** (Apr1984) of FAR Clause **52.243-1, Changes, Fixed Price** (Aug 1987), is substituted therefor.

362

****(USE BELOW AT THE DISCRETION OF THE CONTRACTING OFFICER, IN CONSTRUCTION SOLICITATIONS AND CONTRACTS WHEN THE CONTRACT AMOUNT IS ESTIMATED AT OR BELOW THE SIMPLIFIED ACQUISITION THRESHOLD.)****

hh. FAR Clause **52.248-3, Value Engineering--Construction** (Oct 2020) is applicable to this contract.

363

****(USE BELOW FOR A FIXED-PRICE SOLICITATION OR CONTRACT WITH AN AGENCY OF THE U.S. GOV'T, OR WITH STATE, LOCAL, OR FOREIGN GOV'Ts OR THEIR AGENCIES **AND** THE CO DETERMINES THAT THE REQUIREMENT TO PAY INTEREST ON EXCESS PARTIAL PAYMENTS IS INAPPROPRIATE.)****

ii. **Alternate II,** (Sep 1996), of FAR Clause **52.249-2, Termination for Convenience of the Government (Fixed-Price)** (Apr 2012) is added.

364

****(USE BELOW IF THE SOLICITATION OR CONTRACT IS FOR CONSTRUCTION **AND** WITH AN AGENCY OF THE U.S. GOV'T OR WITH STATE, LOCAL, OR FOREIGN GOVERNMENTS OR THEIR AGENCIES.)****

jj. **Alternate III,** (Sep 1996), of FAR Clause **52.249-2, Termination for Convenience of the Government (Fixed-Price)** (Apr 2012) is added.

365

****(USE BELOW IF THE SOLICITATION OR CONTRACT IS FOR CONSTRUCTION **AND** WITH AN AGENCY OF THE U.S. GOV'T OR WITH STATE, LOCAL, OR FOREIGN GOVERNMENTS OR THEIR AGENCIES **AND** THE CO DETERMINES THAT THE REQUIREMENT TO PAY INTEREST ON EXCESS PARTIAL PAYMENTS IS INAPPROPRIATE.)****

kk. **Alternate II,** (Sep 1996) and **Alternate III,** (Sep 1996), of FAR Clause **52.249-2, Termination for Convenience of the Government (Fixed-Price)** (Apr 2012) are added.

366

****(USE BELOW IN FIXED-PRICE CONSTRUCTION SOLICITATIONS AND CONTRACTS THAT DO NOT EXCEED THE SIMPLIFIED ACQUISITION THRESHOLD.)****

ll. FAR Clause **52.249-2, Termination for Convenience of the Government (Fixed-Price)** (Apr 2012), **Alternate I** (Sep 1996), is deleted in its entirety and FAR Clause **52.249-1, Termination for Convenience of the Government (Fixed-Price) (Short Form)** (Apr 1984) is substituted therefor.

367

****(USE BELOW IN FIXED-PRICE SUPPLY SOLICITATIONS AND CONTRACTS THAT DO NOT EXCEED THE SIMPLIFIED ACQUISITION THRESHOLD.)****

mm. FAR Clause **52.249-2, Termination for Convenience of the Government (Fixed-Price)** (Apr 2012), is deleted in its entirety and FAR Clause **52.249-1, Termination for Convenience of the Government (Fixed-Price) (Short Form)** (Apr 1984) is substituted therefor.

368

****(USE BELOW FOR FIXED-PRICE SERVICE SOLICITATIONS AND CONTRACTS, IF IN ACCORDANCE WITH FAR 49.502(b)(1) AND (c), IT IS DEEMED MORE APPROPRIATE THAN THE CLAUSE AT FAR 52.249-4.)****

nn. FAR Clause **52.249-4, Termination for Convenience of the Government (Services) (Short Form)** (Apr 1984), is deleted in its entirety and FAR Clause **52.249-2, Termination for Convenience of the Government (Fixed Price)** (Apr 2012) is substituted therefor.

369

****(USE BELOW FOR A COST-REIMBURSEMENT CONTRACT WITH AN AGENCY OF THE U.S. GOV'T, OR WITH STATE, LOCAL, OR FOREIGN GOV'Ts OR THEIR AGENCIES **AND** THE CO DETERMINES THAT THE REQUIREMENT TO PAY INTEREST ON EXCESS PARTIAL PAYMENTS IS INAPPROPRIATE.)****

oo. **Alternate II,** (Sep 1996), of FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (May 2004) is added.

370

****(USE BELOW, FOR A TIME & MATERIAL, LABOR HOUR CONTRACT WITH AN AGENCY OF THE U.S. GOV'T OR WITH STATE, LOCAL, OR FOREIGN GOVERNMENTS OR THEIR AGENCIES.)****

pp. **Alternate V,** (Sep 1996), of FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (May 2004) is added.

371

****(USE BELOW, FOR A TIME & MATERIAL, LABOR HOUR CONTRACT WITH AN AGENCY OF THE U.S. GOV'T OR WITH STATE, LOCAL, OR FOREIGN GOVERNMENTS OR THEIR AGENCIES **AND** THE CO DETERMINES THAT THE REQUIREMENT TO PAY INTEREST ON EXCESS PARTIAL PAYMENTS IS INAPPROPRIATE.)****

qq. **Alternate II,** (Sep 1996) and **Alternate V,** (Sep 1996), of FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (Sep 1996) are added.

372

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN A COST-REIMBURSEMENT, R&D CONTRACT IS CONTEMPLATED WITH EDUCATIONAL OR NONPROFIT INSTITUTIONS ON A **NO-FEE** BASIS.)****

Note: *The majority of cost-reimbursement, R&D contracts with educational or nonprofit institutions will fall into this category.*

rr. FAR Clauses **52.249-6, Termination (Cost-Reimbursement)** (May 2004) and **52.249-14, Excusable Delays** (Apr 1984), are deleted in their entirety and FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)** (Aug 2016), is substituted therefore.

373

****(USE BELOW IN FIXED PRICE SOLICITATIONS AND CONTRACTS AT OR BELOW THE SIMPLIFIED ACQUISITION THRESHOLD, AT THE DISCRETION OF THE CO.)****

ss. FAR Clause **52.249-8, Default (Fixed-Price Supply and Service)** (Apr 1984) is applicable to this contract.

374

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN A FIXED-PRICE, R&D CONTRACT IS CONTEMPLATED WITH EDUCATIONAL OR NONPROFIT INSTITUTIONS ON A **NO-PROFIT** BASIS.)****

Note: *The majority of fixed-price, R&D contracts with educational or nonprofit institutions will fall into this category.*

tt. FAR Clause **52.249-9, Default (Fixed-Price Research and Development)** (Apr 1984) is deleted in its entirety and FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)** (Aug 2016), is substituted therefore.

375

****(USE BELOW IN FIXED-PRICE R&D SOLICITATIONS AND CONTRACTS AT OR BELOW THE SIMPLIFIED ACQUISITION THRESHOLD, AT THE DISCRETION OF THE CO.)****

See FAR 49-504.b.

uu. FAR Clause **52.249-9, Default (Fixed-Price Research and Development)** (Apr 1984) is applicable to this contract.

376

****(USE BELOW IN FIXED-PRICE CONSTRUCTION SOLICITATIONS AND CONTRACTS AT OR BELOW THE SIMPLIFIED ACQUISITION THRESHOLD, AT THE DISCRETION OF THE CONTRACTING OFFICER.)****

vv. FAR Clause **52.249-10, Default (Fixed-Price Construction)** (Apr 1984) is applicable to this contract.

377

****(USE BELOW FOR A COST-REIMBURSEMENT CONTRACT, WHEN A NON-PROFIT (OTHER THAN EDUCATIONAL) WILL BE RECEIVING A FEE/CPFF CONTRACT.)****

Note: *These are modifications to the General Clauses for Nonprofit (Other Than Educational Institutions), therefore, DO NOT USE THE CR-R&D General Clauses FOR A NON-PROFIT INSTITUTION RECEIVING A FEE.* Also note that there are 3 clauses modified below.

ww. FAR Clause **52.216-11, Cost Contract--No Fee** (Apr 1984) is deleted in its entirety and FAR Clause **52.216-8 Fixed Fee** (Jun 2011) is substituted therefor.

FAR Clause **52.232-17, Interest** (May 2014) is added.

FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Non-Profit Institutions)** (Aug 2016) is deleted in its entirety and FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (May 2004) is substituted therefor.

378

****(USE BELOW IF NONE OF THE ABOVE CLAUSES ARE APPLICABLE.)****

xx. THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.

379

****(USE BELOW IN ALL SOLICITATIONS.)****

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

380

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

381

****(USE BELOW IN SOLICITATIONS AND CONTRACTS EXPECTED TO EXCEED $5,500,000 AND THE PERFORMANCE PERIOD IS 120 DAYS OR MORE.)****

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (Nov 2021).

382

****(USE BELOW FOR ALL SOLICITATIONS AND CONTRACTS EXPECTED TO EXCEED $6,000,000 UNLESS THE CONTRACT IS FOR THE ACQUISITION OF A COMMERCIAL PRODUCT UNDER FAR PART 12 OR WILL BE PERFORMED ENTIRELY OUTSIDE THE UNITED STATES.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- If the contract is funded with disaster assistance funds, the Contracting Officer must also identify the Department of Homeland Security poster and the website where it can be posted. For more information See FAR 3.1003(c)(2).

2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (Nov 2021).

"....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	https://core-docs.s3.amazonaws.com/documents/asset/uploaded_file/576385/OIG_Hotline_Poster_1_.pdf

383

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FUNDED IN WHOLE OR IN PART WITH RECOVERY ACT FUNDS.)****

3. FAR Clause **52.203-15, Whistleblower Protections Under the American Recovery and Reinvestment Act of** 2009(Jun 2010).

384

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT EXCEED THE SIMPLIFIED ACQUISITION THRESHOLD AND INCLUDE A REQUIREMENT FOR SERVICES BY CONTRACTOR EMPLOYEE(S) THAT INVOLVE PERFORMANCE OF ACQUISITION FUNCTIONS CLOSELY ASSOCIATED WITH INHERENTLY GOVERNMENTAL FUNCTIONS, FOR, OR ON BEHALF OF, A FEDERAL AGENCY OR DEPARTMENT.)****

Note: *This clause is NOT to be included in solicitations or contracts with a self-employed individual if the acquisition functions closely associated with inherently governmental functions are to be performed entirely by the self-employed individual, rather than an employee of the Contractor.*

4. FAR Clause **52.203-16, Preventing Personal Conflicts of Interest** (Jun 2020).

385

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT REQUIRE ACCESS TO CLASSIFIED INFORMATION UNDER NATIONAL SECURITY DESIGNATIONS LEVEL 2 (CONFIDENTIAL OR SECRET), LEVEL 3 (TOP SECRET), OR LEVEL 4 (SPECIAL ACCESS.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. **Alternate I:** should be included in R&D contracts with Educational Institutions.
2. **Alternate II:** should be included in Construction or A&E Contracts which require Employee Identification for security reasons.

5. FAR Clause **52.204-2, Security Requirements** (Mar 2021).

Alternate I (Apr 1984) [is/is not] applicable to this contract.

Alternate II (Apr 1984) [is/is not] applicable to this contract.

386

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN CONTRACT PERFORMANCE WILL REQUIRE THE CONTRACTOR TO HAVE ROUTINE PHYSICAL ACCESS TO A FEDERALLY CONTROLLED FACILITY AND/OR ROUTINE ACCESS TO A FEDERALLY CONTROLLED INFORMATION SYSTEM.)****

Note: *This clause should not be used when contractors require only intermittent access to Federally controlled facilities.*

6. FAR Clause **52.204-9, Personal Identity Verification of Contractor Personnel** (Jan 2011).

387

****(USE IN ALL SOLICITATIONS AND CONTRACTS FOR SERVICES (INCLUDING CONSTRUCTION) THAT MEET OR EXCEED THE THRESHOLDS AT FAR 4.1703, EXCEPT INDEFINITE-DELIVERY CONTRACTS. THIS CLAUSE IS NOT REQUIRED FOR ACTIONS ENTIRELY FUNDED BY DOD, CONTRACTS AWARDED WITH A GENERIC ENTITY IDENTIFIER, OR IN CLASSIFIED SOLICITATIONS, CONTRACTS OR ORDERS.)****

7. FAR Clause **52.204-14** , **Service Contract Reporting Requirements** (Oct 2016).

388

****(USE BELOW IN SOLICITATIONS AND INDEFINITE-DELIVERY CONTRACTS FOR SERVICES (INCLUDING CONSTRUCTION) WHERE ONE OR MORE ORDERS ISSUED THEREUNDER ARE EXPECTED TO EACH MEET OR EXCEED THE THRESHOLDS AT FAR 4.1703. THIS CLAUSE IS NOT REQUIRED FOR ACTIONS ENTIRELY FUNDED BY DOD, CONTRACTS AWARDED WITH A GENERIC ENTITY IDENTIFIER, OR IN CLASSIFIED SOLICITATIONS, CONTRACTS OR ORDERS.)****

8. FAR Clause **52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts** (Oct 2016).

389

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHEN THE SOLICITATION CONTAINS FAR PROVISION 52.204-16 COMMERCIAL AND GOVERNMENT ENTITY CODE REPORTING.)****

9. FAR Clause **52.204-18, Commercial and Government Entity Code Maintenance** (Aug 2020).

390

****(USE BELOW (or a clause substantially the same) IN SOLICITATIONS AND CONTRACTS THAT INVOLVE A LEASE WITH OPTION TO PURCHASE.)****

10. FAR Clause **52.207-5, Option to Purchase Equipment** (Feb 1995).

391

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE A MAJOR HELIUM REQUIREMENT DURING PERFORMANCE.)****

11. FAR Clause **52.208-8, Required Sources for Helium and Helium Usage Data** (Aug 2018).

392

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHICH REQUIRE A CONTRACTOR TO PROVIDE SUPPLIES OR SERVICES FOR GOVERNMENT USE THAT ARE ON THE PROCUREMENT LIST MAINTAINED BY THE COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED.)****

12. FAR Clause **52.208-9, Contractor Use of Mandatory Sources of Supply or Services** (May 2014).

393

****(USE BELOW IN A FIXED-PRICE CONTRACT WHEN IT IS INTENDED THAT THE CONTRACT REQUIRE FIRST ARTICLE APPROVAL THE CONTRACTOR WILL BE REQUIRED TO CONDUCT THE FIRST ARTICLE TESTING.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. **Use with Alternate I:** If it is intended that the Contractor be required to produce the first article and the production quantity at the same facility.
2. **Use with Alternate II:** If it is necessary to authorize the Contractor to purchase material or to commence production before first article approval.

13. FAR Clause **52.209-3, First Article Approval - Contractor Testing** (Sep 1989).

Alternate I (Jan 1997) [is/is not] applicable to this contract.

Alternate II (Sep 1989) [is/is not] applicable to this contract.

394

****(USE BELOW IN A FIXED-PRICE CONTRACT WHEN IT IS INTENDED THAT THE CONTRACT REQUIRE FIRST ARTICLE APPROVAL AND THE GOVERNMENT WILL BE RESPONSIBLE FOR CONDUCTING FIRST ARTICLE TESTING.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. **Use with Alternate I:** If it is intended that the Contractor be required to produce the first article and the production quantity at the same facility.
2. **Use with Alternate II:** If it is necessary to authorize the Contractor to purchase material or to commence production before first article approval.

14. FAR Clause **52.209-4, First Article Approval - Government Testing** (Sep 1989).

Alternate I (Jan 1997) [is/is not] applicable to this contract.

Alternate II (Sep 1989) [is/is not] applicable to this contract.

395

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR THE ACQUISITION OF PRODUCTS AND SERVICES (INCLUDING CONSTRUCTION).)****

15. FAR Clause **52.209-10, Prohibition on Contracting with Inverted Domestic Corporations** (Nov 2015).

396

****(USE BELOW IN SOLICITATIONS AND CONTRACTS OVER $5 MILLION FOR THE PROCUREMENT OF ITEMS OTHER THAN COMMERCIAL PRODUCTS.)****

16. FAR Clause **52.210-1, Market Research** (Nov 2021).

397

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION OTHER THAN COST-PLUS-FIXED-FEE, WHEN THE CO DETERMINES THAT LIQUIDATED DAMAGES ARE APPROPRIATE.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- If the contract specifies more than one completion date for parts or stages of the work, REVISE PARAGRAPH (a) of the clause to state the amount of liquidated damages for delay of each separate part or stage of the work.

17. FAR Clause **52.211-12, Liquidated Damages - Construction** (Sep 2000).

"(a) If the Contractor fails to complete the work within the time specified in the contract, the Contractor shall pay liquidated damages to the Government in the amount of $ _____ for each calendar day of delay until the work is completed or accepted."

398

****(USE BELOW IN FIXED-PRICE CONTRACTS FOR CONSTRUCTION WHICH INCLUDE THE CLAUSE AT FAR 52.211-12, ONLY IF, FAR 52.211-12 HAS BEEN MODIFIED TO PROVIDE FOR LIQUIDATED DAMAGES FOR DELAY OF SEPARATE PARTS OR STAGES OF THE WORK.)****

See FAR 11.503(c) to assure proper use of this clause.

18. FAR Clause **52.211-13, Time Extensions** (Sep 2000).

399

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR A NEGOTIATED FIXED PRICE CONTRACT WITH ECONOMIC PRICE ADJUSTMENT WHEN THE CONDITIONS SPECIFIED IN 16.203-4(c)(1)(i) THROUGH (iv) APPLY [BUT SEE 16.203-4(c)(2)]. THIS CLAUSE MAY BE MODIFIED BY INCREASING THE 10% LIMIT ON AGGREGATE INCREASES SPECIFIED IN SUBPARAGRAPH (c)(4), UPON APPROVAL OF THE CHIEF OF THE CONTRACTING OFFICE)****

19. FAR Clause **52.216-4, Economic Price Adjustment - Labor and Material** (Nov 2021).

400

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN A COST-PLUS-FIXED-FEE CONSTRUCTION CONTRACT IS CONTEMPLATED.)****

20. FAR Clause **52.216-9, Fixed Fee--Construction** (Jun 2011).

401

****(USE BELOW IN COST SHARING RFPs AND CONTRACTS (OTHER THAN FACILITIES CONTRACTS.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- **Use with Alternate I** in R&D Cost Sharing Contracts with Educational Institutions or Non-Profit Organizations, when the CO determines that withholding a portion of allowable costs is not required.

21. FAR Clause **52.216-12, Cost-Sharing Contract--No Fee** (Apr 1984).

Alternate I (Apr 1984) [is/is not] applicable to this contract.

402

****(USE BELOW, FOR R&D CONTRACTS WITH EDUCATIONAL INSTITUTIONS IF PREDETERMINED INDIRECT COST RATES WILL BE USED.)****

Note: In accordance with FAR 42.705-3(b), IF an Educational Institution has established predetermined Indirect Cost Rates, the use of these rates MUST be extended to all Government contracts awarded to the institution.

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- For a Facilities contract: Modify paragraph (c) by deleting the words "Subpart 31.1" and substituting for them "section 31.106."

22. FAR Clause **52.216-15, Predetermined Indirect Cost Rates** (Apr 1998).

403

****(USE BELOW IN INDEFINITE DELIVERY, DEFINITE-QUANTITY SOLICITATIONS AND CONTRACTS.)****

23. FAR Clause **52.216-20, Definite Quantity** (Oct 1995).

"(d) ...the Contractor shall not be required to make any deliveries under this contract after _____ [insert date]..."

404

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN A MULTIYEAR CONTRACT IS CONTEMPLATED.)****

Note: *See FAR 17.1 for more information about this Special Contracting Method.*

24. FAR Clause **52.217-2, Cancellation Under Multiyear Contracts** (Oct 1997).

405

****(USE BELOW FOR SOLICITATIONS AND CONTRACTS OTHER THAN SERVICES, WHERE INCLUSION OF AN OPTION IS APPROPRIATE, AND THE OPTION QUANTITY IS EXPRESSED AS A PERCENTAGE OF THE BASIC CONTRACT QUANTITY OR AS AN ADDITIONAL QUANTITY OF A SPECIFIC LINE ITEM.)****

25. FAR Clause **52.217-6, Option for Increased Quantity** (Mar 1989).

"....The Contracting Officer may exercise the option by written notice to the Contractor within _____ [INSERT THE PERIOD OF TIME IN WHICH THE CONTRACTING OFFICER HAS TO EXERCISE THE OPTION] ...."

406

****(USE BELOW FOR SOLICITATIONS AND CONTRACTS OTHER THAN SERVICES, WHERE INCLUSION OF AN OPTION IS APPROPRIATE, AND THE OPTION QUANTITY IS IDENTIFIED AS A SEPARATELY PRICED LINE ITEM HAVING THE SAME NOMENCLATURE AS A CORRESPONDING BASIC CONTRACT LINE ITEM.)****

26. FAR Clause **52.217-7, Option for Increased Quantity - Separately Priced Line Item** (Mar 1989).

"....The Contracting Officer may exercise the option by written notice to the Contractor within _____ [INSERT THE PERIOD OF TIME IN WHICH THE CONTRACTING OFFICER HAS TO EXERCISE THE OPTION] ...."

407

****(USE BELOW (OR THE CONTRACTING OFFICER MAY SUBSTITUTE SIMILAR LANGUAGE) IN SOLICITATIONS AND CONTRACTS FOR SERVICES WHEN THE INCLUSION OF AN OPTION IS APPROPRIATE.)****

27. FAR Clause **52.217-8, Option to Extend Services** (Nov 1999).

> "..The Contracting Officer may exercise the option by written notice to the Contractor within _____ [INSERT THE PERIOD OF TIME WITHIN WHICH THE CONTRACTING OFFICER MAY EXERCISE THE OPTION].

408

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT ARE SET ASIDE, OR RESERVED FOR, OR AWARDED ON A SOLE SOURCE BASIS TO, HUBZONE SMALL BUSINESS CONCERNS UNDER FAR 19.1305 OR 19.1306. THIS INCLUDES MULTIPLE-AWARD CONTRACTS WHEN ORDERS MAY BE SET ASIDE FOR HUBZone SMALL BUSINESS CONCERNS AS DESCRIBED IN FAR 8.405-5 AND 16.505(b)(2)(i)(F).)****

28. FAR Clause **52.219-3, Notice of HUBZone Set-Aside or Sole Source Award** (Oct 2022).

409

****(USE BELOW TO WAIVE THE 50 PERCENT REQUIREMENT, IF AT LEAST TWO HUBZone SMALL BUSINESS CONCERNS CANNOT MEET THE CONDITIONS AT FAR 19.308(a) (....spend at least 50 percent of the cost of contract performance to be incurred for personnel on their own employees or subcontract employees of other HUBZone small business concerns.) BUT CAN STILL MEET THE FOLLOWING:

- For general construction, at least 15 percent of the cost of the contract performance to be incurred for personnel using the concern's employees; or
- For construction by special trade contractors, at least 25 percent of the cost of contract performance to be incurred for personnel using the concern's employees.)****

Note: *If a waiver is granted, the HUBZone small business prime contractor must still meet the performance of work requirements set for in 13 CFR 125.6(c).*

29. **Alternate I** (Mar 2020), FAR Clause **52.219-3, Notice of HUBZone Set-Aside or Sole Source Award** (Oct 2022).

410

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS USING FULL AND OPEN COMPETITION.)****

Note: *FAR 19.1307 provides additional information on this Price Evaluation Preference.*

30. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (Oct 2022).

"(c) Waiver of evaluation preference.....
[ ] Offeror elects to waive the evaluation preference."

411

****(USE BELOW TO WAIVE THE 50 PERCENT REQUIREMENT, IF AT LEAST TWO HUBZone SMALL BUSINESS CONCERNS CANNOT MEET THE CONDITIONS AT FAR 19.308(a) (....spend at least 50 percent of the cost of contract performance to be incurred for personnel on their own employees or subcontract employees of other HUBZone small business concerns.) BUT CAN STILL MEET THE FOLLOWING:

- For general construction, at least 15 percent of the cost of the contract performance to be incurred for personnel using the concern's employees; or
- For construction by special trade contractors, at least 25 percent of the cost of contract performance to be incurred for personnel using the concern's employees.)****

Note: *If a waiver is granted, the HUBZone small business prime Contractor must still meet the performance of work requirements set for in 13 CFR 125.6(c).*

31. **Alternate I** (Jan 2011), FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (Oct 2022).

412

****(USE BELOW IN SOLICITATIONS AND CONTRACTS INVOLVING TOTAL SMALL BUSINESS SET-ASIDES OR RESERVES. THIS INCLUDES MULTIPLE-AWARD CONTRACTS WHEN ORDERS MAY BE SET ASIDE FOR ANY OF THE SMALL BUSINESS CONCERNS IDENTIFIED IN FAR 19.000(a)(3), AS DESCRIBED IN FAR 8.405-5 AND 16.505(b)(2)(i)(F).)****

Note: *This clause should not be used with SBIR contracts. See Section H, Limitations on Subcontracting-SBIR.*

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. **Use with Alternate I:** IF this acquisition is for a product in a class for which the Small Business Administration has waived the nonmanufacturer rule (See 19.102(f)(4)&(5) select "is" from the drop-down box.

32. FAR Clause **52.219-6, Notice of Total Small Business Set-Aside** (Nov 2020).

Alternate I (Mar 2020) [is/is not] applicable to this contract.

413

****(USE BELOW IN SOLICITATIONS AND CONTRACTS INVOLVING PARTIAL SMALL BUSINESS SET-ASIDES. THIS INCLUDES PART OR PARTS OF MULTIPLE-AWARD CONTRACTS, INCLUDING THOSE DESCRIBED IN FAR 38.101.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. **Use with Alternate I:** IF this acquisition is for a product in a class for which the Small Business Administration has waived the nonmanufacturer rule (See 19.102(f)(4)&(5) select "is" from the drop-down box.
2. **Use with Alternate II** : IF this is a competitive acquisition for supplies and Federal Prison Industries, Inc. (FPI) will be included in the competition in accordance with FAR 19.504 select "is" from the drop-down box.

33. FAR Clause **52.219-7, Notice of Partial Small Business Set-Aside** (Nov 2020).

Alternate I (Mar 2020) [is/is not] applicable to this contract.

414

****(USE BELOW IN SOLICITATIONS AND CONTRACTS TO NOTIFY OFFERORS IF AN ORDER OR ORDERS ARE TO BE SET ASIDE FOR ANY OF THE SMALL BUSINESS CONCERNS IDENTIFIED IN FAR 19.000(A)(3).)****

34. FAR Clause **52.219-13, Notice of Set-Aside of Orders** (Mar 2020).

415

****(USE BELOW WHEN IN SOLICITATIONS AND CONTRACTS FOR SUPPLIES, SERVICES, AND CONSTRUCTIONS, IF ANY PORTION OF THE REQUIREMENT IS TO BE SET ASIDE OR RESERVED FOR SMALL BUSINESS AND THE CONTRACT AMOUNT IS EXPECTED TO EXCEED $150,000. THIS INCLUDES MULTIPLE-AWARD CONTRACTS WHEN ORDERS MAY BE SET ASIDE FOR SMALL BUSINESS CONCERNS, AS DESCRIBED IN FAR 8.405-5 AND 16.505(b)(2)(i)(F).)****

Note: *This clause should not be used with SBIR contracts. See Section H, Limitations on Subcontracting-SBIR.*

35. FAR Clause **52.219-14, Limitations on Subcontracting** (Oct 2022).

416

****(USE BELOW IN SOLICITATIONS AND CONTRACTS SET-ASIDE OR RESERVED FOR, OR AWARDED ON A SOLE SOURCE BASIS TO, SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS CONCERNS UNDER FAR 19.1405 AND 19.1406. THIS INCLUDES MULTIPLE-AWARD CONTRACTS WHEN ORDERS MAY BE SET ASIDE FOR SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS CONCERNS AS DESCRIBED IN FAR 8.405-5 AND 16.505(b)(2)(i)(F).)****

36. FAR Clause **52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside** (Oct 2022).

417

****(USE BELOW FOR ALL SOLICITATIONS AND CONTRACTS WHEN THE CONTRACT WILL BE PERFORMED IN THE UNITED STATES OR ITS OUTLYING AREAS.)****

37. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (Mar 2023).

418

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR ACQUISITIONS THAT ARE SET ASIDE OR RESERVED FOR ECONOMICALLY DISADVANTAGED WOMEN-OWNED SMALL BUSINESS CONCERNS (EDWOSB) UNDER FAR 19.1505(b). THIS INCLUDES MULTIPLE-AWARD CONTRACTS WHEN ORDERS MAY BE SET ASIDE FOR EDWOSB CONCERNS AS DESCRIBED IN 8.405-5 AND 16.505(b)(2)(i)(F).)****
See FAR 19.1505 for additional information about this program.

38. FAR Clause **52.219-29, Notice of Set-Aside for, or Sole Source Award to, Economically Disadvantaged Women-Owned Small Business Concerns** (Oct 2022).

419

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR ACQUISITIONS THAT ARE SET ASIDE OR RESERVED FOR WOMEN-OWNED SMALL BUSINESS (WOSB) CONCERNS UNDER FAR 19.1505(c). THIS INCLUDES MULTIPLE-AWARD CONTRACTS WHEN ORDERS MAY BE SET ASIDE FOR WOSB CONCERNS ELIGIBLE UNDER THE WOSB PROGRAM AS DESCRIBED IN 8.405-5 AND 16.505(b)(2)(i)(F).)****
See FAR 19.1505 for additional information about this program.

39. FAR Clause **52.219-30, Notice of Set-Aside for, or Sole Source Award to, Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program** (Oct 2022).

420

****(USE BELOW IN RFPs AND CONTRACTS OVER $150,000 WHICH MAY REQUIRE OR INVOLVE THE EMPLOYMENT OF LABORERS OR MECHANICS, EXCEPT:

- THOSE CONTRACTS FOR SUPPLIES, MATERIALS OR ARTICLES ORDINARILY AVAILABLE IN THE OPEN MARKET; OR
- THOSE CONTRACTS TO BE PERFORMED SOLELY WITHIN A FOREIGN COUNTRY.

CONTRACTS REQUIRING WORK TO BE DONE SOLELY IN ACCORDANCE WITH THE WALSH-HEALEY PUBLIC CONTRACTS ACT ARE EXEMPT.

CONTRACTS FOR SUPPLIES IN CONNECTION WITH WHICH ANY REQUIRED SERVICES ARE MERELY INCIDENTAL AND DO NOT REQUIRE SUBSTANTIAL EMPLOYMENT OF LABORERS OR MECHANICS ARE EXEMPT.)****

Note: *This clause is not applicable for commercial products.*

40. FAR Clause **52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation - General** (Mar 2018).

421

****(USE BELOW IN SOLICITATIONS FOR CONSTRUCTION WITHIN THE U.S. IN EXCESS OF $2,000.)****

41. FAR Clause **52.222-5, Construction Wage Rate Requirements--Secondary Site of the Work** (May 2014).

422

****(USE BELOW IN SOLICITATIONS AND CONTRACTS UNLESS EXEMPT FROM THE REQUIREMENTS OF EXECUTIVE ORDER 11246 (SEE FAR 52.807(a)). IF THE CONTRACT IS EXEMPT FROM ONE OR MORE, BUT NOT ALL, OF THE REQUIREMENTS OF EXECUTIVE ORDER 11216, USE THIS CLAUSE WITH ITS ALTERNATE I.)****

42. FAR Clause 52.222-26, **Equal Opportunity** (Sep 2016).

423

****(USE BELOW IF THE CONTRACTOR WILL BE REQUIRED TO PERFORM IN OR ON BEHALF OF A FOREIGN COUNTRY AND THE CONTRACT ALSO INCLUDES THE CLAUSE AT 52.222-26, Equal Opportunity.)****

43. FAR Clause **52.222-29, Notification of Visa Denial** (Apr 2015).

424

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS ASSOCIATED WITH LARGE SCALE (OVER $25 MILLION) CONSTRUCTION PROJECTS, WHEN IT IS DETERMINED THAT A PROJECT LABOR AGREEMENT WILL BE REQUIRED.)****

See FAR Subpart 22.5.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **Alternate I:** Include when the submission of the project labor agreement will be allowed after contract award.

44. FAR Clause **52.222-34, Project Labor Agreement** (May 2010)

Alternate I (May 2010) [is/is not] applicable to this contract .

425

****(**USE IN SOLICITATIONS:**

- WHEN THE PROVISION AT 52.222-48, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Certification statute IS APPLICABLE TO THE REQUIREMENT. See FAR 22.1003-4(c).

USE IN CONTRACTS:

- WHEN THE CONTRACTING OFFICER HAS DETERMINED, IN ACCORDANCE WITH FAR 22.1003-4(c)(3), THAT THE SERVICE CONTRACT LABOR STANDARDS DOES NOT APPLY.)****

45. FAR Clause **52.222-51, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements** (May 2014).

426

****(**USE IN SOLICITATIONS:**

- WHEN THE PROVISION AT 52.222-52, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Certification statute IS APPLICABLE TO THE REQUIREMENT. See FAR 22.1003-4(d).

USE IN CONTRACTS:

- WHEN THE CONTRACTING OFFICER HAS DETERMINED, IN ACCORDANCE WITH FAR 22.1003-4(d)(3), THAT THE SERVICE CONTRACT LABOR STANDARDS DOES NOT APPLY.)****

46. FAR Clause **52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements** (May 2014).

427

****(USE BELOW IN SOLICITATIONS WITH with an estimated value of $50 million or more, issued from October 25, 2016 through April 24, 2017, and resultant contracts; and (2) In solicitations that are estimated to exceed $500,000 issued after April 24, 2017 and resultant contracts)****

428

****(USE BELOW IN SERVICE OR CONSTRUCTION SOLICITATIONS AND CONTRACTS, UNLESS THE CONTRACT WILL NOT INVOLVE THE USE OF USDA-DESIGNATED ITEMS AT https://www.biopreferred.gov/BioPreferred/ or 7 CFR Part 2902.)****

47. FAR Clause **52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts** (Sep 2013).

429

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN THE CONTRACT WILL REQUIRE THE DELIVERY OF HAZARDOUS MATERIALS AS DEFINED IN APPENDIX A OF FEDERAL STANDARD 313B, OR ON THE ADVICE OF THE GOVERNMENT'S TECHNICAL REPRESENTATIVE THAT THE CONTRACT WILL INVOLVE EXPOSURE TO HAZARDOUS MATERIALS.)****

48. FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (Feb 2021), with **Alternate I** (Jul 1995).

430

****(USE BELOW IN ALL CONTRACTS THAT PROVIDE FOR PERFORMANCE IN WHOLE, OR IN PART, ON A FEDERAL FACILITY.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. **Use with Alternate I:** When the Contractor operates or maintains a Federal facility or performs on a Federal facility on a Gov't owned Federal facility that has implemented or plans to implement an Environmental Management System (EMS).
2. **Use with Alternate II:** When the Contractor will perform on a federal facility and its activities will be included within the Facility Compliance Audit (FCA) or within an EMS audit.

49. FAR Clause **52.223-5, Pollution Prevention and Right-to-Know Information** (May 2011).
Alternate I (May 2011) [is not/is] applicable to this contract.

Alternate II (May 2011) [is not/is] applicable to this contract.

431

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR CONTRACTOR OPERATION OF GOVERNMENT OWNED OR LEASED FACILITIES AND FOR SUPPORT SERVICES AT SUCH FACILITIES.)****

50. FAR Clause **52.223-10, Waste Reduction Program** (May 2011).

432

****(USE BELOW *EXCEPT FOR CONTRACTS FOR SUPPLIES THAT WILL BE DELIVERED OUTSIDE OF THE UNITED STATES AND ITS OUTLYING AREAS, OR CONTRACTS FOR SERVICES THAT WILL BE PERFORMED OUTSIDE OF THE UNITED STATES AND ITS OUTLYING AREAS* WHEN THE SOLICITATION AND CONTRACT INCLUDE MAINTENANCE, REPAIR, OR DISPOSAL OF ANY EQUIPMENT OR APPLIANCE USING OZONE-DEPLETING SUBSTANCES AS A REFRIGERANT, SUCH AS AIR CONDITIONERS, INCLUDING MOTOR VEHICLES, REFRIGERATORS, CHILLERS OR FREEZERS.)****

51. FAR Clause **52.223-12, Maintenance, Service, Repair, or Disposal of Refrigeration Equipment and Air Conditioners** (Jun 2016).

433

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHEN IMAGING EQUIPMENT (COPIERS, DIGITAL DUPLICATORS, FACSIMILE MACHINES, MAILING MACHINES, MULTIFUNCTION DEVICES, PRINTERS, AND SCANNERS) WILL BE:

- DELIVERED;
- ACQUIRED BY THE CONTRACTOR FOR USE IN PERFORMING SERVICES AT A FEDERALLY CONTROLLED FACILITY; OR
- FURNISHED BY THE CONTRACTOR FOR USE BY THE GOVERNMENT ADDITIONAL INFORMATION ABOUT THIS ITEM:)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Use with Alternate I** : When there are sufficient EPEAT® silver- or gold-registered products available to meet agency needs.

Note *: See FAR 23.704(a) for additional information regarding exceptions to this requirement.*

52. FAR Clause **52.223-13 Acquisition of EPEAT®-Registered Imaging Equipment** (Jun 2014)

Alternate I (Oct 2015) [is not/is] applicable to this contract.

434

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHEN TELEVISIONS WILL BE;

- DELIVERED;
- ACQUIRED BY THE CONTRACTOR FOR USE IN PERFORMING SERVICES AT A FEDERALLY CONTROLLED FACILITY; OR
- FURNISHED BY THE CONTRACTOR FOR USE BY THE GOVERNMENT.)****

Note **:** *See FAR 23.704(a) for additional information regarding exceptions to this requirement.*

53. FAR Clause **52.223-14 Acquisition of EPEAT®-Registered Televisions** (Jun 2014)

Alternate I (Jun 2014) [is not/is] applicable to this contract.

435

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN ENERGY-CONSUMING PRODUCTS LISTED IN THE ENERGY STAR PROGRAM OR FEDERAL ENERGY MANAGEMENT PROGRAM (FEMP) WILL BE:

- DELIVERED;
- ACQUIRED BY THE CONTRACTOR FOR USE IN PERFORMING SERVICES AT A FEDERALLY-CONTROLLED FACILITY;
- FURNISHED BY THE CONTRACTOR FOR USE BY THE GOVERNMENT; OR
- SPECIFIED IN THE DESIGN OF A BUILDING OR WORK, OR INCORPORATED DURING ITS CONSTRUCTION, RENOVATION, OR MAINTENANCE.)****

54. FAR Clause **52.223-15, Energy Efficiency in Energy-Consuming Products** (May 2020).

436

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHEN PERSONAL COMPUTER PRODUCTS WILL BE:

- Delivered;
- Acquired by the contractor for use in performing services at a Federally controlled facility; or
- Furnished by the contractor for use by the Government.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Use with Alternate I:** When there are sufficient EPEAT® silver- or gold-registered products available to meet agency needs.

Note: *See FAR 23.704(a), for additional information in case an exception to the requirement is necessary.*

55. FAR Clause **52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products** (Oct 2015).

Alternate I (Jun 2014) [is not/is] applicable to this contract.

437

****(USE BELOW IN ALL SERVICE AND CONSTRUCTION SOLICITATIONS AND CONTRACTS **UNLESS** THE CONTRACT WILL NOT INVOLVE THE USE OF EPA-DESIGNATED ITEMS.)****

56. FAR Clause **52.223-17, Affirmative Procurement of EPA-designated Items in Service and Construction Contracts** (Aug 2018).

438

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONTRACTOR OPERATION OF GOVERNMENT-OWNED OR -LEASED FACILITIES OR VEHICLES, LOCATED IN THE UNITED STATES.)****

Note: *For facilities located outside the U.S., the agency head may determine that the use of the clause is in the best interest of the Government.*

57. FAR Clause **52.223-19, Compliance with Environmental Management Systems** (May 2011).

439

****(USE BELOW WHICH CONSISTS OF THE FOLLOWING TWO CLAUSES, WHEN THE DESIGN, DEVELOPMENT OR OPERATION OF A SYSTEM OF RECORDS ON INDIVIDUALS IS REQUIRED TO ACCOMPLISH AN AGENCY FUNCTION.)****

58. FAR Clause **52.224-1, Privacy Act Notification** (Apr 1984).

440

59. FAR Clause **52.224-2, Privacy Act** (Apr 1984).

441

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT EXCEED THE SIMPLIFIED ACQUISITION THRESHOLD, THAT PROVIDE FOR SUPPLIES TO BE IMPORTED INTO THE CUSTOMS TERRITORY OF THE U.S.)****

60. FAR Clause **52.225-8, Duty-Free Entry** (Oct 2010).

442

***(USE BELOW, IN SOLICITATIONS AND CONTRACTS FOR PERFORMANCE OF SERVICES AND/OR DELIVERY OF SUPPLIES IN:

- An area of combat operations, as designated by the Secretary of Defense; or
- An area of other significant military operations, as designated by the Secretary of Defense and only upon agreement of the Secretary of Defense and the Secretary of State.)****

Note: See FAR 25.302-6 (b) for details of applicability of this clause.

61. FAR Clause **52.225-26, Contractors Performing Private Security Functions Outside the United States** (Oct 2016).

443

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT CONTAIN THE CLAUSE AT 52.219-9, SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS SUBCONTRACTING PLAN, IF, IN THE OPINION OF THE CONTRACTING OFFICER, SUBCONTRACTING POSSIBILITIES EXIST FOR INDIAN ORGANIZATIONS OR INDIAN-OWNED ECONOMIC ENTERPRISES AND FUNDS ARE AVAILABLE FOR ANY INCREASED COSTS.)****

Note: *See paragraph (c)(2) of the clause.*

62. FAR Clause **52.226-1, Utilization of Indian organizations and Indian-owned Economic Enterprises** (Jun 2000).

444

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INVOLVING LOCAL AREA SET-ASIDES.)****

See FAR Subpart 26.2.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Paragraph (a):** Specify the geographic area for the local area set aside in the text box.

63. FAR Clause **52.226-4, Notice of Disaster or Emergency Area Set-Aside** (Nov 2007).

"(a) *Set Aside Area.* Offers are solicited only from businesses residing or primarily doing business in _____ *[Contracting Officer to fill in with definite geographic boundaries.]....."*

445

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE LOCAL AREA SET-ASIDES.)****

See FAR Part 26.2.

64. FAR Clause **52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area** (Nov 2007).

446

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR COMMUNICATION SERVICES WITH A COMMON CARRIER AND THE SERVICES ARE UNREGULATED AND NOT PRICED BY A TARIFF SCHEDULE SET BY A REGULATORY BODY.)****

65. **Alternate II** (Apr 1984), FAR Clause **52.227-1, Authorization and Consent** (Jun 2020).

447

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT MAY RESULT IN THE DELIVERY OF COMMERCIAL PRODUCTS, UNLESS THE FOLLOWING EXCEPTIONS APPLY:

- PART 12 PROCEDURES ARE USED;
- SIMPLIFIED ACQUISITION PROCEDURES OF PART 13 ARE USED;
- BOTH COMPLETE PERFORMANCE AND DELIVERY ARE OUTSIDE THE UNITED STATES; OR
- THE CO DETERMINES AFTER LEGAL COUNSEL THAT OMISSION OF THE CLAUSE WOULD BE CONSISTENT WITH COMMERCIAL PRACTICE.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

Note: *In addition to the information below, see FAR Subpart 27.2 for additional information regarding the use of Alternates I - III.*

1. **Alternate I:** Use to **exclude** specific items, If the contract also requires delivery of items that are not commercial products, or after consultation with legal counsel, the CO determines that limitation of applicability of the clause would be consistent with commercial practice. If applicable, specify appropriate items in the text box.
2. **Alternate II:** Use to **include** specific items, If the contract also requires delivery of items that are not commercial products, or after consultation with legal counsel, the CO determines that limitation of applicability of the clause would be consistent with commercial practice. If applicable, specify appropriate items in the text box.
3. **Alternate III:** Use if the RFP or Contract is for communication services and facilities where performance is by a common carrier, and the services are not priced by a tariff schedule set by a regulatory body.

66. FAR Clause **52.227-3, Patent Indemnity** (Apr 1984).

Alternate I (Apr 1984) [is not/is] applicable to this contract.

(c) This patent indemnification shall not apply to the following items:
N/A

Alternate II (Apr 1984) [is not/is] applicable to the contract.

(c) This patent indemnification shall cover the following items:
N/A

Alternate III **[is not/is]** applicable to the contract.

448

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR EXPERIMENTAL, DEVELOPMENTAL, OR RESEARCH WORK IF:

1. THE CONTRACTOR IS NOT LOCATED IN THE UNITED STATES OR DOES NOT HAVE A PLACE OF BUSINESS LOCATED IN THE US OR IS SUBJECT TO THE CONTROL OF A FOREIGN GOVERNMENT;
2. THERE ARE EXCEPTIONAL CIRCUMSTANCES IDENTIFIED IN 27.303(e)(1)(ii) OR (iii).)****

Note: *It is recommended that you review section 27.3 and consult with your Office of Technology Transfer to assist in determining use this Clause and any of its Alternates in your contract .*

67. FAR Clause **52.227-13, Patent Rights--Ownership by the Government** (Dec 2007).

449

****(USE BELOW IN SOLICITATIONS AND CONTRACTS IF IT IS CONTEMPLATED THAT DATA WILL BE PRODUCED, FURNISHED, OR ACQUIRED UNDER THE CONTRACT, EXCEPT AS SET FORTH IN FAR 27.409(b)(1).)****

Note: *If this clause is already contained in the applicable General Clause Listing, it is not necessary to include it here.*

68. FAR Clause **52.227-14, Rights in Data - General** (May 2014).

450

****(USE BELOW WHEN THE ALTERNATE DEFINITION OF LIMITED RIGHTS DATA IS APPROPRIATE.)****
See FAR 27.404-2(b).

69. **Alternate I** (Dec 2007), FAR Clause **52.227-14, Rights in Data--General** (May 2014).

451

****(USE BELOW WHEN THE CONTRACTING OFFICER DETERMINES IN ACCORDANCE WITH 27.404-2(c) THAT IT IS NECESSARY TO OBTAIN LIMITED RIGHTS DATA.)****

Note: *FAR 27/402(c)(i)-(v) offers examples of specific purposes that may be included in this Alternate .)*

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- The Contracting Officer shall include the purpose, if any, for which limited rights data are to be disclosed outside the Government. If there are no additional purposes, state that there are none.

70. **Alternate II** (Dec 2007), FAR Clause **52.227-14, Rights in Data--General** (May 2014).

Additional purposes for which the limited rights data may be used are:

452

****(USE BELOW WHEN THE CONTRACTING OFFICER DETERMINES, IN ACCORDANCE WITH 27.404-2(d), IT IS NECESSARY TO OBTAIN RESTRICTED COMPUTER SOFTWARE. ANY GREATER OR LESSER RIGHTS REGARDING THE USE, REPRODUCTION, OR DISCLOSURE OF RESTRICTED COMPUTER SOFTWARE THAN THOSE SET FORTH IN THE RESTRICTED RIGHTS NOTICE OF SUBPARAGRAPH (g)(4) OF THE CLAUSE SHALL BE SPECIFIED BELOW AND THE NOTICE MODIFIED ACCORDINGLY. STATE NONE, IF APPLICABLE.)****

71. **Alternate III** (Dec 2007), FAR Clause **52.227-14, Rights in Data--General** (May 2014).

Additions to, or limitations on, the restricted rights set forth in the Restricted Rights Notice of subparagraph (g)(4) of the clause are expressly stated as follows:

453

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR BASIC OR APPLIED RESEARCH TO BE PERFORMED SOLELY BY COLLEGES AND UNIVERSITIES, OTHER THAN THOSE FOR THE MANAGEMENT OR OPERATION OF GOVERNMENT FACILITIES.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- When this Alternate is used, the clause may be modified to exclude rights to certain data. See FAR 27.409(b)(5) and 27.404-4 for additional information.

72. **Alternate IV** (Dec 2007), FAR Clause **52.227-14, Rights in Data - General** (May 2014).

454

****(USE BELOW. IN ACCORDANCE WITH FAR 27.404-6, IF THE GOVERNMENT NEEDS THE RIGHT TO INSPECT CERTAIN DATA AT A CONTRACTOR'S FACILITY.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- The Contracting Officer shall specify in the text box below, data items that are not subject to inspection under paragraph (j), or state that there are none.

73. **Alternate V** (Dec 2007), FAR Clause **52.227-14, Rights in Data--General** (May 2014).

Specific data items that are not subject to paragraph (j) include:

455

****(USE BELOW FOR EXPERIMENTAL, DEVELOPMENTAL, RESEARCH, OR DEMONSTRATION WORK, EXCEPT:

- Contracts for Basic or Applied Research Performed Solely by a University or College where the contract amount will be $500,000, or less.
- When all the requirements are believed to be known at the time of award and are specified in the contract.)****

Note: *For additional information about this item see FAR 27.409(d).*

74. FAR Clause **52.227-16, Additional Data Requirements** (Jun 1987).

456

****(USE BELOW IN ACCORDANCE WITH 27.405-1 IN SOLICITATIONS AND CONTRACTS PRIMARILY FOR THE PRODUCTION OR COMPILATION OF DATA (other than limited rights data or restricted computer software) FOR THE GOVERNMENT'S INTERNAL USE, OR WHEN THERE IS A SPECIFIC NEED TO LIMIT DISTRIBUTION AND USE OF THE DATA OR TO OBTAIN INDEMNITY FOR LIABILITIES THAT MAY ARISE OUT OF THE CONTENT, PERFORMANCE, OR DISCLOSURE OF THE DATA.)****

Note: *Examples of such contracts are set forth in FAR Subpart 27.405-1.)*

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. The contract may specify the purpose and condition under which the data is used. ***Note:*** *This may be done by the insertion of specific information in the text box below, or specified elsewhere in the contract. If you include this information elsewhere, it is recommended that you use the text box below to specify where, in the contract, this information is located.*
2. FAR Subpart 27.409(e)(1)-(4) prescribes additional situations for use of this Clause.
3. In accordance with 27.409(i)(2), this clause may be appropriate for some A&E and Construction contracts.
4. Refer to FAR 27.405-1 for further guidance on Special Works. It may also be helpful to consult the NIH Technology Transfer Office for guidance in determining special copyright needs.

75. FAR Clause **52.227-17, Rights in Data--Special Works** (Dec 2007).

457

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT ARE EXCLUSIVELY FOR THE ACQUISITION (WITHOUT MODIFICATION) OF EXISTING WORKS AS SET FORTH IN 27.405-2. USE OF THIS CLAUSE WOULD BE LIMITED.)****

76. FAR Clause **52.227-18, Rights in Data--Existing Works** (Dec 2007).

458

****(WHEN USING BELOW, SEE FAR 27.405-3. YOU MAY USE THIS CLAUSE OR DEVELOP OTHER, APPROPRIATE LANGUAGE WHEN ACQUIRING EXISTING COMPUTER SOFTWARE FROM OTHER THAN GSA'S MULTIPLE AWARD SCHEDULE CONTRACTS.)****

77. FAR Clause **52.227-19, Commercial Computer Software License** (Dec 2007).

459

****(USE BELOW IN CONTRACTS FOR MAJOR SYSTEMS ACQUISITIONS OR FOR SUPPORT OF MAJOR SYSTEMS ACQUISITIONS, INCLUDING:

- Contracts for detailed design, development or production of a major system; or
- Contracts for any individual part, component, subassembly, assembly, or subsystem integral to the major system, and other property that may be replaced during the service life of the system, including spare parts.)****

Note: *FAR 2.101 defines a major system as a combination of elements, such as equipment, hardware, software, construction, etc., that exceeds $1.8 million (civilian agencies).*

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- This clause requires that the technical data to which it applies be specified in the contract. Use the text box below to specify this information or to identify where, in the contract, this information is located.

78. FAR Clause **52.227-21, Technical Data Declaration, Revision, and Withholding of Payment--Major Systems** (May 2014).

The following technical information is applicable to this clause:

460

****(USE BELOW WHEN A BID GUARANTEE IS REQUIRED - LANGUAGE MAY BE MODIFIED FOR NEGOTIATED CONTRACTS. See FAR 28.101-2 for additional prescriptive information.)****

79. FAR Clause **52.228-1, Bid Guarantee** (Sep 1996).

"The amount of the bid guarantee shall be % of the bid price or $ whichever is less."

461

****(USE BELOW WHEN BONDS ARE REQUIRED.)****

80. FAR Clause **52.228-2, Additional Bond Security** (Oct 1997).

462

**** (USE BELOW IN FIXED PRICE SOLICITATIONS AND CONTRACTS THAT EXCEED THE SIMPLIFIED ACQUISITION THRESHOLD, WHERE WORK IS REQUIRED TO BE PERFORMED ON A GOVERNMENT INSTALLATION.) ****

81. FAR Clause **52.228-5, Insurance - Work on a Government Installation** (Jan 1997).

463

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHICH REQUIRE THE SUBMISSION OF BID GUARANTEES, PERFORMANCE OR PAYMENT BONDS.)****

82. FAR Clause **52.228-11, Individual Surety - Pledges of Assets** (Feb 2021).

464

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN A PAYMENT BOND WILL BE FURNISHED PURSUANT TO THE MILLER ACT. ***Note:*** *This clause is NOT applicable for Commercial Products.)****

83. FAR Clause **52.228-12, Prospective Subcontractor Requests for Bonds** (May 2014).

465

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR SERVICES, SUPPLIES OR CONSTRUCTION, WHEN A BID GUARANTEE, OR PERFORMANCE AND PAYMENT BONDS ARE REQUIRED.)****

84. FAR Clause **52.228-14, Irrevocable Letter of Credit** (Nov 2014).

466

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR A COST-REIMBURSEMENT CONTRACT TO BE PERFORMED WHOLLY OR PARTLY IN A FOREIGN COUNTRY, UNLESS IT IS CONTEMPLATED THAT THE CONTRACT WILL BE WITH A FOREIGN GOVERNMENT.)****

85. FAR Clause **52.229-8, Taxes-Foreign Cost-Reimbursement Contracts** (Mar 1990).

467

****(USE BELOW IN SOLICITATIONS AND CONTRACTS TO BE AWARDED ON A COST-REIMBURSEMENT BASIS WITH A FOREIGN GOVERNMENT.)****

86. FAR Clause **52.229-9, Taxes-Cost-Reimbursement Contracts with Foreign Governments** (Mar 1990).

468

****(USE BELOW ALL SOLICITATIONS AND CONTRACTS BY THE DEPARTMENT OF HEALTH HUMAN SERVICES WHEN THE FOLLOWING CONDITIONS EXISTS:

1. The Contractor will be performing a cost-reimbursement contract.
2. The contract directs or authorizes the contractor to acquire tangible personal property as a direct cost under a contract and title to such property passes directly to and vests in the United States upon delivery of the property by the vendor.
3. The contract will be for services to be performed in whole or in part within the State of New Mexico.)****

Note: See FAR 29.401-4(c) for a list of the participating agencies that have entered into an agreement with the State of New Mexico to eliminate double taxation of Government cost-reimbursement contracts.

87. FAR Clause **52.229-10, State of New Mexico Gross Receipts and Compensating Tax** (Apr 2003)

469

****(USE BELOW IN NEGOTIATED CONTRACTS OVER $750,000 - FOR FULL CAS COVERAGE EXCEPT Small Businesses, Educational Institutions and Foreign Contractors.)****

Note: *See exceptions at 48 CFR Chapter 99 (Appendix B, FAR looseleaf Edition), Subpart 9903.201-1.*

88. FAR Clause **52.230-2, Cost Accounting Standards** (Jun 2020).

470

****(USE BELOW IN NEGOTIATED CONTRACTS OVER $750,000 BUT LESS THAN $50 MILLION, AND THE OFFEROR CERTIFIES THAT IT IS ELIGIBLE FOR AND ELECTS TO USE MODIFIED CAS COVERAGE, EXCEPT Small Businesses, Educational Institutions, and Foreign Contractors.)****

Note: *See exceptions at 48 CFR Chapter 99 (Appendix B, FAR looseleaf Edition), Subpart 9903.201-1.*

89. FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (Jun 2020).

471

****(USE BELOW IN NEGOTIATED CONTRACTS OVER $750,000 WITH FOREIGN CONCERNS, UNLESS THE CONTRACT IS OTHERWISE EXEMPT FROM CAS REQUIREMENTS. SEE 48 CFR CHAPTER 99 (APPENDIX B, FAR LOOSELEAF EDITION), SUBPART 9903.201-1(b).)****

Note: *Foreign concerns do not include foreign government's or their agents or instrumentalities.*

90. FAR Clause **52.230-4, Disclosure and Consistency of Cost Accounting Practices-Foreign Concerns** (Jun 2020).

472

****(USE BELOW IN NEGOTIATED CONTRACTS AND SUBCONTRACTS AWARDED TO EDUCATIONAL INSTITUTIONS, WHEN THE CONTRACT OR SUBCONTRACT PRICE EXCEEDS $750,000, UNLESS THE CONTRACT IS EXEMPTED (SEE 48 CFR CHAPTER 99, 9903-201-1), THIS CONTRACT IS TO BE PERFORMED BY AN FFRDC (SEE 9903.201-2(c)(5), OR THE PROVISION AT 9903-201-2(c)(6)(FAR APPENDIX B) APPLIES.)****

91. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (Jun 2020).

473

****(USE BELOW IN NEGOTIATED CONTRACTS THAT CONTAIN EITHER FAR CLAUSES 52.230-2, 52.230-3, or 52.230-5.)****

92. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (Jun 2010).

474

****(USE BELOW IN SOLICITATIONS AND CONTRACTS, IF THE CONTRACT IS TO BE CHARGEABLE TO FUNDS OF THE NEW FISCAL YEAR AND THE CONTRACT ACTION IS TO BE INITIATED BEFORE FUNDS ARE AVAILABLE.)****

93. FAR Clause **52.232-18, Availability of Funds** (Apr 1984).

475

****(USE BELOW WHEN PAYMENT UNDER CONTRACT WILL BE MADE EXCLUSIVELY THROUGH USE OF THE GOVERNMENTWIDE COMMERCIAL PURCHASE CARD OR OTHER THIRD PARTY PAYMENT ARRANGEMENT.)****

Note: *Payment by a purchase card may also be made under a contract that does not contain the clause below to the extent the Contractor agrees to accept that method of payment.*

See FAR 32.1108 and 32.1110(d) for further information.

94. FAR Clause **52.232-36, Payment by Third Party** (May 2014).

476

****(USE BELOW IN DELIVERY ORDER CONTRACTS ONLY WHEN THE ORDERING OFFICE WILL DESIGNATE THE METHOD OF PAYMENT FOR INDIVIDUAL ORDERS.)****

Note: *In addition to the inserting the clause below into the solicitation or contract, the CO must indicate to what extent any other EFT payment clauses are applicable; i.e. 52.232-34 and 52.232-36.*

See FAR 32.1110(e) & (f) for further information.

95. FAR Clause **52.232-37, Multiple Payment Arrangements** (May 1999).

477

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR SERVICES TO BE PERFORMED AT GOVERNMENT FACILITIES AND TECHNICAL REPRESENTATIVES ADVISE THAT SPECIAL PRECAUTIONS ARE APPROPRIATE.)****

96. FAR Clause **52.236-13, Accident Prevention** (Nov 1991), with **Alternate I** (Nov 1991).

478

****(USE BELOW IN FIXED-PRICE CONSTRUCTION SOLICITATIONS AND CONTRACTS PROVIDING FOR UNIT PRICING OF ITEMS AND FOR PAYMENT BASED ON QUANTITY SURVEYS.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- **Use with Alternate I:** If it is determined at a level above the Contracting Officer that it is impracticable for Government personnel to perform the original and final surveys and the Government wishes the Contractor to perform these surveys.

Use the dropdown box below to identify applicability.

97. FAR Clause **52.236-16, Quantity Surveys** (Apr 1984).

Alternate I (Apr 1984) [is not/is] applicable to this contract.

479

****(USE BELOW IN ALL ARCHITECT-ENGINEER SOLICITATIONS AND CONTRACTS EXCEPT AS STATED IN FAR 36.609-1(c).)****

98. FAR Clause **52.236-22, Design Within Funding Limitations** (April 1984).

"(c) The estimated construction contract price for the project described in this contract is $ _____ ."

480

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR SERVICES TO BE PERFORMED ON A GOVERNMENT INSTALLATION. NOT APPLICABLE TO CONSTRUCTION CONTRACTS.)****

99. FAR Clause **52.237-2, Protection of Government Buildings, Equipment and Vegetation** (Apr 1984).

481

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR SERVICES, AT CONTRACTING OFFICER'S DISCRETION, WHEN-

1. THE SERVICES UNDER THE CONTRACT ARE CONSIDERED TO BE VITAL TO THE GOVERNMENT AND MUST BE CONTINUED WITHOUT INTERRUPTION; AND,
2. THE GOVERNMENT ANTICIPATES DIFFICULTIES DURING THE TRANSITION FROM ONE CONTRACTOR TO ANOTHER OR TO THE GOVERNMENT.)****

100. FAR Clause **52.237-3, Continuity of Services** (Jan 1991).

482

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR NONPERSONAL HEALTH CARE SERVICES.)****

Note: *See FAR 37.4 for more information about Nonpersonal Health Care Service Contracts.*

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- The FAR sets forth the following instruction for completing the information required for this clause:

  "*Contracting Officer insert the dollar value(s) of standard coverage(s) prevailing within the local community as to the specific medical specialty, or specialties, concerned, or such higher amount as the Contracting Officer deems necessary to protect the Government's interests."

101. FAR Clause **52.237-7, Indemnification and Medical Liability Insurance** (Jan 1997).

"(a) ...The Contractor shall maintain during the term of this contract liability insurance issued by a responsible insurance carrier of not less than the following amount(s) per specialty per occurrence: *

Amount of Liability Insurance	Medical Specialty

483

****(USE BELOW SOLICITATIONS AND CONTRACTS FOR INFORMATION TECHNOLOGY (IT) WHICH REQUIRE SECURITY OF IT AND/OR ARE FOR THE DESIGN, DEVELOPMENT OR OPERATION OF A SYSTEM OF RECORDS USING COMMERCIAL IT SERVICES OR SUPPORT SERVICES.)****

102. FAR Clause **52.239-1, Privacy or Security Safeguards** (Aug 1996).

484

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS OVER $800,000 EXCEPT FIXED-PRICE CONTRACTS WITHOUT COST INCENTIVES OR ANY FIRM-FIXED-PRICE CONTRACT FOR COMMERCIAL PRODUCTS OR COMMERCIAL SERVICES.)****

103. FAR Clause **52.242-3, Penalties for Unallowable Costs** (Dec 2022).

485

****(USE BELOW IN FIXED-PRICE SOLICITATIONS AND CONTRACTS THAT PROVIDE FOR THE ESTABLISHMENT OF FINAL INDIRECT COST RATES.)****

104. FAR Clause **52.242-4, Certification of Final Indirect Costs** (Jan 1997).

486

****(THE BELOW SHOULD BE ADDED TO COST-REIMBURSEMENT CONTRACTS WITH EDUCATIONAL INSTITUTIONS WHENEVER POSSIBLE AND/OR APPROPRIATE.)****

105. FAR Clause **52.243-2, Changes--Cost Reimbursement** (Aug 1987), **Alternate V** (Apr 1984).

487

****(USE BELOW IN SOLICITATIONS AND CONTRACTS IN THE FOLLOWING SITUATIONS: 1) A LETTER CONTRACT OVER THE SIMPLIFIED ACQUISITION THRESHOLD; OR 2) A FIXED-PRICE CONTRACT OVER THE SIMPLIFIED ACQUISITION THRESHOLD, UNDER WHICH UNPRICED CONTRACT ACTIONS ARE ANTICIPATED.)****

Note: *This includes unpriced modifications and/or delivery orders.*

106. FAR Clause **52.244-2, Subcontracts** (Jun 2020).

488

****(USE BELOW WHEN A NEGOTIATED FIRM-FIXED PRICE CONTRACT, OVER THE SIMPLIFIED ACQUISITION THRESHOLD, WILL BE AWARDED USING OTHER THAN FULL AND OPEN COMPETITION OR WHERE THE PRICES ARE NOT SET BY LAW OR REGULATION. THIS CLAUSE IS NOT TO BE USED FOR TIME & MATERIALS, LABOR HOUR, OR A&E CONTRACTS.)****

107. FAR Clause **52.244-5, Competition in Subcontracting** (Dec 1996).

489

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN A FIXED-PRICE CONTRACT WILL BE AWARDED ON THE BASIS OF SUBMISSION OF COST OR PRICING DATA AND THE GOVERNMENT WILL PROVIDE GOVERNMENT PROPERTY.)****

108. FAR Clause **52.245-1, Government Property** (Sept 2021).

490

****(USE BELOW IN FIXED-PRICE SOLICITATIONS AND CONTRACTS WHEN THE GOVERNMENT WILL PROVIDE GOVERNMENT PROPERTY AND AWARD WILL NOT BE MADE ON THE BASIS OF SUBMISSION OF COST OR PRICING DATA.)****

109. **Alternate I** (Apr 2012), FAR Clause **52.245-1, Government Property** (Sept 2021).

491

****(USE BELOW IN FIXED-PRICE SOLICITATIONS AND CONTRACTS WITH EDUCATIONAL OR NONPROFIT INSTITUTIONS WHEN THE GOVERNMENT WILL PROVIDE GOVERNMENT PROPERTY.)****

110. **Alternate II** (Apr 2012), FAR Clause **52.245-1, Government Property** (Sept 2021).

492

****(USE BELOW IN SERVICE CONTRACTS TO BE PERFORMED ON A GOVERNMENT INSTALLATION WHEN GOVERNMENT-FURNISHED PROPERTY WILL BE PROVIDED FOR INITIAL PROVISIONING ONLY AND THE GOVERNMENT IS NOT RESPONSIBLE FOR REPAIR OR REPLACEMENT.)****

111. FAR Clause **52.245-2, Government Property Installation Operation Services** (Apr 2012).

493

****(USE IN ALL FIXED PRICE SOLICITATIONS AND CONTRACTS THAT WILL INCLUDE THE CLAUSE AT 52.245-1, Government Property.)****

112. FAR Clause **52.245-9, Use and Charges** (Apr 2012).

494

****(USE BELOW IN FIXED-PRICE CONSTRUCTION SOLICITATIONS AND CONTRACTS, IF THE CONTRACTING OFFICER CONSIDERS A WARRANTY CLAUSE TO BE NECESSARY. USE ONLY WHERE COST-EFFECTIVE.)****

113. FAR Clause **52.246-21, Warranty of Construction** (Mar 1994).

495

****(USE BELOW IN SOLICITATIONS AND CONTRACTS, OVER THE SIMPLIFIED ACQUISITION THRESHOLD (Other than ADP, A&E Services, Telecommunications, Construction or Maintenance and Rehabilitation of Real Property), SUBJECT TO THE REQUIREMENTS OF FAR 46.801, WHEN THE CONTRACT REQUIRES DELIVERY OF END ITEMS THAT ARE NOT "HIGH-VALUE" ITEMS (Defined in FAR 46.802).)****

Note: *This clause is not applicable to Commercial Products.*

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- This clause is included in some General Clause Listings. Before adding this clause to your contract here, check to see if it is already in the applicable General Clause Listing.

114. FAR Clause **52.246-23, Limitation of Liability** (Feb 1997).

496

****(USE BELOW IN SOLICITATIONS AND CONTRACTS, OVER THE SIMPLIFIED ACQUISITION THRESHOLD (Other than ADP, A&E Services, Telecommunications, Construction or Maintenance and Rehabilitation of Real Property), SUBJECT TO THE REQUIREMENTS OF FAR 46.801, WHEN THE CONTRACT REQUIRES DELIVERY OF END ITEMS THAT ARE CONSIDERED TO BE "HIGH-VALUE" ITEMS AS DEFINED in FAR 46.802 OR DESIGNATED AS "HIGH-VALUE" BY THE CONTRACTING OFFICER.)****

Note: *This clause is not applicable to Commercial Products.*

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- When the contract requires the delivery of both High-value and Other end items:
  - Make sure to also include the FAR Clause at 42.245-23, above;
  - Use with Alternate I; and
  - Make sure that the contract schedule clearly identifies the end products that have been designated as "high-value" items.

115. FAR Clause **52.246-24, Limitation of Liability - High-Value Items** (Feb 1997).

Alternate I (Apr 1984) [is/is not] applicable to this contract

497

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR THE PERFORMANCE OF SERVICES, OVER THE SIMPLIFIED ACQUISITION THRESHOLD (Other than Information Technology including Telecommunications, A&E Services, Construction or Maintenance and Rehabilitation of Real Property).)****

Note : *This clause is not appliable to commercial products.*

ADDITIONAL INFORMATION ABOUT THIS ITEM :

- This clause is included in some General Clause Listings. Before adding this clause to your contract here, check to see if it is already in the applicable General Clause Listing.

116. FAR Clause **52.246-25 Limitation of Liability-Services** (Feb 1997).

498

****(USE BELOW IN SOLICITATIONS AND CONTRACTS, WHEN U.S. GOVERNMENT-FINANCED INTERNATIONAL AIR TRANSPORTATION OF PERSONNEL AND/OR PROPERTY WILL OCCUR IN PERFORMANCE OF THE CONTRACT.)****

Note: *This is not applicable for commercial products.*

117. FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (Jun 2003).

499

****(USE BELOW IN SOLICITATIONS AND CONTRACTS, WHEN OCEAN TRANSPORTATION OF SUPPLIES IS ANTICIPATED.)****

118. FAR Clause **52.247-64, Preference for Privately Owned U.S. Flag Commercial Vessels** (Nov 2021).

500

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN ADVANCE NOTICE OF SHIPMENT IS REQUIRED FOR SAFETY OR SECURITY REASONS. CO MAY ALSO REQUIRE, AS DEEMED NECESSARY WHEN CAR LOAD OR TRUCK LOAD SHIPMENTS WILL BE MADE AND ADVANCE NOTICE IS CONSIDERED NECESSARY.)****

Note: *Generally, this notification is required for classified material, sensitive, controlled, and certain other protected material and some other hazardous materials.*

See FAR 47.208-2 for more information.

119. FAR Clause **52.247-68, Report of Shipment (REPSHIP)** (Feb 2006).

501

****(USE BELOW IN SOLICITATIONS AND CONTRACTS, OVER THE SIMPLIFIED ACQUISITION THRESHOLD, EXCEPT AS SPECIFIED IN SUBPARAGRAPHS (a) 1-5 AND PARAGRAPH f. OF FAR 48.201. THE CONTRACTING OFFICER SHOULD REVIEW AND USE ALTERNATES I, II, OR III AS APPROPRIATE.)****

120. FAR Clause **52.248-1, Value Engineering** (Jun 2020).

502

****(USE BELOW WHEN THE GOVERNMENT REQUIRES AND PAYS FOR A SPECIFIC VALUE ENGINEERING EFFORT IN ARCHITECT-ENGINEER CONTRACTS.)****

121. FAR Clause **52.248-2, Value Engineering Program - Architect-Engineer** (Mar 1990).

503

****(USE BELOW WHEN THE CONTRACTING OFFICER MAY AUTHORIZE THE CONTRACTOR TO ACQUIRE SUPPLIES AND SERVICES FROM A GOVERNMENT SUPPLY SOURCE.)****

122. FAR Clause **52.251-1, Government Supply Sources** (Apr 2012).

504

****(USE BELOW WHEN NONE OF THE ABOVE CLAUSES ARE APPLICABLE TO THE CONTRACT.)****

123. **THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.**

505

****(USE IN ALL SOLICITATIONS AND CONTRACTS.)****

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

506

****(USE BELOW IN SOLICITATIONS, CONTRACTS AND ORDERS OVER THE SIMPLIFIED ACQUISITION THRESHOLD UNLESS PRINTING OR INCREASED DUPLICATION IS AUTHORIZED BY STATUTE.)****

Note: See Manual Chapter 6308: "ACQUISITION OF PRINTING REQUIREMENTS AT THE NIH" https://oma1.od.nih.gov/manualchapters/contracts/6308/index.html for more information regarding exceptions to this policy.

1. HHSAR Clause **352.208-70, Printing and Duplication** (December 2015).

507

****(USE BELOW IN SOLICITATIONS, CONTRACTS AND ORDERS PROVIDING FUNDING WHICH PARTIALLY OR FULLY SUPPORTS A CONFERENCE.)****

2. HHSAR Clause **352.211-2, Conference Sponsorship Request and Conference Materials Disclaimer** (December 2015).

508

****(USE BELOW IN SOLICITATIONS AND CONTRACTS SUBJECT TO THE PAPERWORK REDUCTION ACT REQUIREMENTS REGARDING THE COLLECTION AND RECORDING OF INFORMATION FROM 10 OR MORE PERSONS OTHER THAN FEDERAL EMPLOYEES.)****

3. HHSAR Clause **352.211-3, Paperwork Reduction Act** (December 2015).

509

****USE BELOW IN SOLICITATIONS AND CONTRACTS WITH HOSPTALS (PROFIT OR NON-PROFIT) WHEN COST-REIMBURSEMENT IS COMTEMPLATED.)****

4. HHSAR Clause **352.216-70, Additional Cost Principles for Hospitals (Profit or Non-Profit)** (December 2015).

510

****(USE BELOW WHEN THE CONTRACT WILL REQUIRE FAR Clause 52.219-9, Small Business Subcontracting Plan AND THE CONTRACTOR HAS AN HHS OSDBU-APPROVED MENTOR-PROTEGE AGREEMENT.)****

5. HHSAR Clause **352.219-71, Mentor-Protégé Program Reporting Requirements** (January 2010).

511

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT INVOLVE HAZARDOUS MATERIALS OR HAZARDOUS OPERATIONS FOR THE FOLLOWING TYPES OF REQUIREMENTS: (A) Services OR Products (B) Research, Development OR Test Projects (C) Transportation of Hazardous Materials (D) Construction, Including Construction of Facilities on the Contractor's Premises)****

6. HHSAR Clause **352.223-70, Safety and Health** (December 2015).

512

****(USE BELOW IN SOLICITATIONS AND CONTRACTS, WHEN A COST-REIMBURSEMENT, FIXED-PRICE LEVEL-OF-EFFORT, TIME-AND-MATERIALS, OR LABOR-HOUR CONTRACT IS COMTEMPLATED.)****

7. HHSAR Clause **352.231-70, Salary Rate Limitation** (December 2015).

Note: *The Salary Rate Limitation is at the Executive Level II Rate.*

See the following website for Executive Schedule rates of pay: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/.

(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

513

****(USE BELOW WHEN CONTRACT PERFORMANCE WILL BE OUTSIDE THE UNITED STATES, ITS POSSESSIONS, AND PUERTO RICO, EXCEPT AS OTHERWISE PROVIDED FOR IN A GOVERNMENT-to-GOVERNMENT AGREEMENT.)****

8. HHSAR Clause **352.233-70, Choice of Law (Overseas)** (December 2015).

514

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR DESIGN-BUILD REQUIREMENTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Alternate I** : In all solicitations and contracts for construction when Fast-Track procedures are being used.

9. HHSAR Clause **352.236-70 Design-Build Contracts** (December 2015).

515

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR: (1) KINDERGARTEN, ELEMENTARY, OR SECONDARY EDUCATION OR LIBRARY SERVICES; OR (2) HEALTH OR DAY CARED SERVICES THAT ARE PROVIDED TO CHILDREN UNDER THE AGE OF 18 ON A ROUTINE OR REGULAR BASIS PURSUANT TO THE PRO-CHILDREN ACT OF 1994.)****

10. HHSAR Clause **352.237-70, Pro-Children Act of 1994** (December 2015).

516

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHEN PERFORMANCE WILL TAKE PLACE ON FEDERAL LAND OR IN A FEDERALLY-OPERATED (OR CONTRACTED) FACILITY AND THAT INVOLVE THE PROFESSIONS/ACTIVITIES PERFORMED BY PERSONS SPECIFIED IN THE CRIME CONTROL ACT OF 1990 (42 U.S.C. 13031), INCLUDING, BUT NOT LIMITED TO, TEACHERS, SOCIAL WORKERS, PHYSICIANS, NURSES, DENTISTS, HEALTH CARE PRACTITIONERS, OPTOMETRISTS, PSYCHOLOGISTS, EMERGENCY MEDICAL TECHNICIANS, ALCOHOL OR DRUG TREATMENT PERSONNEL, CHILD CARE WORKERS AND ADMINISTRATORS, EMERGENCY MEDICAL TECHNICIANS AND AMBULANCE DRIVERS.)****

11. HHSAR Clause **352.237-71, Crime Control Act of 1990--Reporting of Child Abuse** (December 2015).

517

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR ALL CHILD CARE SERVICES TO CHILDREN UNDER THE AGE OF 18, INCLUDING SOCIAL SERVICES, HEALTH AND MENTAL HEALTH CARE, CHILD (DAY) CARE, EDUCATION (WHETHER OR NOT DIRECTLY INVOLVED IN TEACHING), AND REHABILITATIVE PROGRAMS COVERED UNDER THE CRIME CONTROL ACT OF 1990.)****

12. HHSAR Clause **352.237-72, Crime Control Act--Requirement for Background Checks** (December 2015).

518

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

519

****(USE BELOW IN SOLICITATIONS AND CONTRACTS INVOLVING PATIENT CARE.)****

1. **NIH(RC)-11, Research Patient Care Costs** (4/1/84).

520

****(USE BELOW IN ALL SOLICITATIONS.)****

ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

521

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

522

(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN THE CONTRACTOR OR A SUBCONTRACTOR AT ANY TIER MAY HAVE FEDERAL CONTRACT INFORMATION RESIDING IN OR TRANSITING THROUGH ITS INFORMATION SYSTEM.)

1. FAR Clause 52.204-21, **Basic Safeguarding of Covered Contractor Information Systems** (Nov 2021)

a. *Definitions.* As used in this clause--

"Covered contractor information system" means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

"Federal contract information" means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

"Information" means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

"Information system" means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

"Safeguarding" means measures or controls that are prescribed to protect information systems.

b. Safeguarding requirements and procedures.

1. The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:
    i. Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).
    ii. Limit information system access to the types of transactions and functions that authorized users are permitted to execute.
    iii. Verify and control/limit connections to and use of external information systems.
    iv. Control information posted or processed on publicly accessible information systems.
    v. Identify information system users, processes acting on behalf of users, or devices.
    vi. Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.
    vii. Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.
    viii. Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.
    ix. Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.
    x. Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.
    xi. Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.
    xii. Identify, report, and correct information and information system flaws in a timely manner.
    xiii. Provide protection from malicious code at appropriate locations within organizational information systems.
    xiv. Update malicious code protection mechanisms when new releases are available.
    xv. Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

2. *Other* requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

c. *Subcontracts.* The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial products, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

523

USE BELOW IN ALL SOLICITATIONS AND INDEFINTE DELIVERY CONTRACT ORDERS

2. FAR Clause **52.204-24, Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment** (Nov 2021).

The Offeror shall not complete the representation at paragraph (d)(1) of this provision if the Offeror has represented that it "does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument" in paragraph (c)(1) in the provision at 52.204-26 , Covered Telecommunications Equipment or Services-Representation, or in paragraph (v)(2)(i) of the provision at 52.212-3 , Offeror Representations and Certifications-Commercial Items. The Offeror shall not complete the representation in paragraph (d)(2) of this provision if the Offeror has represented that it "does not use covered telecommunications equipment or services, or any equipment, system, or service that uses covered telecommunications equipment or services" in paragraph (c)(2) of the provision at 52.204-26 , or in paragraph (v)(2)(ii) of the provision at 52.212-3.

a. *Definitions.* As used in this provision-

Backhaul, covered telecommunications equipment or services, critical technology, interconnection arrangements, reasonable inquiry, roaming, and substantial or essential component have the meanings provided in the clause 52.204-25 , Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

b. *Prohibition.* (1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115- 232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. Nothing in the prohibition shall be construed to-

i. Prohibit the head of an executive agency from procuring with an entity to provide a service that connects to the facilities of a third- party, such as backhaul, roaming, or interconnection arrangements; or
ii. Cover telecommunications equipment that cannot route or redirect user data traffic or cannot permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115- 232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract or extending or renewing a contract with an entity that uses any equipment,

system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract. Nothing in the prohibition shall be construed to-

i Prohibit the head of an executive agency from procuring with an entity to provide a service that connects to the facilities of a third- party, such as backhaul, roaming, or interconnection arrangements; or

ii Cover telecommunications equipment that cannot route or redirect user data traffic or cannot permit visibility into any user data or packets that such equipment transmits or otherwise handles.

c *Procedures.* The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (https://www.sam.gov) for entities excluded from receiving federal awards for" covered telecommunications equipment or services".

d *Representation.* The Offeror represents that-

(1) It [ ] will, [ ] will not provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract or other contractual instrument resulting from this solicitation. The Offeror shall provide the additional disclosure information required at paragraph (e)(1) of this section if the Offeror responds "will" in paragraph (d)(1) of this section; and

(2) After conducting a reasonable inquiry, for purposes of this representation, the Offeror represents that-

It [ ] does, [ ] does not use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services. The Offeror shall provide the additional disclosure information required at paragraph (e)(2) of this section if the Offeror responds " does" in paragraph (d)(2) of this section.

e. *Disclosures.* (1) Disclosure for the representation in paragraph (d)(1) of this provision. If the Offeror has responded "will" in the representation in paragraph (d)(1) of this provision, the Offeror shall provide the following information as part of the offer:

i. For covered equipment-

(A) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code,

and whether the entity was the original equipment manufacturer (OEM) or a distributor, if known).

(B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and

(C) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

ii. For covered services-

(A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or

(B) If not associated with maintenance, the Product Service Code (PSC) of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

(2) Disclosure for the representation in paragraph (d)(2) of this provision. If the Offeror has responded " does" in the representation in paragraph (d)(2) of this provision, the Offeror shall provide the following information as part of the offer:

i. For covered equipment-

(A) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the OEM or a distributor, if known).

(B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and

(C) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would

be permissible under the prohibition in paragraph (b)(2) of this provision.

ii. For covered services-

(A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or

(B) If not associated with maintenance, the PSC of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of this provision.

(End of provision).

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****(USE BELOW IN:

1. **SOLICITATIONS:** WHERE THE RESULTANT CONTRACT IS EXPECTED TO EXCEED $500,000 AND
2. **CONTRACTS:** WHEN THE OFFEROR HAS CHECKED "HAS" CURRENT ACTIVE FEDERAL CONTRACTS AND GRANTS WITH A TOTAL VALUE GREATER THAN $10,000,000 IN PARAGRAPH "b" OF THE PROVISION 52.209-7, Information Regarding Responsibility Matters.)****

3. FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (Oct 2018).

As prescribed in 9.104-7(c), insert the following clause:

a. The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the System for Award Management (SAM) database at https://sam.gov/content/home .
b. As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIIS consists of two segments--
    1. The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by--
        i. Government personnel and authorized users performing business on behalf of the Government; or

ii. The Contractor, when viewing data on itself; and

2. The publicly-available segment, to which all data in the non-public segment of FAPIIS is automatically transferred after a waiting period of 14 calendar days, except for--
   i. Past performance reviews required by subpart 42.15;
   ii. Information that was entered prior to April 15, 2011; or
   iii. Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

c. The Contractor will receive notification when the Government posts new information to the Contractor's record.
   1. If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIIS.
   2. The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.
   3. As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.

d. Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(End of clause).

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****(USE BELOW IN ALL SOLICITATIONS)****

4. FAR Clause **FAR 52.204-26, Covered Telecommunications Equipment or Services-Representation** (Oct 2020).

   a. *Definitions.* As used in this provision, "covered telecommunications equipment or services" and "reasonable inquiry" have the meaning provided in the clause 52.204-25 , Prohibition on Contracting for Certain Telecommunications and Video

Surveillance Services or Equipment.

b. *Procedures.* The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (https://www.sam.gov) for entities excluded from receiving federal awards for "covered telecommunications equipment or services".

c. (1) *Representation.* The Offeror represents that it [ ] does, [ ] does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument.

(2) After conducting a reasonable inquiry for purposes of this representation, the offeror represents that it [ ] does, [ ] does not use covered telecommunications equipment or services, or any equipment, system, or service that uses covered telecommunications equipment or services.

(End of provision).

526

****(USE BELOW IN FIXED PRICE SUPPLY AND INDEFINITE DELIVERY NEGOTIATED SOLICITATIONS AND CONTRACTS WHEN THE CONDITIONS SPECIFIED IN 16.203-4(a)(1)(i) - (iii) APPLY [BUT SEE 16.203-4(a)(2)]. THE CLAUSE MAY BE MODIFIED BY INCREASING THE 10% LIMIT ON AGGREGATE INCREASES SPECIFIED IN SUBPARAGRAPH (c)(1), UPON APPROVAL OF THE CHIEF OF THE CONTRACTING OFFICE.)****

5. FAR Clause **52.216-2, Economic Price Adjustment--Standard Supplies** (Nov 2021).

a. The Contractor warrants that the unit price stated in the Schedule for _____ [offeror insert Schedule line item number] is not in excess of the Contractor's applicable established price in effect on the contract date for like quantities of the same item. The term "unit price" excludes any part of the price directly resulting from requirements for preservation, packaging, or packing beyond standard commercial practice. The term "established price" means a price that--
   1. Is an established catalog or market price for a commercial product sold in substantial quantities to the general public; and
   2. Is the net price after applying any standard trade discounts offered by the Contractor.

b. The Contractor shall promptly notify the Contracting Officer of the amount and effective date of each decrease in any applicable established price. Each corresponding contract unit price shall be decreased by the same percentage that the established price is decreased. The decrease shall apply to those items delivered on and after the effective date of the decrease in the Contractor's established price, and this contract shall be modified accordingly.

c. If the Contractor's applicable established price is increased after the contract date, the corresponding contract unit price shall be increased, upon the Contractor's written request to the Contracting Officer, by the same percentage that the established price is increased, and the contract shall be modified accordingly, subject to the following limitations:
    1. The aggregate of the increases in any contract unit price under this clause shall not exceed 10 percent of the original contract unit price.
    2. The increased contract unit price shall be effective--
        i. On the effective date of the increase in the applicable established price if the Contracting Officer receives the Contractor's written request within 10 days thereafter; or
        ii. If the written request is received later, on the date the Contracting Officer receives the request.
    3. The increased contract unit price shall not apply to quantities scheduled under the contract for delivery before the effective date of the increased contract unit price, unless failure to deliver before that date results from causes beyond the control and without the fault or negligence of the Contractor, within the meaning of the Default clause.
    4. No modification increasing a contract unit price shall be executed under this paragraph (c) until the Contracting Officer verifies the increase in the applicable established price.
    5. Within 30 days after receipt of the Contractor's written request, the Contracting Officer may cancel, without liability to either party, any undelivered portion of the contract items affected by the requested increase.

d. During the time allowed for the cancellation provided for in paragraph (c)(5) of this clause, and thereafter if there is no cancellation, the Contractor shall continue deliveries according to the contract delivery schedule, and the Government shall pay for such deliveries at the contract unit price, increased to the extent provided by paragraph (c) of this clause.

(End of clause).

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****(USE BELOW IN FIXED PRICE SUPPLY NEGOTIATED SOLICITATIONS AND CONTRACTS WHEN THE CONDITIONS SPECIFIED IN 16.203-4(b)(1)(i) - (iii) APPLY [BUT SEE 16.203-4(b)(1)(i)]. THE CLAUSE MAY BE MODIFIED BY INCREASE THE 10% LIMIT ON AGGREGATE INCREASE SPECIFIED IN SUBPARAGRAPH (c)(1), UPON APPROVAL OF THE CHIEF OF THE CONTRACTING OFFICE.)****

6. FAR Clause **52.216-3, Economic Price Adjustment--Semistandard Supplies** (Nov 2021).

    a. The Contractor warrants that the supplies identified as line items _____

[offeror insert Schedule line item number] in the Schedule are, except for modifications required by the contract specifications, supplies for which it has an established price. The term "established price" means a price that (1) is an established catalog or market price for a commercial product sold in substantial quantities to the general public, and (2) is the net price after applying any standard trade discounts offered by the Contractor. The Contractor further warrants that, as of the date of this contract, any difference between the unit prices stated in the contract for these line items and the Contractor's established prices for like quantities of the nearest commercial equivalents are due to compliance with contract specifications and with any contract requirements for preservation, packaging, and packing beyond standard commercial practice.

b. The Contractor shall promptly notify the Contracting Officer of the amount and effective date of each decrease in any applicable established price. Each corresponding contract unit price (exclusive of any part of the unit price that reflects modifications resulting from compliance with specifications or with requirements for preservation, packaging, and packing beyond standard commercial practice) shall be decreased by the same percentage that the established price is decreased. The decrease shall apply to those items delivered on and after the effective date of the decrease in the Contractor's established price, and this contract shall be modified accordingly.
c. If the Contractor's applicable established price is increased after the contract date, the corresponding contract unit price (exclusive of any part of the unit price resulting from compliance with specifications or with requirements for preservation, packaging, and packing beyond standard commercial practice) shall be increased, upon the Contractor's written request to the Contracting Officer, by the same percentage that the established price is increased, and the contract shall be modified accordingly, subject to the following limitations:
    1. The aggregate of the increases in any contract unit price under this clause shall not exceed 10 percent of the original contract unit price.
        i. The increased contract unit price shall be effective-
        ii. On the effective date of the increase in the applicable established price if the Contracting Officer receives the Contractor's written request within 10 days thereafter: or
    2. If the written request is received later, on the date the Contracting Officer receives the request.
    3. The increased contract unit price shall not apply to quantities scheduled under the contract for delivery before the effective date of the increased contract unit price, unless failure to deliver before that date results from causes beyond the control and without the fault or negligence of the Contractor, within the meaning of the Default clause.

4. No modification increasing a contract unit price shall be executed under this paragraph (c) until the Contracting Officer verifies the increase in the applicable established price.
5. Within 30 days after receipt of the Contractor's written request, the Contracting Officer may cancel, without liability to either party, any undelivered portion of the contract items affected by the requested increase.

d. During the time allowed for the cancellation provided for in paragraph (c)(5) of this clause, and thereafter if there is no cancellation, the Contractor shall continue deliveries according to the contract delivery schedule, and the Government shall pay for such deliveries at the contract unit price, increased to the extent provided by paragraph (c) of this clause.

(End of clause).

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****(USE BELOW IN INDEFINITE DELIVERY, DEFINITE-QUANTITY, REQUIREMENTS, OR INDEFINITE-QUANTITY RFPs AND CONTRACTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Subparagraph a:** Insert the dates for the timeframe that orders may be issued under the contract. Note: In accordance with FAR 16.505(a)(2) orders can only be issued within the period of performance of the contract.

7. FAR Clause **52.216-18, Ordering** (Aug 2020).

a. Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from _____ through _____ .
b. All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.
c. If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of clause).

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****(USE BELOW [OR WORDS SUBSTANTIALLY THE SAME] IN INDEFINITE DELIVERY, DEFINITE-QUANTITY, REQUIREMENTS, OR INDEFINITE-QUANTITY SOLICITATIONS AND CONTRACTS.)****

8. FAR Clause **52.216-19, Order Limitations** (Oct 1995).

a. **Minimum Order** . When the Government requires supplies or services covered by this contract in an amount of less than _____ [insert dollar figure or quantity], the

Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

b. **Maximum Order.** The Contractor is not obligated to honor--
   1. Any order for a single item in excess of _____ [insert dollar figure or quantity].
   2. Any order for a combination of items in excess of _____ [insert dollar figure or quantity]; or
   3. A series of orders from the same ordering office within _ days that together call for quantities exceeding the limitation in subparagraph (1) or (2) above.

c. If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) above.

d. Notwithstanding paragraphs (b) and (c) above, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within _ days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

(End of clause).

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****(USE BELOW IN INDEFINITE DELIVERY, REQUIREMENTS SOLICITATIONS AND CONTRACTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Subparagraph f:** Insert an end date for required Contractor deliveries. **Note:** *Make sure allow sufficient time for the Government to receive all deliverables from orders issued within the period of performance of the contract .*

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. **Use with Alternate I:** If the contract is for nonpersonal services and related supplies and covers estimated requirements that exceed a specific Government activity's internal capability to produce or perform.
2. **Use with Alternate II:** If the contract includes subsistence for both Government use and resale in the same Schedule, and similar products may be acquired on a brand-name basis.
3. **Use with Alternate III:** If the contract involves a partial small business set-aside.
4. **Use with Alternate IV:** If the contract includes subsistence for both Government use and resale in the same schedule and similar products may be acquired on a brand-name basis and involves a partial small business set aside.

9. FAR Clause **52.216-21, Requirements** (Oct 1995).

a. This is a requirements contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies or services specified in the Schedule are estimates only and are not purchased by this contract. Except as this contract may otherwise provide, if the Government's requirements do not result in orders in the quantities described as "estimated" or "maximum" in the Schedule, that fact shall not constitute the basis for an equitable price adjustment.

b. Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. Subject to any limitations in the Order Limitations clause or elsewhere in this contract, the Contractor shall furnish to the Government all supplies or services specified in the Schedule and called for by orders issued in accordance with the Ordering clause. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

c. Except as this contract otherwise provides, the Government shall order from the Contractor all the supplies or services specified in the Schedule that are required to be purchased by the Government activity or activities specified in the Schedule.

d. The Government is not required to purchase from the Contractor requirements in excess of any limit on total orders under this contract.

e. If the Government urgently requires delivery of any quantity of an item before the earliest date that delivery may be specified under this contract, and if the Contractor will not accept an order providing for the accelerated delivery, the Government may acquire the urgently required goods or services from another source.

f. Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after _____ .

(End of clause).

Alternate I (Apr 1984) [is not/is] applicable to this contract.

Alternate II (Apr 1984) [is not/not] applicable to this contract.

Alternate III (Oct 1995) [is not/is] applicable to this contract.

Alternate IV (Oct 1995) [is not/is] applicable to this contract.

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****(USE BELOW IN INDEFINITE DELIVERY, INDEFINITE QUANTITY SOLICITATIONS AND CONTRACTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Subparagraph d:** Insert an end date for required Contractor deliveries.

Note: *Make sure allow sufficient time for the Government to receive all deliverables from orders issued within the period of performance of the contract.*

10. FAR Clause **52.216-22, Indefinite Quantity** (Oct 1995)

a. This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

b. Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."

c. Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

d. Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after _____ .

(End of clause).

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****(USE BELOW WHEN THE CONTRACT INCLUDES AN OPTION AND IT IS NECESSARY TO INCLUDE: 1) A REQUIREMENT THAT THE GOVERNMENT SHALL GIVE THE CONTRACTOR A PRELIMINARY WRITTEN NOTICE OF ITS INTENT TO EXTEND THE CONTRACT; 2) A STIPULATION THAT AN EXTENSION OF THE OPTION; AND/OR, 3) A SPECIFIED LIMITATION ON THE TOTAL DURATION OF THE CONTRACT.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Subparagraph a:**
  - **First text box:** Insert the period of time within which the Contracting Officer may exercise the option.
  - **Second text box:** If you intend to notify the contractor of the Government's intent to exercise its option 60 days prior to contract expiration, leave this box blank, otherwise insert the number of days you intend to notify the contractor.
- **Subparagraph c:** Insert the number of months or years (as applicable) of total duration of the contract, including the exercise of any options.

11. FAR Clause **52.217-9, Option to Extend the Term of the Contract** (Mar 2000).

a. The Government may extend the term of this contract by written notice to the Contractor within _____ [INSERT THE PERIOD OF TIME WITHIN WHICH THE CONTRACTING OFFICER MAY EXERCISE THE OPTION]; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least _____ days [60 days unless a different number of days is inserted] before the contract expires. The preliminary notice does not commit the Government to an extension.

b. If the Government exercises this option, the extended contract shall be considered to include this option clause.

c. The total duration of this contract, including the exercise of any options under this clause, shall not exceed _____ [MONTHS/YEARS].

(End of clause).

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INCLUDING FAR 52.222-6 OR 52.222-41, WHERE WORK IS TO BE PERFORMED, IN WHOLE OR IN PART, IN THE UNITED STATES (THE 50 STATES AND THE DISTRICT OF COLUMBIA.)****

12. FAR Clause **52.222-55, Minimum Wages for Contractor Workers Under Executive Order 14026** (Jan 2022)

(a) Definitions. As used in this clause-

United States means the 50 states, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, Johnston Island, Wake Island, and the outer Continental Shelf as defined in the Outer Continental Shelf Lands Act (43 U.S.C. 1331, et seq.).

Worker -

(1) (i) Means any person engaged in performing work on, or in connection with, a contract covered by Executive Order 14026, and -

(A) Whose wages under such contract are governed by the Fair Labor Standards Act (29 U.S.C. chapter 8), the Service Contract Labor Standards statute (41 U.S.C. chapter 67), or the Wage Rate Requirements (Construction) statute (40 U.S.C. chapter 31, subchapter IV);

(B) Other than individuals employed in a bona fide executive, administrative, or professional capacity, as those terms are defined in 29 CFR part 541; and

(C) Regardless of the contractual relationship alleged to exist between the individual and the employer.

(ii) Includes workers performing on, or in connection with, the contract whose wages are calculated pursuant to special certificates issued under 29 U.S.C. 214(c).

(iii) Also includes any person working on, or in connection with, the contract and individually registered in a bona fide apprenticeship or training program registered with the Department of Labor's Employment and Training Administration, Office of Apprenticeship, or with a State Apprenticeship Agency recognized by the Office of Apprenticeship.

(2) (i) A worker performs on a contract if the worker directly performs the specific services called for by the contract; and

(ii) A worker performs in connection with a contract if the worker's work activities are necessary to the performance of a contract but are not the specific services called for by the contract.

(b) Executive Order Minimum wage rate. (1) The Contractor shall pay to workers, while performing in the United States, and performing on, or in connection with, this contract, a minimum hourly wage rate of $15.00 per hour beginning January 30, 2022.

(2) The Contractor shall adjust the minimum wage paid, if necessary, beginning January 1, 2023, and annually thereafter, to meet the applicable annual E.O. minimum wage. The Administrator of the Department of Labor's Wage and Hour Division (the Administrator) will publish annual determinations in the Federal Register no later than 90 days before the effective date of the new E.O. minimum wage rate. The Administrator will also publish the applicable E.O. minimum wage on https://www.sam.gov (or any successor website), and a general notice on all wage determinations issued under the Service Contract Labor Standards statute or the Wage Rate Requirements (Construction) statute, that will provide information on the E.O. minimum wage and how to obtain annual updates. The applicable published E.O. minimum wage is incorporated by reference into this contract.

(3) (i) The Contractor may request a price adjustment only after the effective date of the new annual E.O. minimum wage determination. Prices will be adjusted only for increased labor costs (including subcontractor labor costs) as a result of an increase in the annual E.O. minimum wage, and for associated labor costs (including those for subcontractors). Associated labor costs shall include increases or decreases that result from changes in social security and unemployment taxes and workers' compensation insurance, but will not otherwise include any amount for general and administrative costs, overhead, or profit.

(ii) Subcontractors may be entitled to adjustments due to the new minimum wage, pursuant to paragraph (b)(2). Contractors shall consider any subcontractor requests for such price adjustment.

(iii) The Contracting Officer will not adjust the contract price under this clause for any costs other than those identified in paragraph (b)(3)(i) of this clause, and will not provide duplicate price adjustments with any price adjustment under clauses implementing the Service Contract Labor Standards statute or the Wage Rate Requirements (Construction) statute.

(4) The Contractor warrants that the prices in this contract do not include allowance for any contingency to cover increased costs for which adjustment is provided under this clause.

(5) A pay period under this clause may not be longer than semi-monthly, but may be shorter to comply with any applicable law or other requirement under this contract establishing a shorter pay period. Workers shall be paid no later than one pay period following the end of the regular pay period in which such wages were earned or accrued.

(6) The Contractor shall pay, unconditionally to each worker, all wages due free and clear without subsequent rebate or kickback. The Contractor may make deductions that reduce a worker's wages below the E.O. minimum wage rate only if done in accordance with 29 CFR 23.230, Deductions.

(7) The Contractor shall not discharge any part of its minimum wage obligation under this clause by furnishing fringe benefits or, with respect to workers whose wages are governed by the Service Contract Labor Standards statute, the cash equivalent thereof.

(8) Nothing in this clause shall excuse the Contractor from compliance with any applicable Federal or State prevailing wage law or any applicable law or municipal ordinance or any applicable contract establishing a minimum wage higher than the E.O. 14026 minimum wage. However, wage increases under such other laws or municipal ordinances are not subject to price adjustment under this subpart.

(9) The Contractor shall pay the E.O. minimum wage rate whenever it is higher than any applicable collective bargaining agreement(s) wage rate.

(10) The Contractor shall follow the policies and procedures in 29 CFR 23.240(b) and 23.280 for treatment of workers engaged in an occupation in which they customarily and regularly receive more than $30 a month in tips.

(c) (1) This clause applies to workers as defined in paragraph (a). As provided in that definition-

(i) Workers are covered regardless of the contractual relationship alleged to exist between the contractor or subcontractor and the worker;

(ii) Workers with disabilities whose wages are calculated pursuant to special certificates issued under 29 U.S.C. 214(c) are covered; and

(iii) Workers who are registered in a bona fide apprenticeship program or training program registered with the Department of Labor's Employment and Training Administration, Office of Apprenticeship, or with a State Apprenticeship Agency recognized by the Office of Apprenticeship, are covered.

(2) This clause does not apply to-

(i) Fair Labor Standards Act (FLSA)-covered individuals performing in connection with contracts covered by the E.O., i.e. those individuals who perform duties necessary to the performance of the contract, but who are not directly engaged in performing the specific work called for by the

contract, and who spend less than 20 percent of their hours worked in a particular workweek performing in connection with such contracts;

(ii) Individuals exempted from the minimum wage requirements of the FLSA under 29 U.S.C. 213(a) and 214(a) and (b), unless otherwise covered by the Service Contract Labor Standards statute, or the Wage Rate Requirements (Construction) statute. These individuals include but are not limited to-

(A) Learners, apprentices, or messengers whose wages are calculated pursuant to special certificates issued under 29 U.S.C. 214(a);

(B) Students whose wages are calculated pursuant to special certificates issued under 29 U.S.C. 214(b) ; and

(C) Those employed in a bona fide executive, administrative, or professional capacity (29 U.S.C. 213(a)(1) and 29 CFR part 541).

(d) Notice. The Contractor shall notify all workers performing work on, or in connection with, this contract of the applicable E.O. minimum wage rate under this clause. With respect to workers covered by the Service Contract Labor Standards statute or the Wage Rate Requirements (Construction) statute, the Contractor may meet this requirement by posting, in a prominent and accessible place at the worksite, the applicable wage determination under those statutes. With respect to workers whose wages are governed by the FLSA, the Contractor shall post notice, utilizing the poster provided by the Administrator, which can be obtained at www.dol.gov/agencies/whd/government-contracts , in a prominent and accessible place at the worksite. Contractors that customarily post notices to workers electronically may post the notice electronically provided the electronic posting is displayed prominently on any Web site that is maintained by the contractor, whether external or internal, and customarily used for notices to workers about terms and conditions of employment.

(e) Payroll Records. (1) The Contractor shall make and maintain records, for three years after completion of the work, containing the following information for each worker:

(i) Name, address, and social security number;

(ii) The worker's occupation(s) or classification(s);

(iii) The rate or rates of wages paid;

(iv) The number of daily and weekly hours worked by each worker;

(v) Any deductions made; and

(vi) Total wages paid.

(2) The Contractor shall make records pursuant to paragraph (e)(1) of this clause available for inspection and transcription by authorized representatives of the Administrator. The Contractor shall also make such records available upon request of the Contracting Officer.

(3) The Contractor shall make a copy of the contract available, as applicable, for inspection or transcription by authorized representatives of the Administrator.

(4) Failure to comply with this paragraph (e) shall be a violation of 29 CFR 23.260 and this contract. Upon direction of the Administrator or upon the Contracting Officer's own action, payment shall be withheld until such time as the noncompliance is corrected.

(5) Nothing in this clause limits or otherwise modifies the Contractor's payroll and record keeping obligations, if any, under the Service Contract Labor Standards statute, the Wage Rate Requirements (Construction) statute, the Fair Labor Standards Act, or any other applicable law.

(f) Access. The Contractor shall permit authorized representatives of the Administrator to conduct investigations, including interviewing workers at the worksite during normal working hours.

(g) Withholding. The Contracting Officer, upon his or her own action or upon written request of the Administrator, will withhold funds or cause funds to be withheld, from the Contractor under this or any other Federal contract with the same Contractor, sufficient to pay workers the full amount of wages required by this clause.

(h) Disputes. Department of Labor has set forth in 29 CFR 23.510, Disputes concerning contractor compliance, the procedures for resolving disputes concerning a contractor's compliance with Department of Labor regulations at 29 CFR part 23. Such disputes shall be resolved in accordance with those procedures and not the Disputes clause of this contract. These disputes include disputes between the Contractor (or any of its subcontractors) and the contracting agency, the Department of Labor, or the workers or their representatives.

(i) Antiretaliation. The Contractor shall not discharge or in any other manner discriminate against any worker because such worker has filed any

complaint or instituted or caused to be instituted any proceeding under or related to compliance with the E.O. or this clause, or has testified or is about to testify in any such proceeding.

(j) Subcontractor compliance. The Contractor is responsible for subcontractor compliance with the requirements of this clause and may be held liable for unpaid wages due subcontractor workers.

(k) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (k) in all subcontracts, regardless of dollar value, that are subject to the Service Contract Labor Standards statute or the Wage Rate Requirements (Construction) statute, and are to be performed in whole or in part in the United States.

(End of clause).

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INCLUDING FAR 52.222-6 OR 52.222-41, WHERE WORK IS TO BE PERFORMED, IN WHOLE OR IN PART, IN THE UNITED STATES (THE 50 STATES AND THE DISTRICT OF COLUMBIA.)****

13. FAR Clause **52.222-62, Paid Sick Leave Under Executive Order 13706** (Jan 2022).

(a) Definitions. As used in this clause (in accordance with 29 CFR 13.2)-

Child, "domestic partner", and "domestic violence" have the meaning given in 29 CFR 13.2.

Employee-

(1)(i) Means any person engaged in performing work on or in connection with a contract covered by Executive Order (E.O.) 13706; and

(A) Whose wages under such contract are governed by the Service Contract Labor Standards statute (41 U.S.C. chapter 67), the Wage Rate Requirements (Construction) statute (40 U.S.C. chapter 31, subchapter IV), or the Fair Labor Standards Act (29 U.S.C. chapter 8);

(B) Including employees who qualify for an exemption from the Fair Labor Standards Act's minimum wage and overtime provisions;

(C) Regardless of the contractual relationship alleged to exist between the individual and the employer; and

(ii) Includes any person performing work on or in connection with the contract and individually registered in a bona fide apprenticeship or training program registered with the Department of Labor's Employment and Training Administration, Office of Apprenticeship, or with a State Apprenticeship Agency recognized by the Office of Apprenticeship.

(2)(i) An employee performs "on" a contract if the employee directly performs the specific services called for by the contract; and

(ii) An employee performs "in connection with" a contract if the employee's work activities are necessary to the performance of a contract but are not the specific services called for by the contract.

Individual related by blood or affinity whose close association with the employee is the equivalent of a family relationship has the meaning given in 29 CFR 13.2.

Multiemployer plan means a plan to which more than one employer is required to contribute and which is maintained pursuant to one or more collective bargaining agreements between one or more employee organizations and more than one employer.

Paid sick leave means compensated absence from employment that is required by E.O. 13706 and 29 CFR Part 13.

Parent, "sexual assault", "spouse", and "stalking" have the meaning given in 29 CFR 13.2.

United States means the 50 States and the District of Columbia.

(b) Executive Order 13706.

(1) This contract is subject to E.O. 13706 and the regulations issued by the Secretary of Labor in 29 CFR Part 13 pursuant to the E.O.

(2) If this contract is not performed wholly within the United States, this clause only applies with respect to that part of the contract that is performed within the United States.

(c) Paid sick leave. The Contractor shall-

(1) Permit each employee engaged in performing work on or in connection with this contract to earn not less than 1 hour of paid sick leave for every 30 hours worked;

(2) Allow accrual and use of paid sick leave as required by E.O. 13706 and 29 CFR Part 13;

(3) Comply with the accrual, use, and other requirements set forth in 29 CFR 13.5 and 13.6, which are incorporated by reference in this contract;

(4) Provide paid sick leave to all employees when due free and clear and without subsequent deduction (except as otherwise provided by 29 CFR 13.24), rebate, or kickback on any account;

(5) Provide pay and benefits for paid sick leave used no later than one pay period following the end of the regular pay period in which the paid sick leave was taken; and

(6) Be responsible for the compliance by any subcontractor with the requirements of E.O. 13706, 29 CFR Part 13, and this clause.

(d) Contractors may fulfill their obligations under E.O. 13706 and 29 CFR Part 13 jointly with other contractors through a multiemployer plan, or may fulfill their obligations through an individual fund, plan, or program (see 29 CFR 13.8).

(e) Withholding. The Contracting Officer will, upon his or her own action or upon written request of an authorized representative of the Department of Labor, withhold or cause to be withheld from the Contractor under this or any other Federal contract with the same Contractor, so much of the accrued payments or advances as may be considered necessary to pay employees the full amount owed to compensate for any violation of the requirements of E.O. 13706, 29 CFR Part 13, or this clause, including-

(1) Any pay and/or benefits denied or lost by reason of the violation;

(2) Other actual monetary losses sustained as a direct result of the violation; and

(3) Liquidated damages.

(f) Payment suspension/contract termination/contractor debarment.

(1) In the event of a failure to comply with E.O. 13706, 29 CFR Part 13, or this clause, the contracting agency may, on its own action or after authorization or by direction of the Department of Labor and written notification to the Contractor take action to cause suspension of any further payment, advance, or guarantee of funds until such violations have ceased.

(2) Any failure to comply with the requirements of this clause may be grounds for termination for default or cause.

(3) A breach of the contract clause may be grounds for debarment as a contractor and subcontractor as provided in 29 CFR 13.52.

(g) The paid sick leave required by E.O. 13706, 29 CFR Part 13, and this clause is in addition to the Contractor's obligations under the Service Contract Labor Standards statute and Wage Rate Requirements (Construction) statute, and the Contractor may not receive credit toward its prevailing wage or fringe benefit obligations under those Acts for any paid sick leave provided in satisfaction of the requirements of E.O. 13706 and 29 CFR Part 13.

(h) Nothing in E.O. 13706 or 29 CFR Part 13 shall excuse noncompliance with or supersede any applicable Federal or State law, any applicable law or municipal ordinance, or a collective bargaining agreement requiring greater paid sick leave or leave rights than those established under E.O. 13706 and 29 CFR Part 13.

(i) Recordkeeping. (1) The Contractor shall make and maintain, for no less than three (3) years from the completion of the work on the contract, records containing the following information for each employee, which the Contractor shall make available upon request for inspection, copying, and transcription by authorized representatives of the Administrator of the Wage and Hour Division of the Department of Labor:

(i) Name, address, and social security number of each employee.

(ii) The employee's occupation(s) or classification(s).

(iii) The rate or rates of wages paid (including all pay and benefits provided).

(iv) The number of daily and weekly hours worked.

(v) Any deductions made.

(vi) The total wages paid (including all pay and benefits provided) each pay period.

(vii) A copy of notifications to employees of the amount of paid sick leave the employee has accrued, as required under 29 CFR 13.5(a)(2).

(viii) A copy of employees' requests to use paid sick leave, if in writing, or, if not in writing, any other records reflecting such employee requests.

(ix) Dates and amounts of paid sick leave taken by employees (unless the Contractor's paid time off policy satisfies the requirements of E.O. 13706 and 29 CFR Part 13 as described in 29 CFR 13.5 (f)(5), leave shall be designated in records as paid sick leave pursuant to E.O. 13706).

(x) A copy of any written responses to employees' requests to use paid sick leave, including explanations for any denials of such requests, as required under 29 CFR 13.5(d)(3).

(xi) Any records reflecting the certification and documentation the Contractor may require an employee to provide under 29 CFR 13.5 (e), including copies of any certification or documentation provided by an employee.

(xii) Any other records showing any tracking of or calculations related to an employee's accrual or use of paid sick leave.

(xiii) The relevant contract.

(xiv) The regular pay and benefits provided to an employee for each use of paid sick leave.

(xv) Any financial payment made for unused paid sick leave upon a separation from employment intended, pursuant to 29 CFR 13.5 (b)(5), to relieve the Contractor from the obligation to reinstate such paid sick leave as otherwise required by 29 CFR 13.5(b)(4).

(2)(i) If the Contractor wishes to distinguish between an employee's covered and noncovered work, the Contractor shall keep records or other proof reflecting such distinctions. Only if the Contractor adequately segregates the employee's time will time spent on noncovered work be excluded from hours worked counted toward the accrual of paid sick leave. Similarly, only if the Contractor adequately segregates the employee's time may the Contractor properly refuse an employee's request to use paid sick leave on the ground that the employee was scheduled to perform noncovered work during the time he or she asked to use paid sick leave.

(ii) If the Contractor estimates covered hours worked by an employee who performs work in connection with contracts covered by the E.O. pursuant to 29 CFR 13.5 (a)(i) or (iii), the Contractor shall keep

records or other proof of the verifiable information on which such estimates are reasonably based. Only if the Contractor relies on an estimate that is reasonable and based on verifiable information will an employee's time spent in connection with noncovered work be excluded from hours worked counted toward the accrual of paid sick leave. If the Contractor estimates the amount of time an employee spends performing in connection with contracts covered by the E.O., the Contractor shall permit the employee to use his or her paid sick leave during any work time for the Contractor.

(3) In the event the Contractor is not obligated by the Service Contract Labor Standards statute, the Wage Rate Requirements (Construction) statute, or the Fair Labor Standards Act to keep records of an employee's hours worked, such as because the employee is exempt from the Fair Labor Standards Act's minimum wage and overtime requirements, and the Contractor chooses to use the assumption permitted by 29 CFR 13.5 (a)(1)(iii), the Contractor is excused from the requirement in paragraph (i)(1)(iv) of this clause and 29 CFR 13.25(a)(4) to keep records of the employee's number of daily and weekly hours worked.

(4) (i) Records relating to medical histories or domestic violence, sexual assault, or stalking, created for purposes of E.O. 13706, whether of an employee or an employee's child, parent, spouse, domestic partner, or other individual related by blood or affinity whose close association with the employee is the equivalent of a family relationship, shall be maintained as confidential records in separate files/records from the usual personnel files.

(ii) If the confidentiality requirements of the Genetic Information Nondiscrimination Act of 2008 (GINA), section 503 of the Rehabilitation Act of 1973, and/or the Americans with Disabilities Act (ADA) apply to records or documents created to comply with the recordkeeping requirements in this contract clause, the records and documents shall also be maintained in compliance with the confidentiality requirements of the GINA, section 503 of the Rehabilitation Act of 1973, and/or ADA as described in 29 CFR 1635.9, 41 CFR 60-741.23(d), and 29 CFR 1630.14(c)(1), respectively.

(iii) The Contractor shall not disclose any documentation used to verify the need to use 3 or more consecutive days of paid sick leave for the purposes listed in 29 CFR 13.5 (c)(1)(iv) (as described in 29 CFR 13.5 (e)(1)(ii)) and shall maintain confidentiality about any domestic abuse, sexual assault, or stalking, unless the employee consents or when disclosure is required by law.

(5) The Contractor shall permit authorized representatives of the Wage and Hour Division to conduct interviews with employees at the worksite during normal working hours.

(6) Nothing in this contract clause limits or otherwise modifies the Contractor's recordkeeping obligations, if any, under the Service Contract Labor Standards statute, the Wage Rate Requirements (Construction) statute, the Fair Labor Standards Act, the Family and Medical Leave Act, E.O. 14026, their respective implementing regulations, or any other applicable law.

(j) Interference/discrimination. (1) The Contractor shall not in any manner interfere with an employee's accrual or use of paid sick leave as required by E.O. 13706 or 29 CFR Part 13. Interference includes, but is not limited to-

(i) Miscalculating the amount of paid sick leave an employee has accrued;

(ii) Denying or unreasonably delaying a response to a proper request to use paid sick leave;

(iii) Discouraging an employee from using paid sick leave;

(iv) Reducing an employee's accrued paid sick leave by more than the amount of such leave used;

(v) Transferring an employee to work on contracts not covered by the E.O. to prevent the accrual or use of paid sick leave;

(vi) Disclosing confidential information contained in certification or other documentation provided to verify the need to use paid sick leave; or

(vii) Making the use of paid sick leave contingent on the employee's finding a replacement worker or the fulfillment of the Contractor's operational needs.

(2) The Contractor shall not discharge or in any other manner discriminate against any employee for-

(i) Using, or attempting to use, paid sick leave as provided for under E.O. 13706 and 29 CFR Part 13;

(ii) Filing any complaint, initiating any proceeding, or otherwise asserting any right or claim under E.O. 13706 and 29 CFR Part 13;

(iii) Cooperating in any investigation or testifying in any proceeding under E.O. 13706 and 29 CFR Part 13; or

(iv) Informing any other person about his or her rights under E.O. 13706 and 29 CFR Part 13.

(k) Notice. The Contractor shall notify all employees performing work on or in connection with a contract covered by the E.O. of the paid sick leave requirements of E.O. 13706, 29 CFR Part 13, and this clause by posting a notice provided by the Department of Labor in a prominent and accessible place at the worksite so it may be readily seen by employees. Contractors that customarily post notices to employees electronically may post the notice electronically, provided such electronic posting is displayed prominently on any website that is maintained by the Contractor, whether external or internal, and customarily used for notices to employees about terms and conditions of employment.

(l) Disputes concerning labor standards. Disputes related to the application of E.O. 13706 to this contract shall not be subject to the general disputes clause of the contract. Such disputes shall be resolved in accordance with the procedures of the Department of Labor set forth in 29 CFR Part 13. Disputes within the meaning of this contract clause include disputes between the Contractor (or any of its subcontractors) and the contracting agency, the Department of Labor, or the employees or their representatives.

(m) Subcontracts. The Contractor shall insert the substance of this clause, including this paragraph (m), in all subcontracts, regardless of dollar value, that are subject to the Service Contract Labor Standards statute or the Wage Rate Requirements (Construction) statute, and are to be performed in whole or in part in the United States.

(End of clause).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR SUPPLIES WHICH ARE, OR WHICH CONTAIN:

- RADIOACTIVE MATERIAL REQUIRING SPECIFIC LICENSING UNDER REGULATIONS ISSUED PURSUANT TO THE ATOMIC ENERGY ACT OF 1954; OR
- RADIOACTIVE MATERIAL NOT REQUIRING SPECIFIC LICENSING IN WHICH THE SPECIFIC ACTIVITY IS GREATER THAN 0.002 MICROCURIES PER GRAM OR THE ACTIVITY PER ITEM EQUALS OR EXCEEDS 0.01 MICROCURIES.

SUCH SUPPLIES INCLUDE, BUT ARE NOT LIMITED TO, AIRCRAFT, AMMUNITION, MISSILES, VEHICLES, ELECTRONIC TUBES, INSTRUMENT PANEL GAUGES, COMPASSES AND IDENTIFICATION MARKERS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM :

- **Subparagraph a:** The Contracting Officer shall insert the number of days required in advance of delivery of the item or completion of the servicing to assure that required licenses are obtained and appropriate personnel are notified to institute any necessary safety and health precautions. See FAR 23.601(d).

14. FAR Clause **52.223-7, Notice of Radioactive Materials** (Jan 1997).

a. The Contractor shall notify the Contracting Officer or designee, in writing, _____ days prior to completion of any servicing required by this contract of, items containing either (1) radioactive material requiring specific licensing under the regulations issued pursuant to the Atomic Energy Act of 1954, as amended, as set forth in Title 10 of the Code of Federal Regulations, in effect on the date of this contract, or (2) other radioactive material not requiring specific licensing in which the specific activity is greater than 0.002 microcuries per gram or the activity per item equals or exceeds 0.01 microcuries. Such notice shall specify the part or parts of the items which contain radioactive materials, a description of the materials, the name and activity of the isotope, the manufacturer of the materials, and any other information known to the Contractor which will put users of the items on notice as to the hazards involved (OMB No. 9000-0107).

b. If there has been no change affecting the quantity of activity, or the characteristics and composition of the radioactive material from deliveries under this contract or prior contracts, the Contractor may request that the Contracting Officer or designee waive the notice requirement in paragraph (a) of this clause. Any such request shall-

   1. Be submitted in writing;
   2. State that the quantity of activity, characteristics, and composition of the radioactive material have not changed; and
   3. Cite the contract number on which the prior notification was submitted and the contracting office to which it was submitted.

c. All items, parts, or subassemblies which contain radioactive materials in which the specific activity is greater than 0.002 microcuries per gram or activity per item equals or exceeds 0.01 microcuries, and all containers in which such items, parts or subassemblies are delivered to the Government shall be clearly marked and labeled

as required by the latest revision of MIL-STD 129 in effect on the date of the contract.

d. This clause, including this paragraph (d), shall be inserted in all subcontracts for radioactive materials meeting the criteria in paragraph (a) of this clause.

(End of clause).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS EXCEEDING $150,000 THAT ARE FOR, OR SPECIFY THE USE OF EPA DESIGNATED ITEMS CONTAINING RECOVERED MATERIALS.)****

15. FAR Clause **52.223-9, Estimate of Percentage of Recovered Material Content for EPA Designated Items** (May 2008).

a. *Definitions.* As used in this clause --

Postconsumer material means a material or finished product that has served its intended use and has been discarded for disposal or recovery, having completed its life as a consumer item. Postconsumer material is a part of the broader category of "recovered material."

Recovered material means waste materials and by-products recovered or diverted from solid waste, but the term does not include those materials and by-products generated from, and commonly reused within, an original manufacturing process.

b. The Contractor, on completion of this contract, shall--

1. Estimate the percentage of the total recovered material content for EPA-designated item(s) delivered and/or used in contract performance, including, if applicable, the percentage of post-consumer material content; and
2. Submit this estimate to _____ [*Contracting Officer complete in accordance with agency procedures*].

(End of clause).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT CONTAIN FAR Clause 52.223-9, ABOVE, IF TECHNICAL PERSONNEL ADVISE THAT ESTIMATES CAN BE VERIFIED.)****

16. **Alternate I** (May 2008), FAR Clause 52.223-9, **Estimate of Percentage of Recovered Material Content for EPA-Designated Items** (May 2008).

As prescribed in 23.406(d), redesignate paragraph (b) of the basic clause as paragraph (c) and add the following paragraph (b) to the basic clause:

b) The Contractor shall execute the following certification required by the Resource Conservation and Recovery Act of 1976 (42 U.S.C. 6962(i)(2)(C)):

Certification

I, _____ (name of certifier), am an officer or employee responsible for the performance of this contract and hereby certify that the percentage of recovered material content for EPA-designated items met the applicable contract specifications or other contractual requirements.

_____
(Signature of the Officer or Employee)

_____
(Typed Name of the Officer or Employee)

_____
(Title)

_____
(Name of Company, Firm, or Organization)

_____
(Date)

(End of certification).

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****(USE BELOW WHEN THE SOLICITATIONS AND CONTRACTS, *EXCEPT FOR CONTRACTS FOR SUPPLIES THAT WILL BE DELIVERED OUTSIDE OF THE UNITED STATES AND ITS OUTLYING AREAS, OR CONTRACTS FOR SERVICES THAT WILL BE PERFORMED OUTSIDE OF THE UNITED STATES AND ITS OUTLYING AREAS* FOR REFRIGERATION EQUIPMENT; AIR CONDITIONING EQUIPMENT; CLEAN AGENT FIRE SUPPRESSION SYSTEMS/EQUIPMENT; BULK REFRIGERANTS AND FIRE SUPPRESSANTS; SOLVENTS, DUSTERS, FREEZING COMPOUNDS, MOLD RELEASE AGENTS, AND ANY OTHER MISCELLANEOUS CHEMICAL SPECIALTY THAT MAY CONTAIN CONTEMPLATING SUBSTANCES OR HIGH GLOBAL WARMING POTENTIAL HYDROFLUOROCARBONS; CORROSION PREVENTION COMPOUNDS, FOAM SEALANTS, AEROSOL MOLD RELEASE AGENTS, AND ANY OTHER PRESERVATIVE OR SEALING COMPOUND THAT MAY CONTAIN CONTEMPLATING SUBSTANCES OR HIGH GLOBAL WARMING POTENTIAL HYDROFLUOROCARBONS; FLUROCARBON LUBRICANTS (PRIMARILY AEROSOLS); AND ANY OTHER MANUFACTURED END PRODUCTS THAT MAY CONTAIN OR BE MANUFACTURED WITH CONTEMPLATING SUBSTANCES.)****

17. FAR Clause **52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons** (Jun 2016)

a. Definitions. As used in this clause--

"Global warming potential" means how much a given mass of a chemical contributes to global warming over a given time period compared to the same mass of carbon dioxide. Carbon Dioxide's global warming potential is defined as 1.0.

"High global warming potential hydrofluorocarbons" means any hydrofluorocarbons in a particular end use for which EPA's Significant New Alternatives Policy (SNAP) program has identified other acceptable alternatives that have lower global warming potential. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables of alternatives available at (http://www.epa.gov/snap/).

"Hydrofluorocarbons" means compounds that only contain hydrogen, fluorine, and carbon.

"Ozone-depleting substance" means any substance the Environmental Protection Agency designates in 40 CFR Part 82 as--

1. Class I, including, but not limited to, chlorofluorocarbons, halons, carbon tetrachloride, and methyl chloroform; or
2. Class II , including, but not limited to hydrochlorofluorocarbons.

b. The Contractor shall label products which contain or are manufactured with ozone-depleting substances in the manner and to the extent required by 42 U.S.C. 7671j (b), (c), (d), and (e) and 40 CFR Part 82, Subpart E, as follows:

Warning

Contains (or manufactured with, if applicable) *_____, a substance(s) which harm(s) public health and environment by destroying ozone in the upper atmosphere.

* The Contractor shall insert the name of the substance(s).

c. *Reporting* . For equipment and appliances that normally each contain 50 or more pounds of hydrofluorocarbons or refrigerant blends containing hydrofluorocarbons, the Contractor shall-

1. Track on an annual basis, between October 1 and September 30, the amount in pounds of hydrofluorocarbons or refrigerant blends containing hydrofluorocarbons contained in the equipment and appliances delivered to the Government under this contract by-
    i. Type of hydrofluorocarbon (e.g., HFC-134a, HFC-125, R-410A, R-404A, etc.);
    ii. Contract number; and
    iii. Equipment/appliance;

2. Report that information to the Contracting Officer for FY16 and to https://sam.gov/content/home , for FY17 and after FY00
    i. Annually by November 30 of each year during contract performance; and
    ii. At the end of contract performance.

d. The Contractor shall refer to EPA's SNAP program (available at http://www.epa.gov/snap) to identify alternatives. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables available at http://www.epa.gov/snap

(End of clause).

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(USE BELOW IN SOLICITATIONS AND CONTRACTS, EXCEPT FOR CONTRACTS FOR SUPPLIES THAT WILL BE DELIVERED OUTSIDE OF THE UNITED STATES AND ITS OUTLYING AREAS, OR CONTRACTS FOR SERVICES THAT WILL BE PERFORMED OUTSIDE OF THE UNITED STATES AND ITS OUTLYING AREAS, FOR PRODUCTS THAT MAY CONTAIN HIGH GLOBAL WARMING POTENTIAL HYDROFLUOROCARBONS AS A PROPELLANT, OR AS A SOLVENT; OR THAT INVOLVE MAINTENANCE OR REPAIR OF ELECTRONIC OR MECHANICAL DEVICES.)

18. FAR Clause **52.223-20, Aerosols** (Jun 2016).

a. *Definitions.* As used in this clause--

"Global warming potential" means how much a given mass of a chemical contributes to global warming over a given time period compared to the same mass of carbon dioxide. Carbon dioxide's global warming potential is defined as 1.0.

"High global warming potential hydrofluorocarbons" means any hydrofluorocarbons in a particular end use for which EPA's Significant New Alternatives Policy (SNAP) program has identified other acceptable alternatives that have lower global warming potential. The SNAP list of alternatives is found at 40 CFR part 82, subpart G. with supplemental tables of alternatives available at http://www.epa.gov/snap/).

"Hydrofluorocarbons" means compounds that contain only hydrogen, fluorine, and carbon.

b. Unless otherwise specified in the contract, the Contractor shall reduce its use, release, or emissions of high global warming potential hydrofluorocarbons, when feasible, from aerosol propellants or solvents under this contract. When determining feasibility of using a particular

alternative, the Contractor shall consider environmental, technical, and economic factors such as--

1. In-use emission rates, energy efficiency;
2. Safety, such as flammability or toxicity;
3. Ability to meet technical performance requirements; and
4. Commercial availability at a reasonable cost.

c. The Contractor shall refer to EPA's SNAP program to identify alternatives. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables available at http://www.epa.gov/snap/.

(End of clause).

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(USE BELOW IN SOLICITATIONS AND CONTRACTS, EXCEPT FOR CONTRACTS FOR SUPPLIES THAT WILL BE DELIVERED OUTSIDE OF THE UNITED STATES AND ITS OUTLYING AREAS, OR CONTRACTS FOR SERVICES THAT WILL BE PERFORMED OUTSIDE OF THE UNITED STATES AND ITS OUTLYING AREAS, FOR PRODUCTS THAT MAY CONTAIN HIGH GLOBAL WARNING POTENTIAL HYDROFLUOROCARBONS OR REFRIGERANT BLENDS CONTAINING HYDROFLUOROCARBONS AS A FOAM BLOWING AGENT.)

19. FAR Clause **52.223-21, Foams** (Jun 2016)

a. *Definitions.* As used in this clause--

"Global warming potential" means how much a given mass of a chemical contributes to global warming over a given time period compared to the same mass of carbon dioxide. Carbon dioxide's global warming potential is defined as 1.0.

"High global warming potential hydrofluorocarbons" means any hydrofluorocarbons in a particular end use for which EPA's Significant New Alternatives Policy (SNAP) program has identified other acceptable alternatives that have lower global warming potential. The SNAP list of alternatives is found at 40 CFR part 82, subpart G. with supplemental tables of alternatives available at http://www.epa.gov/snap/).

"Hydrofluorocarbons" means compounds that contain only hydrogen, fluorine, and carbon.

b. Unless otherwise specified in the contract, the Contractor shall reduce its use, release, and emissions of high global warming potential hydrofluorocarbons and refrigerant blends containing hydrofluorocarbons,

when feasible, from foam blowing agents, under this contract. When determining feasibility of using a particular alternative, the Contractor shall consider environmental, technical, and economic factors such as--

1. In-use emission rates, energy efficiency, and safety;
2. Ability to meet performance requirements; and;
3. Commercial availability at a reasonable cost.

c. The Contractor shall refer to EPA's SNAP program to identify alternatives. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables available at http://www.epa.gov/snap/.

(End of clause).

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****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT LESS THAN $7,032,000.)****

Note: *The Contracting Officer must list all foreign construction material excepted from the requirements of the Buy American statute in paragraph (b)(2).*

20. FAR Clause **52.225-9, Buy American--Construction Materials** (Nov 2021).

(a) *Definitions.* As used in this clause-

Commercially available off-the-shelf (COTS) item -

(1) Means any item of supply (including construction material) that is-

(i) A commercial product (as defined in paragraph (1) of the definition of "commercial product" at Federal Acquisition Regulation (FAR) 2.101);

(ii) Sold in substantial quantities in the commercial marketplace; and

(iii) Offered to the Government, under a contract or subcontract at any tier, without modification, in the same form in which it is sold in the commercial marketplace; and

(2) Does not include bulk cargo, as defined in 46 U.S.C. 40102(4), such as agricultural products and petroleum products.

"Construction material" means an article, material, or supply brought to the construction site by the Contractor or a subcontractor for incorporation

into the building or work. The term also includes an item brought to the site preassembled from articles, materials, or supplies. However, emergency life safety systems, such as emergency lighting, fire alarm, and audio evacuation systems, that are discrete systems incorporated into a public building or work and that are produced as complete systems, are evaluated as a single and distinct construction material regardless of when or how the individual parts or components of those systems are delivered to the construction site. Materials purchased directly by the Government are supplies, not construction material.

Cost of components means-

(1) For components purchased by the Contractor, the acquisition cost, including transportation costs to the place of incorporation into the construction material (whether or not such costs are paid to a domestic firm), and any applicable duty (whether or not a duty-free entry certificate is issued); or

(2) For components manufactured by the Contractor, all costs associated with the manufacture of the component, including transportation costs as described in paragraph (1) of this definition, plus allocable overhead costs, but excluding profit. Cost of components does not include any costs associated with the manufacture of the construction material.

Domestic construction material means-

(1) For construction material that does not consist wholly or predominantly of iron or steel or a combination of both-

(i) An unmanufactured construction material mined or produced in the United States; or

(ii) A construction material manufactured in the United States, if-

(A) The cost of its components mined, produced, or manufactured in the United States exceeds 55 percent of the cost of all its components. Components of foreign origin of the same class or kind for which nonavailability determinations have been made are treated as domestic. Components of unknown origin are treated as foreign; or

(B) The construction material is a COTS item; or

(2) For construction material that consists wholly or predominantly of iron or steel or a combination of both, a construction material manufactured in the United States if the cost of foreign iron and steel constitutes less than

5 percent of the cost of all components used in such construction material. The cost of foreign iron and steel includes but is not limited to the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the construction material and a good faith estimate of the cost of all foreign iron or steel components excluding COTS fasteners. Iron or steel components of unknown origin are treated as foreign. If the construction material contains multiple components, the cost of all the materials used in such construction material is calculated in accordance with the definition of "cost of components".

Fastener means a hardware device that mechanically joins or affixes two or more objects together. Examples of fasteners are nuts, bolts, pins, rivets, nails, clips, and screws.

Foreign construction material means a construction material other than a domestic construction material.

Foreign iron and steel means iron or steel products not produced in the United States. Produced in the United States means that all manufacturing processes of the iron or steel must take place in the United States, from the initial melting stage through the application of coatings, except metallurgical processes involving refinement of steel additives. The origin of the elements of the iron or steel is not relevant to the determination of whether it is domestic or foreign.

Predominantly of iron or steel or a combination of both means that the cost of the iron and steel content exceeds 50 percent of the total cost of all its components. The cost of iron and steel is the cost of the iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the product and a good faith estimate of the cost of iron or steel components excluding COTS fasteners.

Steel means an alloy that includes at least 50 percent iron, between 0.02 and 2 percent carbon, and may include other elements.

"United States" means the 50 States, the District of Columbia, and outlying areas.

b) Domestic preference. (1) This clause implements 41 U.S.C.chapter 83 , Buy American, by providing a preference for domestic construction material. In accordance with 41 U.S.C. 1907 , the domestic content test of the Buy American statute is waived for construction material that is a COTS item, except that for construction material that consists wholly or predominantly of iron or steel or a combination of both, the domestic content test is applied only to the iron and steel content of the construction materials, excluding

COTS fasteners. (See FAR 12.505 (a)(2)). The Contractor shall use only domestic construction material in performing this contract, except as provided in paragraphs (b)(2) and (b)(3) of this clause.

(2) This requirement does not apply to information technology that is a commercial product or to the construction materials or components listed by the Government as follows: _____ *[Contracting Officer to list applicable excepted materials or indicate "none"]*

(3) The Contracting Officer may add other foreign construction material to the list in paragraph (b)(2) of this clause if the Government determines that-

(i) The cost of domestic construction material would be unreasonable. The cost of a particular domestic construction material subject to the requirements of the Buy American statute is unreasonable when the cost of such material exceeds the cost of foreign material by more than 20 percent;

(ii) The application of the restriction of the Buy American statute to a particular construction material would be impracticable or inconsistent with the public interest; or

(iii) The construction material is not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities of a satisfactory quality.

(c) Request for determination of inapplicability of the Buy American statute. (1) (i) Any Contractor request to use foreign construction material in accordance with paragraph (b)(3) of this clause shall include adequate information for Government evaluation of the request, including-

(A) A description of the foreign and domestic construction materials;

(B) Unit of measure;

(C) Quantity;

(D) Price;

(E) Time of delivery or availability;

(F) Location of the construction project;

(G) Name and address of the proposed supplier; and

(H) A detailed justification of the reason for use of foreign construction materials cited in accordance with paragraph (b)(3) of this clause.

(ii) A request based on unreasonable cost shall include a reasonable survey of the market and a completed price comparison table in the format in paragraph (d) of this clause.

(iii) The price of construction material shall include all delivery costs to the construction site and any applicable duty (whether or not a duty-free certificate may be issued).

(iv) Any Contractor request for a determination submitted after contract award shall explain why the Contractor could not reasonably foresee the need for such determination and could not have requested the determination before contract award. If the Contractor does not submit a satisfactory explanation, the Contracting Officer need not make a determination.

(2) If the Government determines after contract award that an exception to the Buy American statute applies and the Contracting Officer and the Contractor negotiate adequate consideration, the Contracting Officer will modify the contract to allow use of the foreign construction material. However, when the basis for the exception is the unreasonable price of a domestic construction material, adequate consideration is not less than the differential established in paragraph (b)(3)(i) of this clause.

(3) Unless the Government determines that an exception to the Buy American statute applies, use of foreign construction material is noncompliant with the Buy American statute.

(d) *Data.* To permit evaluation of requests under paragraph (c) of this clause based on unreasonable cost, the Contractor shall include the following information and any applicable supporting data based on the survey of suppliers:

FOREIGN AND DOMESTIC CONSTRUCTION MATERIALS PRICE COMPARISON

Construction Material Description	Unit of Measure	Quantity	Price (dollars)*
Item 1			
Foreign construction material			

Construction Material Description	Unit of Measure	Quantity	Price (dollars)*
Domestic construction material			
Item 2			
Foreign construction material			
Domestic construction material			

[** Include all delivery costs to the construction site and any applicable duty (whether or not a duty-free entry certificate is issued)].*

[List name, address, telephone number, and contact for suppliers surveyed. Attach copy of response; if oral, attach summary.]

[Include other applicable supporting information.]

(End of clause).

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****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,032,000 OR MORE.)****

Note: *The Contracting Officer must list in paragraph (b)(3) of the clause, all foreign construction material excepted from the requirements of the Buy American statute, other than designated country construction material.*

21. FAR Clause **52.225-11, Buy American--Construction Materials Under Trade Agreements** (Dec 2022).

(a) *Definitions.* As used in this clause-

Caribbean Basin country construction material means a construction material that-

(1) Is wholly the growth, product, or manufacture of a Caribbean Basin country; or

(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in a Caribbean Basin country into a new and different construction material distinct from the materials from which it was transformed.

Commercially available off-the-shelf (COTS) item -

(1) Means any item of supply (including construction material) that is-

(i) A commercial product (as defined in paragraph (1) of the definition at Federal Acquisition Regulation (FAR) 2.101);

(ii) Sold in substantial quantities in the commercial marketplace; and

(iii) Offered to the Government, under a contract or subcontract at any tier, without modification, in the same form in which it is sold in the commercial marketplace; and

(2) Does not include bulk cargo, as defined in 46 U.S.C.40102(4) , such as agricultural products and petroleum products.

Component means an article, material, or supply incorporated directly into a construction material.

Construction material means an article, material, or supply brought to the construction site by the Contractor or subcontractor for incorporation into the building or work. The term also includes an item brought to the site preassembled from articles, materials, or supplies. However, emergency life safety systems, such as emergency lighting, fire alarm, and audio evacuation systems, that are discrete systems incorporated into a public building or work and that are produced as complete systems, are evaluated as a single and distinct construction material regardless of when or how the individual parts or components of those systems are delivered to the construction site. Materials purchased directly by the Government are supplies, not construction material.

Cost of components means -

(1) For components purchased by the Contractor, the acquisition cost, including transportation costs to the place of incorporation into the construction material (whether or not such costs are paid to a domestic firm), and any applicable duty (whether or not a duty-free entry certificate is issued); or

(2) For components manufactured by the Contractor, all costs associated with the manufacture of the component, including transportation costs as described in paragraph (1) of this definition, plus allocable overhead costs, but excluding profit. Cost of components does not include any costs associated with the manufacture of the construction material.

Designated country means any of the following countries:

(1) A World Trade Organization Government Procurement Agreement (WTO GPA) country (Armenia, Aruba, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, Ukraine, or United Kingdom);

(2) A Free Trade Agreement (FTA) country (Australia, Bahrain, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Oman, Panama, Peru, or Singapore);

(3) A least developed country (Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kiribati, Laos, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, South Sudan, Tanzania, Timor-Leste, Togo, Tuvalu, Uganda, Vanuatu, Yemen, or Zambia); or

(4) A Caribbean Basin country (Antigua and Barbuda, Aruba, Bahamas, Barbados, Belize, Bonaire, British Virgin Islands, Curacao, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saba, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Sint Eustatius, Sint Maarten, or Trinidad and Tobago).

"Designated country construction material" means a construction material that is a WTO GPA country construction material, an FTA country construction material, a least developed country construction material, or a Caribbean Basin country construction material.

Domestic construction material means-

(1) For construction material that does not consist wholly or predominantly of iron or steel or a combination of both-

(i) An unmanufactured construction material mined or produced in the United States; or

(ii) A construction material manufactured in the United States, if-

(A) The cost of its components mined, produced, or manufactured in the United States exceeds 55 percent of the cost of all its components. Components of foreign origin of the same class or kind for which nonavailability determinations have been made are treated as domestic. Components of unknown origin are treated as foreign; or

(B) The construction material is a COTS item; or

(2) For construction material that consists wholly or predominantly of iron or steel or a combination of both, a construction material manufactured in the United States if the cost of foreign iron and steel constitutes less than 5 percent of the cost of all components used in such construction material. The cost of foreign iron and steel includes but is not limited to the cost of foreign iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the construction material and a good faith estimate of the cost of all foreign iron or steel components excluding COTS fasteners. Iron or steel components of unknown origin are treated as foreign. If the construction material contains multiple components, the cost of all the materials used in such construction material is calculated in accordance with the definition of "cost of components".

Fastener means a hardware device that mechanically joins or affixes two or more objects together. Examples of fasteners are nuts, bolts, pins, rivets, nails, clips, and screws.

Foreign construction material means a construction material other than a domestic construction material.

Foreign iron and steel means iron or steel products not produced in the United States. Produced in the United States means that all manufacturing processes of the iron or steel must take place in the United States, from the initial melting stage through the application of coatings, except metallurgical processes involving refinement of steel additives. The origin of the elements of the iron or steel is not relevant to the determination of whether it is domestic or foreign.

Free Trade Agreement country construction material means a construction material that-

(1) Is wholly the growth, product, or manufacture of a Free Trade Agreement (FTA) country; or

(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed

in a FTA country into a new and different construction material distinct from the materials from which it was transformed.

Least developed country construction material means a construction material that-

(1) Is wholly the growth, product, or manufacture of a least developed country; or

(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in a least developed country into a new and different construction material distinct from the materials from which it was transformed.

Predominantly of iron or steel or a combination of both means that the cost of the iron and steel content exceeds 50 percent of the total cost of all its components. The cost of iron and steel is the cost of the iron or steel mill products (such as bar, billet, slab, wire, plate, or sheet), castings, or forgings utilized in the manufacture of the product and a good faith estimate of the cost of iron or steel components excluding COTS fasteners.

Steel means an alloy that includes at least 50 percent iron, between 0.02 and 2 percent carbon, and may include other elements.

United States means the 50 States, the District of Columbia, and outlying areas.

WTO GPA country construction material means a construction material that-

(1) Is wholly the growth, product, or manufacture of a WTO GPA country; or

(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in a WTO GPA country into a new and different construction material distinct from the materials from which it was transformed.

(b) Construction materials. (1) This clause implements 41 U.S.C.chapter 83 , Buy American, by providing a preference for domestic construction material. In accordance with 41 U.S.C.1907 , the domestic content test of the Buy American statute is waived for construction material that is a COTS item, except that for construction material that consists wholly or predominantly of iron or steel or a combination of both, the domestic content test is applied only to the iron and steel content of the construction

material, excluding COTS fasteners. (See FAR 12.505 (a)(2)). In addition, the Contracting Officer has determined that the WTO GPA and Free Trade Agreements (FTAs) apply to this acquisition. Therefore, the Buy American restrictions are waived for designated country construction materials.

(2) The Contractor shall use only domestic or designated country construction material in performing this contract, except as provided in paragraphs (b)(3) and (b)(4) of this clause.

(3) The requirement in paragraph (b)(2) of this clause does not apply to information technology that is a commercial product or to the construction materials or components listed by the Government as follows: _____

[Contracting Officer to list applicable excepted materials or indicate "none"]

(4) The Contracting Officer may add other foreign construction material to the list in paragraph (b)(3) of this clause if the Government determines that-

(i) The cost of domestic construction material would be unreasonable. The cost of a particular domestic construction material subject to the restrictions of the Buy American statute is unreasonable when the cost of such material exceeds the cost of foreign material by more than 20 percent;

(ii) The application of the restriction of the Buy American Act to a particular construction material would be impracticable or inconsistent with the public interest; or

(iii) The construction material is not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities of a satisfactory quality.

(c) Request for determination of inapplicability of the Buy American statute. (1) (i) Any Contractor request to use foreign construction material in accordance with paragraph (b)(4) of this clause shall include adequate information for Government evaluation of the request, including-

(A) A description of the foreign and domestic construction materials;

(B) Unit of measure;

(C) Quantity;

(D) Price;

(E) Time of delivery or availability;

(F) Location of the construction project;

(G) Name and address of the proposed supplier; and

(H) A detailed justification of the reason for use of foreign construction materials cited in accordance with paragraph (b)(3) of this clause.

(ii) A request based on unreasonable cost shall include a reasonable survey of the market and a completed price comparison table in the format in paragraph (d) of this clause.

(iii) The price of construction material shall include all delivery costs to the construction site and any applicable duty (whether or not a duty-free certificate may be issued).

(iv) Any Contractor request for a determination submitted after contract award shall explain why the Contractor could not reasonably foresee the need for such determination and could not have requested the determination before contract award. If the Contractor does not submit a satisfactory explanation, the Contracting Officer need not make a determination.

(2) If the Government determines after contract award that an exception to the Buy American statute applies and the Contracting Officer and the Contractor negotiate adequate consideration, the Contracting Officer will modify the contract to allow use of the foreign construction material. However, when the basis for the exception is the unreasonable price of a domestic construction material, adequate consideration is not less than the differential established in paragraph (b)(4)(i) of this clause.

(3) Unless the Government determines that an exception to the Buy American statute applies, use of foreign construction material is noncompliant with the Buy American statute.

(d) *Data.* To permit evaluation of requests under paragraph (c) of this clause based on unreasonable cost, the Contractor shall include the following information and any applicable supporting data based on the survey of suppliers:

Foreign and Domestic Construction Material

Construction Material Description	Unit of Measure	Quantity	Price (dollars)*
Item 1			
Foreign construction material			
Domestic construction material			
Item 2			
Foreign construction material			
Domestic construction material			

[**Include all delivery cots to the construction site and any applicable duty (whether or not a duty-free entry certificate is issued*)].

[*List name, address, telephone number, and contact for suppliers surveyed. Attach copy of response; if oral, attach summary.*]

[*Include other applicable supporting information.*]

(End of clause).

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****(WHEN USING FUNDS OTHER THAN RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,032,000 OR MORE, BUT LESS THAN $12,001,460.)****

Note: *The Contracting Officer must list in paragraph (b)(3) of the clause, all foreign construction material excepted from the requirements of the Buy American statute, unless the excepted foreign construction material is from a designated country other than Bahrain, Mexico, and Oman.*

22. **Alternate I** (Dec 2022), FAR Clause **52.225-11, Buy American--Construction Materials Under Trade Agreements** (Dec 2022).

As prescribed in 25.1102(c)(3), add the following definition of "Bahrainian, Mexican, or Omani construction material" to paragraph (a) of the basic clause, and substitute the following paragraphs (b)(1) and (b)(2) for paragraphs (b)(1) and (b)(2) of the basic clause:

Bahrainian, Mexican, or Omani construction material means a construction material that--

(1) Is wholly the growth, product, or manufacture of Bahrain, Mexico, or Oman; or

(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in Bahrain, Mexico, or Oman into a new and different construction material distinct from the materials from which it was transformed.

b) Construction materials.

(1) This clause implements the Buy American (41 U.S.C. chapter 83) by providing a preference for domestic construction material. In accordance with 41 U.S.C. 1907, the domestic content test of the Buy American statute is waived for construction material that is a COTS item, except that for construction material that consists wholly or predominantly of iron or steel or a combination of both, the domestic content test is applied only to the iron and steel content of the construction material, excluding COTS fasteners. (See 12.505(a)(2)). In addition, the Contracting Officer has determined that the WTO GPA and all the Free Trade Agreements except the Bahrain FTA, United States-Mexico-Canada Agreement, and the Oman FTA apply to this acquisition. Therefore, the Buy American statute restrictions are waived for designated country construction materials other than Bahrainian, Mexican, or Omani construction materials.

(2) The Contractor shall use only domestic or designated country construction material other than Bahrainian, Mexican, or Omani construction material in performing this contract, except as provided in paragraphs (b)(3) and (b)(4) of this clause.

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****(WHEN USING RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT LESS THAN $7,032,000.)****

Note: *The Contracting Officer must list all foreign construction material excepted from the requirements of the Buy American statute in paragraph (b)(3).*

23. FAR Clause **52.225-21, Required Use of American Iron, Steel, and Manufactured Goods-Buy American Statute--Construction Materials** (Jan 2021).

(a) *Definitions.* As used in this clause-

Component means an article, material, or supply incorporated directly into a construction material.

Construction material means an article, material, or supply brought to the construction site by the Contractor or a subcontractor for incorporation into the building or work. The term also includes an item brought to the site preassembled from articles, materials, or supplies. However, emergency life safety systems, such as emergency lighting, fire alarm, and audio evacuation

systems, that are discrete systems incorporated into a public building or work and that are produced as complete systems, are evaluated as a single and distinct construction material regardless of when or how the individual parts or components of those systems are delivered to the construction site.

Domestic construction material means the following-

(1) An unmanufactured construction material mined or produced in the United States. (The Buy American statute applies.)

(2) A manufactured construction material that is manufactured in the United States and, if the construction material consists wholly or predominantly of iron or steel, the iron or steel was produced in the United States. (Section 1605 of the Recovery Act applies.)

Foreign construction material means a construction material other than a domestic construction material.

Manufactured construction material means any construction material that is not unmanufactured construction material.

Steel means an alloy that includes at least 50 percent iron, between 0.02 and 2 percent carbon, and may include other elements.

United States means the 50 States, the District of Columbia, and outlying areas.

Unmanufactured construction material means raw material brought to the construction site for incorporation into the building or work that has not been-

(1) Processed into a specific form and shape; or

(2) Combined with other raw material to create a material that has different properties than the properties of the individual raw materials.

(b) Domestic preference. (1) This clause implements-

(i) Section 1605 of the American Recovery and Reinvestment Act of 2009 (Recovery Act) (Pub. L. 111-5), by requiring, unless an exception applies, that all manufactured construction material in the project is manufactured in the United States and, if the construction material consists wholly or predominantly of iron or steel, the iron or steel was produced in the United States (produced in the United States means that all manufacturing

processes of the iron or steel must take place in the United States, except metallurgical processes involving refinement of steel additives); and

(ii) 41 U.S.C chapter 83 , Buy American, by providing a preference for unmanufactured construction material mined or produced in the United States over unmanufactured construction material mined or produced in a foreign country.

(2) The Contractor shall use only domestic construction material in performing this contract, except as provided in paragraph (b)(3) and (b)(4) of this clause.

(3) This requirement does not apply to the construction material or components listed by the Government as follows: _____ *[Contracting Officer to list applicable excepted materials or indicate "none"]*

(4) The Contracting Officer may add other foreign construction material to the list in paragraph (b)(3) of this clause if the Government determines that-

(i) The cost of domestic construction material would be unreasonable;

(A) The cost of domestic manufactured construction material, when compared to the cost of comparable foreign manufactured construction material, is unreasonable when the cumulative cost of such material will increase the cost of the contract by more than 25 percent;

(B) The cost of domestic unmanufactured construction material is unreasonable when the cost of such material exceeds the cost of comparable foreign unmanufactured construction material by more than 20 percent;

(ii) The construction material is not mined, produced, or manufactured in the United States in sufficient and reasonably available quantities and of a satisfactory quality;

(iii) The application of the restriction of section 1605 of the Recovery Act to a particular manufactured construction material would be inconsistent with the public interest or the application of the Buy American statute to a particular unmanufactured construction material would be impracticable or inconsistent with the public interest.

(c) *Request for determination of inapplicability of section 1605 of the Recovery Act or the Buy American statute.* (1) (i) Any Contractor request to

use foreign construction material in accordance with paragraph (b)(4) of this clause shall include adequate information for Government evaluation of the request, including-

(A) A description of the foreign and domestic construction materials;

(B) Unit of measure;

(C) Quantity;

(D) Cost;

(E) Time of delivery or availability;

(F) Location of the construction project;

(G) Name and address of the proposed supplier; and

(H) A detailed justification of the reason for use of foreign construction materials cited in accordance with paragraph (b)(4) of this clause.

(ii) A request based on unreasonable cost shall include a reasonable survey of the market and a completed cost comparison table in the format in paragraph (d) of this clause.

(iii) The cost of construction material shall include all delivery costs to the construction site and any applicable duty.

(iv) Any Contractor request for a determination submitted after contract award shall explain why the Contractor could not reasonably foresee the need for such determination and could not have requested the determination before contract award. If the Contractor does not submit a satisfactory explanation, the Contracting Officer need not make a determination.

(2) If the Government determines after contract award that an exception to section 1605 of the Recovery Act or the Buy American statute applies and the Contracting Officer and the Contractor negotiate adequate consideration, the Contracting Officer will modify the contract to allow use of the foreign construction material. However, when the basis for the exception is the unreasonable cost of a domestic construction material, adequate consideration is not less than the differential established in paragraph (b)(4)(i) of this clause.

(3) Unless the Government determines that an exception to section 1605 of the Recovery Act or the Buy American statute applies, use of foreign construction material is noncompliant with section 1605 of the American Recovery and Reinvestment Act or the Buy American statute.

(d) *Data.* To permit evaluation of requests under paragraph (c) of this clause based on unreasonable cost, the Contractor shall include the following information and any applicable supporting data based on the survey of suppliers:

FOREIGN AND DOMESTIC CONSTRUCTION MATERIALS PRICE COMPARISON

Construction Material Description	Unit of Measure	Quantity	Price (dollars)*
Item 1			
Foreign construction material			
Domestic construction material			
Item 2			
Foreign construction material			
Domestic construction material			

[List name, address, telephone number, and contact for suppliers surveyed. Attach copy of response; if oral, attach summary.]

[Include other applicable supporting information.]

*[*Include all delivery costs to the construction site.]*

(End of clause).

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****(WHEN USING RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,032,000 OR MORE.)****

Note: *The Contracting Officer must list, in paragraph (b)(3) of the clause, all foreign construction material excepted from the Buy American statute or section 1605 of the Recovery Act, other than Recovery Act designated country construction material.*

24. FAR Clause **52.225-23, Required Use of American Iron, Steel, and Manufactured Goods--Buy American Statute--Construction Materials Under Trade Agreements** (Dec 2022).

(a) Definitions. As used in this clause-

Component means an article, material, or supply incorporated directly into a construction material.

Construction material means an article, material, or supply brought to the construction site by the Contractor or subcontractor for incorporation into the building or work. The term also includes an item brought to the site preassembled from articles, materials, or supplies. However, emergency life safety systems, such as emergency lighting, fire alarm, and audio evacuation systems, that are discrete systems incorporated into a public building or work and that are produced as complete systems, are evaluated as a single and distinct construction material regardless of when or how the individual parts or components of those systems are delivered to the construction site.

Designated country means any of the following countries:

(1) A World Trade Organization Government Procurement Agreement (WTO GPA) country (Armenia, Aruba, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, Ukraine, or United Kingdom);

(2) A Free Trade Agreement (FTA) country (Australia, Bahrain, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Oman, Panama, Peru, or Singapore);

(3) A least developed country (Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kiribati, Laos, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, South Sudan, Tanzania, Timor-Leste, Togo, Tuvalu, Uganda, Vanuatu, Yemen, or Zambia); or

(4) A Caribbean Basin country (Antigua and Barbuda, Aruba, Bahamas, Barbados, Belize, Bonaire, British Virgin Islands, Curacao, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saba, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, Sint Eustatius, Sint Maarten, or Trinidad and Tobago).

Designated country construction material means a construction material that is a WTO GPA country construction material, an FTA country construction material, a least developed country construction material, or a Caribbean Basin country construction material.

Domestic construction material means the following:

(1) An unmanufactured construction material mined or produced in the United States. (The Buy American statute applies.)

(2) A manufactured construction material that is manufactured in the United States and, if the construction material consists wholly or predominantly of iron or steel, the iron or steel was produced in the United States. (Section 1605 of the Recovery Act applies.)

Foreign construction material means a construction material other than a domestic construction material.

Free trade agreement (FTA) country construction material means a construction material that-

(1) Is wholly the growth, product, or manufacture of an FTA country; or

(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in an FTA country into a new and different construction material distinct from the materials from which it was transformed.

Least developed country construction material means a construction material that-

(1) Is wholly the growth, product, or manufacture of a least developed country; or

(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in a least developed country into a new and different construction material distinct from the materials from which it was transformed.

Manufactured construction material means any construction material that is not unmanufactured construction material.

Nondesignated country means a country other than the United States or a designated country.

Recovery Act designated country means any of the following countries:

(1) A World Trade Organization Government Procurement Agreement (WTO GPA) country (Armenia, Aruba, Australia, Austria, Belgium, Bulgaria, Canada, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Moldova, Montenegro, Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, Ukraine, or United Kingdom);

(2) A Free Trade Agreement country (FTA) (Australia, Bahrain, Chile, Colombia, Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras, Korea (Republic of), Mexico, Morocco, Nicaragua, Oman, Panama, Peru, or Singapore); or

(3) A least developed country (Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kiribati, Laos, Lesotho, Liberia, Madagascar, Malawi, Mali, Mauritania, Mozambique, Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, South Sudan, Tanzania, Timor-Leste, Togo, Tuvalu, Uganda, Vanuatu, Yemen, or Zambia).

Recovery Act designated country construction material means a construction material that is a WTO GPA country construction material, an FTA country construction material, or a least developed country construction material.

Steel means an alloy that includes at least 50 percent iron, between 0.02 and 2 percent carbon, and may include other elements.

United States means the 50 States, the District of Columbia, and outlying areas.

Unmanufactured construction material means raw material brought to the construction site for incorporation into the building or work that has not been-

(1) Processed into a specific form and shape; or

(2) Combined with other raw material to create a material that has different properties than the properties of the individual raw materials.

WTO GPA country construction material means a construction material that-

(1) Is wholly the growth, product, or manufacture of a WTO GPA country; or

(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in a WTO GPA country into a new and different construction material distinct from the materials from which it was transformed.

(b) Construction materials.

(1) The restrictions of section 1605 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act) do not apply to Recovery Act designated country manufactured construction material. The restrictions of the Buy American statute do not apply to designated country unmanufactured construction material. Consistent with U.S. obligations under international agreements, this clause implements-

(i) Section 1605 of the Recovery Act by requiring, unless an exception applies, that all manufactured construction material in the project is manufactured in the United States and, if the construction material consists wholly or predominantly of iron or steel, the iron or steel was produced in the United States (produced in the United States means that all manufacturing processes of the iron or steel must take place in the United States, except metallurgical processes involving refinement of steel additives); and.

(ii) The Buy American statute by providing a preference for unmanufactured construction material mined or produced in the United States over unmanufactured construction material mined or produced in a nondesignated country.

(2) The Contractor shall use only domestic construction material, Recovery Act designated country manufactured construction material, or designated country unmanufactured construction material in performing this contract, except as provided in paragraphs (b)(3) and (b)(4) of this clause.

(3) The requirement in paragraph (b)(2) of this clause does not apply to the construction materials or components listed by the Government as follows:

[Contracting Officer to list applicable excepted materials or indicate "none".]

(4) The Contracting Officer may add other construction material to the list in paragraph (b)(3) of this clause if the Government determines that-

(i) The cost of domestic construction material would be unreasonable;

(A) The cost of domestic manufactured construction material is unreasonable when the cumulative cost of such material, when compared to the cost of comparable foreign manufactured construction material, other than Recovery Act designated country construction material, will increase the overall cost of the contract by more than 25 percent;

(B) The cost of domestic unmanufactured construction material is unreasonable when the cost of such material exceeds the cost of comparable foreign unmanufactured construction material, other than designated country construction material, by more than 20 percent;

(ii) The construction material is not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities of a satisfactory quality; or

(iii) The application of the restriction of section 1605 of the Recovery Act to a particular manufactured construction material would be inconsistent with the public interest or the application of the Buy American statute to a particular unmanufactured construction material would be impracticable or inconsistent with the public interest.

(c) *Request for determination of inapplicability of section 1605 of the Recovery Act or the Buy American statute.*

(1)(i) Any Contractor request to use foreign construction material in accordance with paragraph (b)(4) of this clause shall include adequate information for Government evaluation of the request, including-

(A) A description of the foreign and domestic construction materials;

(B) Unit of measure;

(C) Quantity;

(D) Cost;

(E) Time of delivery or availability;

(F) Location of the construction project;

(G) Name and address of the proposed supplier; and

(H) A detailed justification of the reason for use of foreign construction materials cited in accordance with paragraph (b)(4) of this clause.

(ii) A request based on unreasonable cost shall include a reasonable survey of the market and a completed cost comparison table in the format in paragraph (d) of this clause.

(iii) The cost of construction material shall include all delivery costs to the construction site and any applicable duty.

(iv) Any Contractor request for a determination submitted after contract award shall explain why the Contractor could not reasonably foresee the need for such determination and could not have requested the determination before contract award. If the Contractor does not submit a satisfactory explanation, the Contracting Officer need not make a determination.

(2) If the Government determines after contract award that an exception to section 1605 of the Recovery Act or the Buy American statute applies and the Contracting Officer and the Contractor negotiate adequate consideration, the Contracting Officer will modify the contract to allow use of the foreign construction material. However, when the basis for the exception is the unreasonable cost of a domestic construction material, adequate consideration is not less than the differential established in paragraph (b)(4)(i) of this clause.

(3) Unless the Government determines that an exception to section 1605 of the Recovery Act or the Buy American statute applies, use of foreign construction material other than manufactured construction material from a Recovery Act designated country or unmanufactured construction material from a designated country is noncompliant with the applicable statute.

(d) *Data.* To permit evaluation of requests under paragraph (c) of this clause based on unreasonable cost, the Contractor shall include the following information and any applicable supporting data based on the survey of suppliers:

FOREIGN (NONDESIGNATED COUNTRY) AND DOMESTIC CONSTRUCTION MATERIALS COST COMPARISON

Construction Material Description	Unit of Measure	Quantity	Cost (dollars)*
Item 1:			
Foreign construction material			
Domestic construction material			
Item 2:			
Foreign construction material			
Domestic construction material			

[List name, address, telephone number, and contact for suppliers surveyed. Attach copy of response; if oral, attach summary.]

[Include other applicable supporting information.]

*[*Include all delivery costs to the construction site.]*

(End of clause).

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****(WHEN USING RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES, VALUED AT $7,032,000 OR MORE BUT LESS THAN $12,001,460.)****

Note: *The Contracting Officer must list, in paragraph (b)(3) of the clause, all foreign construction material excepted from the Buy American statute or section 1605 of the Recovery Act, unless the excepted foreign construction material is from a Recovery Act designated country other than Bahrain, Mexico, or Oman.*

25. **Alternate I** (May 2014) FAR Clause **52.225-23, Required Use of American Iron, Steel, and Manufactured Goods-Buy American Statue-Construction Materials under Trade Agreements** (Dec 2022).

Alternate I (May 2014). As prescribed in 25.1102 (e), add the following definition of "Bahrainian, Mexican, or Omani construction material" to paragraph (a) of the basic clause, and substitute the following paragraphs (b)(1) and (b)(2) for paragraphs (b)(1) and (b)(2) of the basic clause:

Bahrainian, Mexican, or Omani construction material" means a construction material that --

(1) Is wholly the growth, product, or manufacture of Bahrain, Mexico, or Oman; or
(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in Bahrain, Mexico, or Oman into a new and different construction material distinct from the materials from which it was transformed.

(b) *Construction materials* . (1) The restrictions of section 1605 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act) do not apply to Recovery Act designated country manufactured construction material. The restrictions of the Buy American statute do not apply to designated country unmanufactured construction material. Consistent with U.S. obligations under international agreements, this clause implements--

(i) Section 1605 of the Recovery Act, by requiring, unless an exception applies, that all manufactured construction material in the project is manufactured in the United States and, if the construction material consists wholly or predominantly of iron or steel, the iron or steel was produced in the United States (produced in the United States means that all manufacturing processes of the iron or steel must take place in the United States, except metallurgical processes involving refinement of steel additives); and
(ii) The Buy American statute by providing a preference for unmanufactured construction material mined or produced in the United States over unmanufactured construction material mined or produced in a nondesignated country.

(2) The Contractor shall use only domestic construction material, Recovery Act designated country manufactured construction material, or designated country unmanufactured construction material, other than Bahrainian, Mexican, or Omani construction material, in performing this contract, except as provided in paragraphs (b)(3) and (b)(4) of this clause.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS GREATER THAN $30,000 FOR THE PROVISION, SERVICE, OR SALE OF FOOD IN THE UNITED STATES.)****

26. FAR Clause **52.226-6, Promoting Excess Food Donation to Nonprofit Organizations** (Jun 2020).

(a) *Definitions* . As used in this clause--

Apparently wholesome food means food that meets all quality and labeling standards imposed by Federal, State, and local laws and regulations even

though the food may not be readily marketable due to appearance, age, freshness, grade, size, surplus, or other conditions.

Excess food means food that--

(1) Is not required to meet the needs of the executive agencies; and
(2) Would otherwise be discarded.

Food-insecure means inconsistent access to sufficient, safe, and nutritious food.
Nonprofit organization means any organization that is--

(1) Described in section 501(c) of the Internal Revenue Code of 1986; and
(2) Exempt from tax under section 501(a) of that Code.

(b) In accordance with the Federal Food Donation Act of 2008 (Pub. L. 110-247), the Contractor is encouraged, to the maximum extent practicable and safe, to donate excess, apparently wholesome
food to nonprofit organizations that provide assistance to food-insecure people in the United States.

(c) *Costs*. (1) The Contractor, including any subcontractors, shall assume the responsibility for all the costs and the logistical support to collect, transport, maintain the safety of, or distribute the excess, apparently wholesome food to the nonprofit organization(s) that provides assistance to food-insecure people.

(2) The Contractor will not be reimbursed for any costs incurred or associated with the donation of excess foods. Any costs incurred for excess food donations are unallowable.

(d) *Liability* . The Government and the Contractor, including any subcontractors, shall be exempt from civil and criminal liability to the extent provided under the Bill Emerson Good Samaritan Food Donation Act (42 U.S.C. 1791). Nothing in this clause shall be construed to supersede State or local health regulations (subsection (f) of 42 U.S.C. 1791).

(e) *Flowdown*. The Contractor shall insert this clause in all contracts, task orders, delivery orders, purchase orders, and other similar instruments greater than $25,000 with its subcontractors or suppliers, at any tier, who will perform, under this contract, the provision, service, or sale of food in the United States.

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****(USE BELOW IN RFPs AND CONTRACTS FOR CONSTRUCTION, WHEN THE ESTIMATED VALUE OF THE ACQUISITION EXCEEDS $35,000 BUT DOES NOT EXCEED $150,000.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- Subparagraph (a): FAR 28.102-1(b) contains information about payment protections to be included in this subparagraph.

27. FAR Clause **52.228-13, Alternative Payment Protections** (Jul 2000).

(a) The Contractor shall submit one of the following payment protections:

(b) The amount of the payment protection shall be 100 percent of the contract price.

(c) The submission of the payment protection is required within _ days of contract award.

(d) The payment protection shall provide protection for the full contract performance period plus a one-year period.

(e) Except for escrow agreements and payment bonds, which provide their own protection procedures, the Contracting Officer is authorized to access funds under the payment protection when it has been alleged in writing by a supplier of labor or material that a nonpayment has occurred, and to withhold such funds pending resolution by administrative or judicial proceedings or mutual agreement of the parties.

(f) When a tripartite escrow agreement is used, the Contractor shall utilize only suppliers of labor and material that signed the escrow agreement.

(End of clause).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS (OTHER THAN CONSTRUCTION) THAT CONTAIN A REQUIREMENT FOR BOTH PAYMENT AND PERFORMANCE BONDS. THE CO MUST DETERMINE THE AMOUNT OF EACH BOND FOR INSERTION IN THE CLAUSE AND SET A PERIOD OF TIME (NORMALLY 10 DAYS) FOR RETURN OF THE EXECUTED BONDS.)****

28. FAR Clause **52.228-16, Performance And Payment Bonds--Other Than Construction** (Nov 2006).

(a) **Definitions**. As used in this clause --

Original Contract price means the award price of the contract or, for requirements contracts, the price payable for the estimated quantity; or, for indefinite-quantity contracts, the price payable for the specified minimum quantity. Original contract price does not include the price of any options, except those options exercised at the time of contract award.

(b) The Contractor shall furnish a performance bond (Standard Form 1418) for the protection of the Government in an amount equal to _ percent of the original contract price and a payment bond (Standard Form 1416) in an amount equal to _ percent of the original contract price.

(c) The Contractor shall furnish all executed bonds, including any necessary reinsurance agreements, to the Contracting Officer, within _ days, but in any event, before starting work.

(d) The Government may require additional performance and payment bond protection if the contract price is increased. The Government may secure the additional protection by directing the Contractor to increase the penal amount of the existing bonds or to obtain additional bonds.

(e) The bonds shall be in the form of firm commitment, supported by corporate sureties whose names appear on the list contained in Treasury Department Circular 570, individual sureties, or by other acceptable security such as postal money order, certified check, cashier's check, irrevocable letter of credit, or, in accordance with Treasury Department regulations, certain bonds or notes of the United States. Treasury Circular 570 is published in the Federal Register, or may be obtained from the U.S. Department of Treasury, Financial Management Service, Surety Bond Branch, 3700 East West Highway, Room 6F01, Hyattsville, MD 20782. or via the internet at http://www.fms.treas.gov/c570.

(End of clause).

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****(USE BELOW WITH THE ABOVE CLAUSE (ALTERNATE I) WHEN ONLY PERFORMANCE BONDS ARE REQUIRED.)****

Alternate I (Jul 2000) of FAR Clause **52.228-16, Performance and Payment Bonds--Other Than Construction** (Nov 2006).

As prescribed in 28.103-4, substitute the following paragraphs (b) and (d) for paragraphs (b) and (d) of the basic clause:

(b) The Contractor shall furnish a performance bond (Standard Form 1418) for the protection to the Government in an amount equal to percent of the original contract price.

(d) The Government may require additional performance bond protection if the contract price is increased. The Government may secure the additional protection by directing the Contractor to increase the penal amount of the existing bond or to obtain an additional bond.

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****(USE BELOW IN ONE YEAR INDEFINITE QUANTITY AND REQUIREMENTS SOLICITATIONS AND CONTRACTS FOR SERVICES WHEN THE CONTRACT IS FUNDED BY ANNUAL APPROPRIATIONS AND IS TO EXTEND BEYOND THE INITIAL FISCAL YEAR.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. Enter the last date in which contract funds are presently available in the first text area.
2. Enter the last date in which the Government shall be legally liable for payment of performance under the contract in the second text area.

29. FAR Clause **52.232-19, Availability of Funds for the Next Fiscal Year** (Apr 1984).

Funds are not presently available for performance under this contract beyond _____ . The Government's obligation for performance of this contract beyond that date is contingent upon the availability of appropriated funds from which payment for contract purposes can be made. No legal liability on the part of the Government for any payment may arise for performance under this contract beyond _____ , until funds are made available to the Contracting Officer for performance and until the Contractor receives notice of availability, to be confirmed in writing by the Contracting Officer.

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****(USE BELOW IN NEGOTIATED FIXED PRICE CONTRACTS (excluding A&E and Construction contracts) WHERE PERFORMANCE-BASED CONTRACT FINANCING WILL BE PROVIDED.)****

See FAR Subpart 32.10 for more information.

A DESCRIPTION OF THE BASIS FOR PAYMENT AND LIQUIDATION MUST BE PROVIDED AS REQUIRED BY FAR 32.1004.

30. FAR Clause **52.232-32, Performance-Based Payments** (Apr 2012).

(a) *Amount of payments and limitations on payments* . Subject to such other limitations and conditions as are specified in this contract and this clause, the amount of payments and limitations on payments shall be specified in the contract's description of the basis for payment.

(b) *Contractor request for performance-based payment* . The Contractor may submit requests for payment of performance-based payments not more frequently than monthly, in a form and manner acceptable to the Contracting Officer. Unless otherwise authorized by the Contracting Officer, all performance-based payments in any period for which payment is being requested shall be included in a single request, appropriately itemized and totaled. The Contractor's request shall contain the information and certification detailed in paragraphs (l) and (m) of this clause.

(c) *Approval and payment of requests* . (1) The Contractor shall not be entitled to payment of a request for performance-based payment prior to successful accomplishment of the event or performance criterion for which payment is requested. The Contracting Officer shall determine whether the event or performance criterion for which payment is requested has been successfully accomplished in accordance with the terms of the contract. The Contracting Officer may, at any time, require the Contractor to substantiate the successful performance of any event or performance criterion which has been or is represented as being payable.

(2) A payment under this performance-based payment clause is a contract financing payment under the Prompt Payment clause of this contract and not subject to the interest penalty provisions of the Prompt Payment Act. The designated payment office will pay approved requests on the ___ *[Contracting Officer insert day as prescribed by agency head; if not prescribed, insert "30th"]* day after receipt of the request for performance-based payment by the designated payment office. However, the designated payment office is not required to provide payment if the Contracting Officer requires substantiation as provided in paragraph (c)(1) of this clause, or inquiries into the status of an event or performance criterion, or into any of the conditions listed in paragraph (e) of this clause, or into the Contractor certification. The payment period will not begin until the Contracting Officer approves the request.

(3) The approval by the Contracting Officer of a request for performance-based payment does not constitute an acceptance by the Government and does not excuse the Contractor from performance of obligations under this contract.

(d) *Liquidation of performance-based payments* . (1) Performance-based finance amounts paid prior to payment for delivery of an item shall be

liquidated by deducting a percentage or a designated dollar amount from the delivery payment. If the performance-based finance payments are on a delivery item basis, the liquidation amount for each such line item shall be the percent of that delivery item price that was previously paid under performance-based finance payments or the designated dollar amount. If the performance-based finance payments are on a whole contract basis, liquidation shall be by either predesignated liquidation amounts or a liquidation percentage.

(2) If at any time the amount of payments under this contract exceeds any limitation in this contract, the Contractor shall repay to the Government the excess. Unless otherwise determined by the Contracting Officer, such excess shall be credited as a reduction in the unliquidated performance-based payment balance(s), after adjustment of invoice payments and balances for any retroactive price adjustments.

(e) *Reduction or suspension of performance-based payments* . The Contracting Officer may reduce or suspend performance-based payments, liquidate performance-based payments by deduction from any payment under the contract, or take a combination of these actions after finding upon substantial evidence any of the following conditions:

(1) The Contractor failed to comply with any material requirement of this contract (which includes paragraphs (h) and (i) of this clause).
(2) Performance of this contract is endangered by the Contractor's-

(i) Failure to make progress; or
(ii) Unsatisfactory financial condition.

(3) The Contractor is delinquent in payment of any subcontractor or supplier under this contract in the ordinary course of business.

(f) *Title* . (1) Title to the property described in this paragraph (f) shall vest in the Government. Vestiture shall be immediately upon the date of the first performance-based payment under this contract, for property acquired or produced before that date. Otherwise, vestiture shall occur when the property is or should have been allocable or properly chargeable to this contract.

(2) "Property," as used in this clause, includes all of the following described items acquired or produced by the Contractor that are or should be allocable or properly chargeable to this contract under sound and generally accepted accounting principles and practices:

(i) Parts, materials, inventories, and work in process;
(ii) Special tooling and special test equipment to which the Government is to acquire title;
(iii) Nondurable (i.e., noncapital) tools, jigs, dies, fixtures, molds, patterns, taps, gauges, test equipment and other similar manufacturing aids, title to which would not be obtained as special tooling under paragraph (f)(2)(ii) of this clause; and
(iv) Drawings and technical data, to the extent the Contractor or subcontractors are required to deliver them to the Government by other clauses of this contract.

(3) Although title to property is in the Government under this clause, other applicable clauses of this contract (e.g., the termination clauses) shall determine the handling and disposition of the property.

(4) The Contractor may sell any scrap resulting from production under this contract, without requesting the Contracting Officer's approval, provided that any significant reduction in the value of the property to which the Government has title under this clause is reported in writing to the Contracting Officer.

(5) In order to acquire for its own use or dispose of property to which title is vested in the Government under this clause, the Contractor shall obtain the Contracting Officer's advance approval of the action and the terms. If approved, the basis for payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.

(6) When the Contractor completes all of the obligations under this contract, including liquidation of all performance-based payments, title shall vest in the Contractor for all property (or the proceeds thereof) not-

(i) Delivered to, and accepted by, the Government under this contract; or
(ii) Incorporated in supplies delivered to, and accepted by, the Government under this contract and to which title is vested in the Government under this clause.

(7) The terms of this contract concerning liability for Government-furnished property shall not apply to property to which the Government acquired title solely under this clause.

(g) *Risk of loss* . Before delivery to and acceptance by the Government, the Contractor shall bear the risk of loss for property, the title to which vests in the Government under this clause, except to the extent the Government expressly assumes the risk. If any property is lost (see 45.101), the basis of payment (the events or performance criteria) to which the property is related shall be deemed to be not in compliance with the terms of the contract and not payable (if the property is part of or needed for performance), and the Contractor shall refund the related performance-based payments in accordance with paragraph (d) of this clause.

(h) *Records and controls* . The Contractor shall maintain records and controls adequate for administration of this clause. The Contractor shall have no entitlement to performance-based payments during any time the Contractor's records or controls are determined by the Contracting Officer to be inadequate for administration of this clause.

(i) *Reports and Government access* . The Contractor shall promptly furnish reports, certificates, financial statements, and other pertinent information requested by the Contracting Officer for the administration of this clause and to determine that an event or other criterion prompting a financing payment has been successfully accomplished. The Contractor shall give the Government reasonable opportunity to examine and verify the Contractor's records and to examine and verify the Contractor's performance of this contract for administration of this clause.

(j) *Special terms regarding default* . If this contract is terminated under the Default clause, (1) the Contractor shall, on demand, repay to the Government the amount of unliquidated performance-based payments, and (2) title shall vest in the Contractor, on full liquidation of all performance-based payments, for all property for which the Government elects not to require delivery under the Default clause of this contract. The Government shall be liable for no payment except as provided by the Default clause.

(k) *Reservation of rights* . (1) No payment or vesting of title under this clause shall-

(i) Excuse the Contractor from performance of obligations under this contract; or
(ii) Constitute a waiver of any of the rights or remedies of the parties under the contract.

(2) The Government's rights and remedies under this clause-

(i) Shall not be exclusive, but rather shall be in addition to any other rights and remedies provided by law or this contract; and

(ii) Shall not be affected by delayed, partial, or omitted exercise of any right, remedy, power, or privilege, nor shall such exercise or any single exercise preclude or impair any further exercise under this clause or the exercise of any other right, power, or privilege of the Government.

(l) *Content of Contractor's request for performance-based payment* . The Contractor's request for performance-based payment shall contain the following:

(1) The name and address of the Contractor;
(2) The date of the request for performance-based payment;
(3) The contract number and/or other identifier of the contract or order under which the request is made;
(4) Such information and documentation as is required by the contract's description of the basis for payment; and
(5) A certification by a Contractor official authorized to bind the Contractor, as specified in paragraph (m) of this clause.

(m) *Content of Contractor's certification* . As required in paragraph (l)(5) of this clause, the Contractor shall make the following certification in each request for performance-based payment:

I certify to the best of my knowledge and belief that-

(1) This request for performance-based payment is true and correct; this request (and attachments) has been prepared from the books and records of the Contractor, in accordance with the contract and the instructions of the Contracting Officer;

(2) (Except as reported in writing on _____), all payments to subcontractors and suppliers under this contract have been paid, or will be paid, currently, when due in the ordinary course of business;

(3) There are no encumbrances (except as reported in writing on _____) against the property acquired or produced for, and allocated or properly chargeable to, the contract which would affect or impair the Government's title;

(4) There has been no materially adverse change in the financial condition of the Contractor since the submission by the Contractor to the Government of the most recent written information dated _____; and

(5) After the making of this requested performance-based payment, the amount of all payments for each deliverable item for which performance-based payments have been requested will not exceed any limitation in the contract, and the amount of all payments under the contract will not exceed any limitation in the contract.

(End of clause).

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****(USE BELOW IN FIXED PRICE SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION WHEN PHYSICAL DATA (E.G., TEST BORINGS, HYDROGRAPHIC DATA, WEATHER CONDITIONS DATA) WILL BE FURNISHED OR MADE AVAILABLE TO OFFERORS.)****
ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. All information to be furnished or made available to offerors before award that pertains to the performance of the work should be identified in the clause.
2. When paragraphs are not applicable they may be deleted.

31. FAR Clause **52.236-4, Physical Data** (Apr 1984).

Data and Data and information furnished or referred to below is for the Contractor's information. The Government shall not be responsible for any interpretation of or conclusion drawn from the data or information by the Contractor.

(a) The indications of physical conditions on the drawings and in the specifications are the result of site investigations by _____ [insert a description of investigational methods used, such as surveys, auger borings, core borings, test pits, probings, test tunnels].

(b) Weather conditions _____ [insert a summary of weather records and warnings].

(c) Transportation facilities _____ [insert a summary of transportation facilities providing access from the site, including information about their availability and limitations].

(d) _____ [insert other pertinent information].

(End of clause).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHENEVER THE CONTRACT INVOLVES THE PURCHASE OF GAS IN CONTRACTOR-FURNISHED RETURNABLE CYLINDERS AND THE CONTRACTOR RETAINS TITLE TO THE CYLINDERS)****

32. FAR Clause **52.247-66, Returnable Cylinders** (May 1994).

(a) Cylinder, referred to in this clause, is a pressure vessel designed for pressures higher than 40 psia and having a circular cross section excluding a portable tank, multi-tank car tank, cargo tank or tank car.

(b) Returnable cylinders shall remain the Contractor's property but shall be loaned without charge to the Government for a period of _ days [Contracting Officer shall insert number of days] (hereafter referred to as loan period) following the day of delivery to the f.o.b. point specified in the contract. Any cylinder not returned within the loan period shall be charged a daily rental beginning with the first day after the loan period expires, to and including the day the cylinders are delivered to the Contractor (if the original delivery was f.o.b. Origin) or are delivered or made available for delivery to the Contractor's designated carrier (if the original deliver was f.o.b. destination). The Government shall pay the Contractor a rental of $ _____ [Contracting Officer shall insert dollar amount for rental, after evaluation of offers] per cylinder, per day, computed separately for cylinders by type, size, and capacity and for each point of delivery named in the contract. No rental shall accrue to the Contractor in excess of replacement value per cylinder specified in paragraph (c) of this clause.

(c) For each cylinder lost or damaged beyond repair while in the Government's possession, the Government shall pay to the Contractor the replacement value, less the allocable rental paid for that cylinder as follows: _____ [Contracting Officer shall insert the cylinder types, sizes, capacities, and associated replacement values.] These cylinders shall become Government property.

(d) If any lost cylinder is located within _ [Contracting Officer shall insert number of days] calendar days after payment by the Government, it may be returned to the Contractor by the Government, and the Contractor shall pay to the Government an amount equal to the replacement value, less rental computed in accordance with paragraph (b) of this clause, beginning at the expiration of the loan period specified in paragraph (b) of this clause, and continuing to the date on which the cylinder was delivered to the Contractor.

(End of clause).

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****(USE BELOW IN COST-REIMBURSEMENT SOLICITATIONS AND CONTRACTS WHEN THE CONTRACT OR A FIRST TIER COST-REIMBURSEMENT SUBCONTRACT THEREUNDER WILL AUTHORIZE REIMBURSEMENT OF TRANSPORTATION AS A DIRECT CHARGE TO THE CONTRACT OR SUBCONTRACT.)****

33. FAR Clause **52.247-67, Submission of Transportation Documents for Audit** (Feb 2006).

(a) The Contractor shall submit to the address identified below, for prepayment audit, transportation documents on which the United States will assume freight charges that were paid--

(1) By Contractor under a cost-reimbursement contract; and
(2) By a first-tier subcontractor under a cost-reimbursement subcontract thereunder.

(b) Cost-reimbursement Contractors shall only submit for audit those bills of lading with freight shipment charges exceeding $100. Bills under $100 shall be retained on-site by the Contractor and made available for on-site audits. This exception only applies to freight shipment bills and is not intended to apply to bills and invoices for any other transportation services.

(c) Contractors shall submit the above referenced transportation documents to--

_____

_____

_____

[To be filled in by the Contracting Officer]

(End of clause).

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FUNDED IN WHOLE OR IN PART WITH PREVENTION AND PUBLIC HEALTH FUND (PPHF) FUNDS. THIS INCLUDES (but not is limited to) AWARDING OR MODIFYING ORDERS AGAINST EXISTING OR NEW CONTRACTS ISSUED UNDER FAR SUBPARTS 8.4 AND 16.5 THAT WILL BE FUNDED WITH PPHF FUNDS.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- Contracting Officers may not use PPHF funds on any existing or new contract or order if this clause is not incorporated in the contract.
- This clause is not required for any task and/or delivery order when it is contained in the "parent contract."

1. HHSAR **352.204-70, Prevention and Public Health Fund--Reporting Requirements** (December 2015).

(a) Pursuant to Public Law this contract requires the Contractor to provide products and/or services that are funded from the Prevention and Public Health Fund (PPHF), Public Law 111-148, sec. 4002. Section 220(a)(5) requires each Contractor to report on its use of these funds under this contract. These reports will be made available to the public.

(b) Semi-annual reports from the Contractor for all work funded, in whole or in part, by the PPHF, are due no later than 20 days following the end of each six-month period. The six-month reporting periods are January through June and July through December. The first report is due no later than 20 days after the end of the six-month period following contract award. Subsequent reports are due no later than 20 days after the end of each reporting period. If applicable, the Contractor shall submit its final report for the remainder of the contract period no later than 20 days after the end of the reporting period in which the contract ended.

(c) The Contractor shall provide the following information in an electronic and 508 compliant format to the Contracting Officer.

(1) The Government contract and order number, as applicable.

(2) The amount of PPHF funds invoiced by the Contractor for the reporting period and the cumulative amount invoiced for the contract or order.

(3) A list of all significant services performed or supplies delivered, including construction, for which the contractor invoiced in the reporting period.

(4) Program or project title, if any.

(5) The Contractor shall report any subcontract funded in whole or in part with PPHF funding, that is valued at $25,000 or more. The Contractor shall advise the subcontractor that the information will be made available to the public. The Contractor shall report:

(i) Name and address of the subcontractor.

(ii) Amount of the subcontract award.

(iii) Date of the subcontract award.

(iv) A description of the products or services (including construction) being provided under the subcontract.

(End of clause).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR PERSONAL PROTECTIVE EQUIPMENT (PPE) WHEN THE ACQUISITION IS ABOVE THE MICRO PURCHASE THRESHOLD.)****
ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:
PPE should be obtained through the NIH Supply Center, the VA, and the GSA.

2. HHSAR **352.225-70, Made in America - Personal Protective Equipment** (February 2023).

(a) *Definitions.* As used in this clause-

Component, as applied to an item described in subsection (b) of this clause, means an article, material, or supply incorporated directly into personal protective equipment.

Domestic personal protective equipment, as applied to an item described in subsection (b) of this clause, means personal protective equipment, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the United States.

Foreign-made domestic personal protective equipment, as applied to an item described in subsection (b) of this clause, means personal protective equipment that is assembled outside the United States containing only materials and components that are grown, reprocessed, reused, or produced in the United States.

Foreign personal protective equipment means personal protective equipment other than domestic personal protective equipment or foreign-made domestic personal protective equipment.

Personal protective equipment, as applied to an item described in subsection (b) of this clause, means surgical masks, respirator masks and powered air purifying respirators and required filters, face shields and protective eyewear, gloves, disposable and reusable surgical and isolation gowns, head and foot coverings, and other gear or clothing used to protect an individual from the transmission of disease.

United States, as applied to an item described in subsection (b) of this clause, means the 50 States, the District of Columbia, and the possessions of the United States.

(b) The Contractor shall deliver only domestic personal protective equipment, unless it specified delivery of foreign-made domestic personal protective equipment in the provision of the solicitation entitled "Made in America Certificate - Personal Protective Equipment."

(End of clause).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR PERSONAL PROTECTIVE EQUIPMENT (PPE) WHEN THE ACQUISITION IS ABOVE THE MICRO PURCHASE THRESHOLD.)****
ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:
PPE should be obtained through the NIH Supply Center, the VA, and the GSA.

3. HHSAR **352.225-71, Made in America Certificate - Personal Protective Equipment** (February 2023).

(a)(1) The Offeror certifies that each item of personal protective equipment, except those listed in paragraph (b) of this provision, is domestic personal protective equipment.

(2) The Offeror shall list offered foreign-made domestic personal protective equipment items in paragraph (b).

(3) The terms "domestic personal protective equipment," "foreign-made domestic personal protective equipment," foreign personal protective equipment," and "personal protective equipment," are defined in the clause of this solicitation entitled "Made in America-Personal Protective Equipment."

(b) Foreign-made Domestic Personal Protective Equipment:

Line-Item No.	Country of Origin

[List as necessary.]

(End of provision).

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****(USE BELOW AND ANY APPROPRIATE ALTERNATES IN LIEU OF FAR 52.227-11 WHENEVER A DETERMINATION OF EXCEPTIONAL CIRCUMSTANCES (DEC) INVOLVING THE PROVISION OF MATERIALS HAS BEEN EXECUTED IN ACCORDANCE WITH AGENCY POLICY AND PROCEDURES CALLS FOR ITS USE AND ALL CIRCUMSTANCES ARE COVERED UNDER THIS CLAUSE.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM :

- ALTERNATE I: Insert the description of the license to Class 2 inventions.

4. HHSAR **352.227-11, Patent Rights--Exceptional Circumstances** (September 2014).

This clause applies to all Contractor and subcontractor (at all tiers) Subject Inventions.

(a) *Definitions.* As used in this clause-

Agency means the Agency of the U.S. Department of Health and Human Services that is entering into this contract.

Class 1 Subject Invention means a Subject Invention described and defined in the DEC that will be assigned to a third party assignee, or assigned as directed by the Agency.

Class 2 Subject Invention means a Subject Invention described and defined in the DEC.

Class 3 Subject Invention means a Subject Invention that does not fall into Class 1 or Class 2 as defined in this clause.

DEC means the Determination of Exceptional Circumstances signed by [insert approving official] ____ on ____ [insert date] ____ and titled "[insert description]."

Invention means any invention or discovery, which is or may be patentable or otherwise protectable under Title 35 of United States Code, or any novel variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, *et. seq.*)

Made means: When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of such invention; or when used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Material means any proprietary material, method, product, composition, compound, or device, whether patented or unpatented, which is provided to the Contractor under this contract.

Nonprofit organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

Practical application means to manufacture, in the case of a composition or product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

Small business firm means a small business concern as defined at section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.

Subject Invention means any invention of the Contractor made in the performance of work under this contract.

Third party assignee means any entity or organization that may, as described in the DEC, be assigned Class 1 inventions.

(b) *Allocation of principal rights.* (1) *Retention of pre-existing rights.* Third party assignees shall retain all preexisting rights to Material in which the Third party assignee has a proprietary interest.

(2) *Allocation of Subject Invention rights.*

(i) *Disposition of Class 1 Subject Inventions.*

(A) Assignment to the Third party assignee or as directed by the Agency. The Contractor shall assign to the Third party assignee designated by the Agency the entire right, title, and interest throughout the world to each Subject Invention, or otherwise dispose of or transfer those rights as directed by the Agency, except to the extent that rights are retained by the Contractor under paragraph (b)(3) of this clause. Any such assignment or other disposition or transfer of rights will be subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the U.S. Government to practice or have practiced the Subject Invention for or on behalf of the U.S. throughout the world. Any assignment shall additionally be subject to the "March-in rights" of 35 U.S.C. 203. If the Contractor is a U.S. nonprofit organization it may retain a royalty free, nonexclusive, nontransferable license to practice the invention for all nonprofit research including for educational purposes, and to permit other U.S. nonprofit organizations to do so.

(B) [Reserved]

(ii) *Disposition of Class 2 and 3 Subject Inventions.* Class 2 Subject Inventions shall be governed by FAR clause 52.227-11, Patent Rights-Ownership (December 2007) (incorporated herein by reference). However, the Contractor shall grant a license in the Class 2 Subject Inventions to the provider of the Material or other party designated by the Agency as set forth in Alternate I.

(iii) Class 3 Subject Inventions shall be governed by FAR clause 52.227-11, Patent Rights-Ownership by the Contractor (December 2007) (previously incorporated herein by reference).

(3) *Greater Rights Determinations.*

The Contractor, or an employee-inventor after consultation by the Agency with the Contractor, may request greater rights than are provided in paragraph (b)(1) of this clause in accordance with the

procedures of FAR paragraph 27.304-1(c). In addition to the considerations set forth in paragraph 27.304-1(c), the Agency may consider whether granting the requested greater rights will interfere with rights of the Government or any Third party assignee or otherwise impede the ability of the Government or the Third party assignee to, for example, develop and commercialize new compounds, dosage forms, therapies, preventative measures, technologies, or other approaches with potential for the diagnosis, prognosis, prevention, and treatment of human diseases.

A request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the Agency Contracting Officer at the time of the first disclosure of the invention pursuant to paragraph (c)(1) of this clause, or not later than 8 months thereafter, unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the Contractor. Each determination of greater rights under this contract shall be subject to paragraph (c) of the FAR clause at 52.227-13 (incorporated herein by reference), and to any reservations and conditions deemed to be appropriate by the Agency such as the requirement to assign or exclusively license the rights to Subject Inventions to the Third party assignee.

A determination by the Agency denying a request by the Contractor for greater rights in a Subject Invention may be appealed within 30 days of the date the Contractor is notified of the determination to an Agency official at a level above the individual who made the determination. If greater rights are granted, the Contractor must file a patent application on the invention. Upon request, the Contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English-language version if filed in a language other than English), and patent number and issue date for any Subject Invention in any country for which the Contractor has retained title. Upon request, the Contractor shall furnish the Government an irrevocable power to inspect and make copies of the patent application file.

(c) *Invention disclosure by Contractor.* The Contractor shall disclose in writing each Subject Invention to the Agency Contracting Officer and to the Director, Division of Extramural Inventions and Technology Resources (DEITR), if directed by the Contracting Officer, as provided in paragraph (j) of this clause within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure to the Agency Contracting Officer shall be in the form of a written report and shall identify the contract under which the invention was Made and all inventors. It shall

be sufficiently complete in technical detail to convey a clear understanding to the extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale (offer for sale), or public use of the invention and whether a manuscript describing the invention has been submitted for publication, and if so, whether it has been accepted for publication at the time of disclosure.

In addition, after disclosure to the Agency, the Contractor will promptly notify the Contracting Officer and DEITR of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the Contractor. If the Contractor assigns a Subject Invention to the Third party assignee, then the Contractor and its employee inventors shall assist the Third party assignee in securing patent protection. All costs of securing the patent, including the cost of the Contractor's assistance, are at the Third party's expense. Any assistance provided by the Contractor and its employee inventors to the Third party assignee or other costs incurred in securing patent protection shall be solely at the Third party's expense and not billable to the contract.

(d) *Contractor action to protect the Third party assignee's and the Government's interest.*

(1) The Contractor agrees to execute or to have executed and promptly deliver to the Agency all instruments necessary to: Establish or confirm the rights the Government has throughout the world in Subject Inventions pursuant to paragraph (b) of this clause; convey title to a Third party assignee in accordance with paragraph (b) of this clause; and enable the Third party assignee to obtain patent protection throughout the world in that Subject Invention.

(2) The Contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor, each Subject Invention "Made" under contract in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on Subject Inventions and to establish the Government's rights or a Third party assignee's rights in the Subject Inventions. This disclosure format should require, as a minimum, the information required by subparagraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in

sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) If the Contractor is granted greater rights, the Contractor agrees to include, within the specification of any United States non-provisional patent application it files, and any patent issuing thereon, covering a Subject Invention the following statement: "This invention was made with Government support under (identify the Contract) awarded by (identify the specific Agency). The Government has certain rights in the invention."

(4) The Contractor agrees to provide a final invention statement and certification prior to the closeout of the contract listing all Subject Inventions or stating that there were none.

(e) *Subcontracts.*

(1) The Contractor will include this clause in all subcontracts, regardless of tier, for experimental, developmental, or research work. At all tiers, the clause must be modified to identify the parties as follows: References to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor will not, as part of the consideration for awarding the contract, obtain rights in the subcontractor's Subject Inventions.

(2) In subcontracts, at any tier, the Agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (c)(1)(ii) of FAR clause 52.227-13.

(f) *Reporting on utilization of Subject Inventions in the event greater rights are granted to the Contractor.*

The Contractor agrees to submit, on request, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees when a request under subparagraph b.3. has been granted by the Agency. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and such other data and information as the Agency may reasonably specify. The Contractor also agrees to provide additional reports as may be

requested by the Agency in connection with any march-in proceeding undertaken by the Agency in accordance with paragraph (h) of this clause. As required by 35 U.S.C. 202(c)(5), the Agency agrees it will not disclose such information to persons outside the Government without permission of the Contractor.

(g) *Preference for United States industry in the event greater rights are granted to the Contractor.*

Notwithstanding any other provision of this clause, the Contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any Subject Invention in the United States unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(h) *March-in rights in the event greater rights are granted to the Contractor.*

The Contractor acknowledges that, with respect to any Subject Invention in which it has acquired ownership through the exercise of the rights specified in paragraph (b)(3) of this clause, the Agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of Agency in effect on the date of contract award.

(i) Special provisions for contracts with nonprofit organizations in the event greater rights are granted to the Contractor. If the Contractor is a nonprofit organization, it shall:

(1) Not assign rights to a Subject Invention in the United States without the written approval of the Agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a Subject Invention with the inventor, including Federal employee co-inventors (but through their Agency if the Agency deems it appropriate) when the Subject Invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to Subject Inventions, after payment of expenses (including payments to inventors) incidental to the administration of Subject Inventions for the support of scientific research or education;

(4) Make efforts that are reasonable under the circumstances to attract licensees of Subject Inventions that are small business concerns, and give a preference to a small business concern when licensing a Subject Invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor; and

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) *Communications.*

All invention disclosures and requests for greater rights shall be sent to the Agency Contracting Officer, as directed by the Contracting Officer. Additionally, a copy of all disclosures, confirmatory licenses to the Government, face page of the patent applications, waivers and other routine communications under this funding agreement at all tiers must be sent to:

[Insert Agency Address]

Agency Invention Reporting Web site: http://www.iEdison.gov.

Alternate I (Sept 2014). As prescribed in *327.303,* the license to Class 2 inventions recited in 352.227-11(b)(2)(a) is as follows:

[Insert description of license to Class 2 inventions]

(End of clause).

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****(USE BELOW WITH ANY APPROPRIATE ALTERNATES IN ACCORDANCE WITH HHSAR 327.409 IN LIEU OF FAR 52.227-14 WHENEVER A DETERMINATION OF EXCEPTIONAL CIRCUMSTANCES (DEC) EXECUTED IN ACCORDANCE WITH AGENCY POLICY AND PROCEDURES CALLS FOR ITS USE.)****

NOTE: *Prior to use of this clause a DEC must be executed in accordance with agency policy and procedures. The Contracting Officer should reference the DEC in the solicitation and shall attach a copy of the executed DEC to the contract.*

5. HHSAR **352.227-14 Rights in Data-Exceptional Circumstances** (September 2014).

(a) *Definitions.* As used in this clause-[Definitions may be added or modified in paragraph (a) as applicable.]

Computer database or *database* means a collection of recorded information in a form capable of, and for the purpose of, being stored in, processed, and operated on by a computer. The term does not include computer software.

Computer software -(i) Means (A) Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and

(B) Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

(ii) Does not include computer databases or computer software documentation.

Computer software documentation means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

Data means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

Form, fit, and function data means data relating to items, components, or processes that are sufficient to enable physical and functional

interchangeability, and data identifying source, size, configuration, mating and attachment characteristics, functional characteristics, and performance requirements. For computer software it means data identifying source, functional characteristics, and performance requirements but specifically excludes the source code, algorithms, processes, formulas, and flow charts of the software.

Limited rights means the rights of the Government in limited rights data as set forth in the Limited Rights Notice in Alternate II paragraph (g)(3) if included in this clause. "Limited rights data" means data, other than computer software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.

Restricted computer software means computer software developed at private expense and that is a trade secret, is commercial or financial and confidential or privileged, or is copyrighted computer software, including minor modifications of the computer software.

Restricted rights, as used in this clause, means the rights of the Government in restricted computer software, as set forth in a Restricted Rights Notice of Alternate III paragraph (g)(4) if included in this clause, or as otherwise may be provided in a collateral agreement incorporated in and made part of this contract, including minor modifications of such computer software.

Technical data means recorded information (regardless of the form or method of the recording) of a scientific or technical nature (including computer databases and computer software documentation). This term does not include computer software or financial, administrative, cost or pricing, or management data or other information incidental to contract administration. The term includes recorded information of a scientific or technical nature that is included in computer databases (See 41 U.S.C. 403(8)).

Unlimited rights means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

(b) *Allocation of rights.*

(1) Except as provided in paragraph (c) of this clause, the Government shall have unlimited rights in-

(i) Data first produced in the performance of this contract;

(ii) Form, fit, and function data delivered under this contract;

(iii) Data delivered under this contract (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this contract; and

(iv) All other data delivered under this contract unless provided otherwise for limited rights data or restricted computer software in accordance with paragraph (g) of this clause.

(2) The Contractor shall have the right to-

(i) Assert copyright in data first produced in the performance of this contract to the extent provided in paragraph (c)(1) of this clause;

(ii) Use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, unless provided otherwise in paragraph (d) of this clause;

(iii) Substantiate the use of, add, or correct limited rights, restricted rights, or copyright notices and to take other appropriate action, in accordance with paragraphs (e) and (f) of this clause; and

(iv) Protect from unauthorized disclosure and use those data that are limited rights data or restricted computer software to the extent provided in paragraph (g) of this clause.

(c) *Copyright.*

(1) *Data first produced in the performance of this contract.*

(i) Unless provided otherwise in paragraph (d) of this clause, the Contractor may, without prior approval of the Contracting Officer, assert copyright in scientific and technical articles based on or containing data first produced in the performance of this contract and published in academic, technical or professional journals, symposia proceedings, or similar works. The prior, express written permission of the Contracting Officer is required to assert copyright in all other data first produced in the performance of this contract.

(ii) When authorized to assert copyright to the data, the Contractor shall affix the applicable copyright notices of 17 U.S.C. 401 or 402, and an acknowledgment of Government sponsorship (including contract number).

(iii) For data other than computer software, the Contractor grants to the Government and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government. For computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public) by or on behalf of the Government.

(2) Data not first produced in the performance of this contract. The Contractor shall not, without the prior written permission of the Contracting Officer, incorporate in data delivered under this contract any data not first produced in the performance of this contract unless the Contractor-

(i) Identifies the data; and

(ii) Grants to the Government, or acquires on its behalf, a license of the same scope as set forth in paragraph (c)(1) of this clause or, if such data are restricted computer software, the Government shall acquire a copyright license as set forth in paragraph (g)(4) of this clause (if included in this contract) or as otherwise provided in a collateral agreement incorporated in or made part of this contract.

(3) *Removal of copyright notices.* The Government will not remove any authorized copyright notices placed on data pursuant to this paragraph (c), and will include such notices on all reproductions of the data.

(d) Release, publication, and use of data. The Contractor shall have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, except-

(1) As prohibited by Federal law or regulation (*e.g.,* export control or national security laws or regulations);

(2) As expressly set forth in this contract; or

(3) If the Contractor receives or is given access to data necessary for the performance of this contract that contain restrictive markings, the Contractor shall treat the data in accordance with such markings unless specifically authorized otherwise in writing by the Contracting Officer or in the following paragraphs.

(4) In addition to any other provisions, set forth in this contract, the Contractor shall ensure that information concerning possible inventions made under this contract is not prematurely published thereby adversely affecting the ability to obtain patent protection on such inventions. Accordingly, the Contractor will provide the Contracting Officer a copy of any publication or other public disclosure relating to the work performed under this contract at least 30 days in advance of the disclosure. Upon the Contracting Officer's request the Contractor agrees to delay the public disclosure of such data or publication of a specified paper for a reasonable time specified by the Contracting Officer, not to exceed 6 months, to allow for the filing of domestic and international patent applications in accordance with Clause 352.227-11, Patent Rights-Exceptional Circumstances (abbreviated month and year of Final Rule publication).

(5) *Data on Material(s).* The Contractor agrees that in accordance with paragraph (d)(2), proprietary data on Material(s) provided to the Contractor under or through this contract shall be used only for the purpose for which they were provided, including screening, evaluation or optimization and for no other purpose.

(6) *Confidentiality.*

(i) The Contractor shall take all reasonable precautions to maintain Confidential Information as confidential, but no less than the steps Contractor takes to secure its own confidential information.

(ii) Contractor shall maintain Confidential Information as confidential unless specifically authorized otherwise in writing by the Contracting Officer. Confidential Information includes/does not include [Government may define confidential information here.]

(e) *Unauthorized marking of data.*

(1) Notwithstanding any other provisions of this contract concerning inspection or acceptance, if any data delivered under this contract are marked with the notices specified in paragraph (g)(3) or (4) of this clause

(if those alternate paragraphs are included in this clause), and use of the notices is not authorized by this clause, or if the data bears any other restrictive or limiting markings not authorized by this contract, the Contracting Officer may cancel or ignore the markings. However, pursuant to 41 U.S.C. 253 d, the following procedures shall apply prior to canceling or ignoring the markings.

(i) The Contracting Officer will make written inquiry to the Contractor affording the Contractor 60 days from receipt of the inquiry to provide written justification to substantiate the propriety of the markings;

(ii) If the Contractor fails to respond or fails to provide written justification to substantiate the propriety of the markings within the 60-day period (or a longer time approved in writing by the Contracting Officer for good cause shown), the Government shall have the right to cancel or ignore the markings at any time after said period and the data will no longer be made subject to any disclosure prohibitions.

(iii) If the Contractor provides written justification to substantiate the propriety of the markings within the period set in paragraph (e)(1)(i) of this clause, the Contracting Officer will consider such written justification and determine whether or not the markings are to be cancelled or ignored. If the Contracting Officer determines that the markings are authorized, the Contractor will be so notified in writing. If the Contracting Officer determines, with concurrence of the head of the contracting activity, that the markings are not authorized, the Contracting Officer will furnish the Contractor a written determination, which determination will become the final Agency decision regarding the appropriateness of the markings unless the Contractor files suit in a court of competent jurisdiction within 90 days of receipt of the Contracting Officer's decision. The Government will continue to abide by the markings under this paragraph(e)(1)(iii) until final resolution of the matter either by the Contracting Officer's determination becoming final (in which instance the Government will thereafter have the right to cancel or ignore the markings at any time and the data will no longer be made subject to any disclosure prohibitions), or by final disposition of the matter by court decision if suit is filed.

(2) The time limits in the procedures set forth in paragraph (e)(1) of this clause may be modified in accordance with Agency regulations implementing the Freedom of Information Act (5 U.S.C. 552) if necessary to respond to a request there under.

(3) Except to the extent the Government's action occurs as the result of final disposition of the matter by a court of competent jurisdiction, the Contractor is not precluded by this paragraph (e) from bringing a claim, in accordance with the Disputes clause of this contract, that may arise as the result of the Government removing or ignoring authorized markings on data delivered under this contract.

(f) *Omitted or incorrect markings.*

(1) Data delivered to the Government without any restrictive markings shall be deemed to have been furnished with unlimited rights. The Government is not liable for the disclosure, use, or reproduction of such data.

(2) If the unmarked data has not been disclosed without restriction outside the Government, the Contractor may request, within 6 months (or a longer time approved by the Contracting Officer in writing for good cause shown) after delivery of the data, permission to have authorized notices placed on the data at the Contractor's expense. The Contracting Officer may agree to do so if the Contractor-

(i) Identifies the data to which the omitted notice is to be applied;

(ii) Demonstrates that the omission of the notice was inadvertent;

(iii) Establishes that the proposed notice is authorized; and

(iv) Acknowledges that the Government has no liability for the disclosure, use, or reproduction of any data made prior to the addition of the notice or resulting from the omission of the notice.

(3) If data has been marked with an incorrect notice, the Contracting Officer may-

(i) Permit correction of the notice at the Contractor's expense if the Contractor identifies the data and demonstrates that the correct notice is authorized; or

(ii) Correct any incorrect notices.

(g) *Protection of limited rights data and restricted computer software.*

(1) The Contractor may withhold from delivery qualifying limited rights data or restricted computer software that are not data identified in

paragraphs (b)(1)(i) through (iii) of this clause. As a condition to this withholding, the Contractor shall-

(i) Identify the data being withheld; and

(ii) Furnish form, fit, and function data instead.

(2) Limited rights data that are formatted as a computer database for delivery to the Government shall be treated as limited rights data and not restricted computer software.

(3) [Reserved]

(h) *Subcontracting.*

The Contractor shall obtain from its subcontractors all data and rights therein necessary to fulfill the Contractor's obligations to the Government under this contract. If a subcontractor refuses to accept terms affording the Government those rights, the Contractor shall promptly notify the Contracting Officer of the refusal and shall not proceed with the subcontract award without authorization in writing from the Contracting Officer.

(i) *Relationship to patents or other rights.* Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government.

(End of clause).

Alternate I (SEPT 2014). As prescribed in *327.409,* substitute the following definition for "limited rights data" in paragraph (a) of the basic clause:

Limited rights data means data, other than computer software, developed at private expense that embody trade secrets or are commercial or financial and confidential or privileged.

Alternate II (SEPT 2014). As prescribed in *327.409,* insert the following paragraph (g)(3) in the basic clause:

(g)(3) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data, or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be entitled to be withheld. If delivery of that data is required, the Contractor shall affix the following "Limited

Rights Notice" to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

Limited Rights Notice (SEPT 2014)

(a) These data are submitted with limited rights under Government Contract No. ____ (and subcontract ____, if appropriate). These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure: [Agencies may list additional purposes or if none, so state.]

(b) This notice shall be marked on any reproduction of these data, in whole or in part.

(End of notice).

Alternate III (SEPT 2014). As prescribed in *327.409,* insert the following paragraph (g)(4) in the basic clause: (g)(4)(i) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of restricted computer software, or the Contracting Officer may require by written request the delivery of restricted computer software that has been withheld or would otherwise be entitled to be withheld. If delivery of that computer software is required, the Contractor shall affix the following "Restricted Rights Notice" to the computer software and the Government will treat the computer software, subject to paragraphs (e) and (f) of this clause, in accordance with the notice:

Restricted Rights Notice (SEPT 2014)

(a) This computer software is submitted with restricted rights under Government Contract No. ____ (and subcontract ____, if appropriate). It may not be used, reproduced, or disclosed by the Government except as provided in paragraph (b) of this notice or as otherwise expressly stated in the contract.

(b) This computer software may be-

(1) Used or copied for use with the computer(s) for which it was acquired, including use at any Government installation to which the computer(s) may be transferred;

(2) Used or copied for use with a backup computer if any computer for which it was acquired is inoperative;

(3) Reproduced for safekeeping (archives) or backup purposes;

(4) Modified, adapted, or combined with other computer software, provided that the modified, adapted, or combined portions of the derivative software incorporating any of the delivered, restricted computer software shall be subject to the same restricted rights;

(5) Disclosed to and reproduced for use by support service Contractors or their subcontractors in accordance with paragraphs (b)(1) through (4) of this notice; and

(6) Used or copied for use with a replacement computer.

(c) Notwithstanding the foregoing, if this computer software is copyrighted computer software, it is licensed to the Government with the minimum rights set forth in paragraph (b) of this notice.

(d) Any other rights or limitations regarding the use, duplication, or disclosure of this computer software are to be expressly stated in, or incorporated in, the contract.

(e) This notice shall be marked on any reproduction of this computer software, in whole or in part.

(End of notice).

(ii) Where it is impractical to include the Restricted Rights Notice on restricted computer software, the following short-form notice may be used instead:

Restricted Rights Notice Short Form (SEPT 2014).

Use, reproduction, or disclosure is subject to restrictions set forth in Contract No. ____ (and subcontract, if appropriate) with ____ (name of Contractor and subcontractor).

(End of notice).

(iii) If restricted computer software is delivered with the copyright notice of 17 U.S.C. 401 , it will be presumed to be licensed to the Government without

disclosure prohibitions, with the minimum rights set forth in paragraph (b) of this clause.

Alternate IV (SEPT 2014). As prescribed in *327.409,* substitute the following paragraph (c)(1) for paragraph (c)(1) of the basic clause:

(c) *Copyright* -

(1) *Data first produced in the performance of the contract.* Except as otherwise specifically provided in this contract, the Contractor may assert copyright in any data first produced in the performance of this contract. When asserting copyright, the Contractor shall affix the applicable copyright notice of 17 U.S.C. 401 or 402, and an acknowledgment of Government sponsorship (including contract number), to the data when such data are delivered to the Government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office. For data other than computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all such data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. For computer software, the Contractor grants to the Government and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all such computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public), by or on behalf of the Government.

Alternate V (SEPT 2014). As prescribed in *327.409,* add the following paragraph (j) to the basic clause:

(j) The Contractor agrees, except as may be otherwise specified in this contract for specific data deliverables listed as not subject to this paragraph, that the Contracting Officer may, up to 3 years after acceptance of all deliverables under this contract, inspect at the Contractor's facility any data withheld pursuant to paragraph (g)(1) of this clause, for purposes of verifying the Contractor's assertion of limited rights or restricted rights status of the data or for evaluating work performance. When the Contractor whose data are to be inspected demonstrates to the Contracting Officer that there would be a possible conflict of interest if a particular representative made the inspection, the Contracting Officer shall designate an alternate inspector.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS AWARDED OR MODIFIED AFTER MARCH 21, 2022.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- All NIH Contractors will transition to the Department of Treasury's Invoice Processing Platform (IPP) for invoice submission.
- Requests for use of alternate procedures under HHSAR 352.232-71, paragraph (c), must be approved in writing by the Deputy Director, Office of Acquisition and Logistics Management (OALM).
- All IPP invoices must contain a Unique Entity Identifier (UEI) which is located in the System for Award Management (SAM) and replaces the Dun & Bradstreet Data Universal Numbering System (DUNS) number.

This applies to all contracts and task/delivery orders and Blanket Purchase agreements awarded.

6. HHSAR **352.232-71 Electronic Submission of Payment Requests** (February 2, 2022).

(a) *Definitions.* As used in this clause-

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at https://www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(End of clause).

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****(USE BELOW SOLICITATIONS, CONTRACTS AND ORDERS TO DELIVER SERVICES UNDER HHS' PROGRAMS DIRECTLY TO THE PUBLIC.)****

7. HHSAR **352.237-74, Non-Discrimination in Service Delivery** (December 2015).

It is the policy of the Department of Health and Human Services that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as race, color, national origin, religion, sex, gender identity, sexual orientation, or disability (physical or mental). By acceptance of this contract, the contractor agrees to comply with this policy in supporting the program and in performing the services called for under this contract. The contractor shall include this clause in all subcontracts awarded under this contract for supporting or performing the specified program and services. Accordingly, the contractor shall ensure that each of its employees, and any sub-contractor staff, is made aware of, understands, and complies with this policy.

(End of Clause).

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS, ISSUED BY OR ON BEHALF OF NIH, THAT INVOLVE IMPLEMENTING, ACQUIRING, OR UPGRADING HEALTH IT USED (1) FOR THE DIRECT EXCHANGE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION BETWEEN AGENCIES AND NON-FEDERAL ENTITIES, AND (2) BY HEALTH CARE PROVIDERS, HEALTH PLANS, OR HEALTH INSURANCE ISSUERS.)****
NOTE: The prescribed clause is inserted in new solicitations issued and contracts awarded on or after the effective date of the deviation. Contracting Officers should consider amending existing applicable solicitations or modifying existing applicable contracts to include the prescribed clause.

8. HHSAR **352.239-70 Standards for Health Information Technology** (December 2022) (DEVIATION).

(a) *Definitions*. As used in this clause—

Health information technology (health IT) means hardware, software, integrated technologies or related licenses, intellectual property, upgrades, or packaged solutions sold as services that are designed for or support the use by health care entities or patients for the electronic creation, maintenance, access, or exchange of health information. (42 U.S.C. 300jj)

Individually identifiable health information means information that is a subset of health information, including demographic information collected from an individual, and:

(1) Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(2) Relates to the past, present, or future physical or mental health condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

(i) That identifies the individual; or

(ii) With respect to which there is a reasonable basis to believe the information can be used to identify the individual. (42 U.S.C. 300jj, 1320d)

ONC Health Information Technology Certification Program means the certification program administered by the HHS Office of the National Coordinator for Health Information Technology (ONC) using a third-party conformity assessment program for health IT. Certification criteria for the Program, which incorporate standards and implementation specifications in 45 CFR part 170 subpart B, are found in 45 CFR part 170, subpart C.

(b) Pursuant to the Health Information Technology for Economic and Clinical Health Act (HITECH Act), Pub. L. 111-5, Title XIII, sections 13111 and 13112, by submission of an offer and execution of a contract, the Contractor agrees that—

(1) For any work performed under the contract that involves implementing, acquiring, or upgrading health IT used for the direct exchange of individually identifiable health information between agencies and with non-Federal entities, the Contractor will utilize health IT that—

(i) Meets standards and implementation specifications adopted in 45 CFR part 170, subpart B, if such standards and implementation specifications can support the work performed under the contract; and

(ii) Is certified under the ONC Health Information Technology Certification Program, if certified technology can support the work performed under the contract (see certification criteria in 45 CFR part 170, subpart C), when the Contractor is an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102 and 4201 of the HITECH Act, or when the Contractor is implementing, acquiring or upgrading technology to be used by an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102 and 4201 of the HITECH Act.

(2) If the Contractor is a health care provider, health plan, or health insurance issuer, or is establishing an agreement with a health care provider, health plan, or health insurance issuer, for work performed under the contract that involves implementing, acquiring, or upgrading health IT, the Contractor will utilize health IT that—

(i) Meets standards and implementation specifications adopted in 45 CFR part 170, subpart B, if such standards and implementation specifications can support the work performed under the contract; and

(ii) Is certified under the ONC Health Information Technology Certification Program, if certified technology can support the work performed under the contract (see certification criteria in 45 CFR part 170, subpart C), when the Contractor is an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102 and 4201 of the HITECH Act, or when the Contractor is implementing, acquiring or upgrading technology to be used by an eligible professional in an ambulatory setting, or a hospital, eligible under sections 4101, 4102 and 4201 of the HITECH Act.

(c) If standards and implementation specifications adopted in 45 CFR part 170, subpart B, cannot support the work as specified in the contract, the Contractor is encouraged to use health IT that meets non-proprietary standards and implementation specifications developed by consensus-based standards development organizations. This may include standards identified in the ONC Interoperability Standards Advisory, available at https://www.healthit.gov/isa/.

(End of clause).

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****(USE BELOW WHEN NO FULL TEXT FAR CLAUSES ARE APPLICABLE TO THE CONTRACT.)****

c. **THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.**

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**** USE BELOW IN SOLICITATIONS AS APPROPRIATE.)****

Any contract resulting from this RFP will contain the following Article:

ARTICLE I.5. SMALL BUSINESS ADMINISTRATION - 8(a) PROGRAM

This contract has been awarded in accordance with the program established in Section 8(a) of the Small Business Act (15 U.S.C. 637(a)) and the Partnership Agreement (PA) between the U.S. Small Business Administration (SBA) and the U.S. Department of Health and Human Services (HHS) effective October 23, 2012 until amended. The following clauses are hereby incorporated and made a part of this contract. All clauses incorporated by reference have the same force and effect as if they were given full text. Upon request, the Contracting Officer will make their full text available.

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****(USE BELOW IN ALL COMPETITIVE 8(a) SOLICITATIONS AND CONTRACTS.)****
NOTE: The clauses below are those prescribed by the "Direct 8(a) Contracting Model Coverage" developed by the CAAC under CAAC Letter 98-3 to implement and supplement the Partnership Agreement between SBA and DHHS effective October 23, 2012 until amended.

a. FAR Clause **52.219-18, Notification Of Competition Limited To Eligible 8(a) Participants** (Oct 2022) **with Alternate For Acquisitions Under FAR 19.800 (Deviation)** (HHS/SBA PA - October 23, 2012 until amended)

(a) Offers are solicited only from -

(1) Small business concerns expressly certified by the Small Business Administration (SBA) for participation in the SBA's 8(a) Program and which meet the following criteria at the time of submission of offer--

(i) The Offeror is in conformance with the 8(a) support limitation set forth in its approved business plan; and
(ii) The Offeror is in conformance with the Business Activity Targets set forth in its approved business plan or any remedial action directed by SBA.

(2) A joint venture, in which at least one of the 8(a) program participants that is a party to the joint venture complies with the criteria set forth in paragraph (a)(1) of this clause, that complies with 13 CFR 124-513(c); or

(3) A joint venture -

(i) That is comprised of a mentor and an 8(a) protégé with an approved mentor-protégé agreement under the 8(a) program;

(ii) In which at least one of the 8(a) program participants that is a party to the joint venture complies with the criteria set forth in paragraph (a)(1) of this clause; and

(iii) That complies with 13 CFR 124-513(c)

(b) By submission of its offer, the Offeror represents that it meets the applicable criteria set forth in paragraph (a) of this clause.

(c) Any award resulting from this solicitation will be made directly by the Contracting Officer to the successful 8(a) offeror selected through the evaluation criteria set forth in this solicitation.

(d) The _____ [*insert name of SBA`s contractor*] will notify the _____ [*insert name of contracting agency*] Contracting Officer in writing immediately upon entering an agreement (either oral or written) to transfer all or part of its stock. A contracting officer may consider a joint venture for contract award. SBA does not approve joint ventures for competitive awards, but see 13 CFR 124-501(g) for SBA's determination of participant eligibility.

(End of clause).

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**** (USE BELOW WHEN COMPETITION IS LIMITED TO 8(a) CONCERNS WITHIN ONE OR MORE SPECIFIC SBA DISTRICT(S)/REGION(S) PURSUANT TO 19.804-3.) ****

b. **Alternate I** , (Mar 2023) is added to FAR Clause **52.219-18, Notification of Competition Limited to Eligible 8(a) Participants** (Oct 2022) as follows:

If the competition is to be limited to 8(a) participants within one or more specific SBA regions or districts, add the following paragraph (a)(1)(iii) to paragraph (a) of the clause:

(iii) The offeror's approved business plan is on the file and serviced by _____ [Contracting Officer completes by inserting the appropriate SBA District and/or Area Office(s) as identified by the SBA].

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****(USE BELOW FOR SOLICITATIONS SUBJECT TO THE SERVICE CONTRACT LABOR STANDARDS STATUTE.)****

Any contract awarded from this RFP will contain the following article:

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ARTICLE I.6. SERVICE CONTRACT LABOR STANDARDS

This contract is subject to the Service Contract Labor Standards. The following clauses are hereby incorporated and made a part of this contract. All clauses incorporated by reference have the same force and effect as if they were given full text. Upon request, the Contracting Officer will make their full text available.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR (1) SERVICE CONTRACTS, AS DEFINED AT FAR 22.001, (2) THAT SUCCEED CONTRACTS FOR PERFORMANCE OF THE SAME OR SIMILAR WORK AT THE SAME LOCATION AND (3) THAT ARE NOT EXEMPTED BY FAR 22.1203-2 OR WAIVED IN ACCORDANCE WITH 22.1203-3.)****

a. FAR Clause **52.222-41, Service Contract Labor Standards** (Aug 2018).

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**** (USE BELOW IN ALL SOLICITATIONS AND CONTRACTS SUBJECT TO THE SERVICE CONTRACT LABOR STANDARDS STATUTE.) ****

b. FAR Clause **52.222-42, Statement of Equivalent Rates for Federal Hires** (May 2014)

In compliance with the Contract Labor Standards statute and the regulations of the Secretary of Labor (29 CFR Part 4), this clause identifies the classes of service employees expected to be employed under the contract and states the wages and fringe benefits payable to each if they were employed by the contracting agency subject to the provisions of 5 U.S.C. 5341 or 5332.

THIS STATEMENT IS FOR INFORMATION ONLY: IT IS NOT A WAGE DETERMINATION

Employee Class	Monetary Wage-Fringe Benefit

(End of Clause).

573

**** (USE BELOW FOR FIXED PRICE, TIME AND MATERIALS, OR LABOR-HOUR SOLICITATIONS AND CONTRACTS THAT EXCEED THE SIMPLIFIED ACQUISITION THRESHOLD, SUBJECT TO THE SERVICE CONTRACT LABOR STANDARDS STATUTE, WHICH ARE MULTIPLE YEAR, OR WITH OPTIONS TO RENEW. THIS CLAUSE MAY BE USED AT THE DISCRETION OF THE CONTRACTING OFFICER, IN SOLICITATIONS AND CONTRACTS AT OR BELOW THE SIMPLIFIED ACQUISITION.)****
NOTE: The CO may modify this clause in overseas contracts when laws, regulations, or international agreements require contractors to pay higher wage rates. Also, the CO may use an economic price adjustment clause authorized by FAR 16.203 when potential fluctuations require coverage and are not included in cost contingencies provided by this clause (FAR 52.222-43.

c. FAR Clause **52.222-43, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (Multiple Year And Option Contracts)** (Aug 2018).

574

**** (USE BELOW FOR FIXED PRICE, TIME AND MATERIALS, OR LABOR-HOUR SOLICITATIONS AND CONTRACTS THAT EXCEED THE SIMPLIFIED ACQUISITION THRESHOLD, SUBJECT TO THE SERVICE CONTRACT LABOR STANDARDS STATUTE, WHICH ARE NOT MULTIPLE YEAR OR WITH OPTIONS TO RENEW. THIS CLAUSE MAY BE USED AT THE DISCRETION OF THE CONTRACTING OFFICER, IN SOLICITATIONS AND CONTRACTS AT OR BELOW THE SIMPLIFIED ACQUISITION THRESHOLD.) ****

d. FAR Clause **52.222-44, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment** (May 2014).

575

**** (USE BELOW WHEN THE CO IS UNABLE TO IDENTIFY ALL POSSIBLE PLACE(S) OF PERFORMANCE OF CONTRACT AT THE TIME OF SOLICITATION. SEE FAR 22.1009-4 FOR MORE INFORMATION.) ****

e. FAR Clause **52.222-49, Service Contract Labor Standards--Place of Performance Unknown** (May 2014)

"(a) ....., wage determinations have been requested for the following: _____ [insert places or areas]. The Contracting Officer will request wage determinations for additional places or areas of performance if asked to do so in writing by _____ [insert time and date]....."

576

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INCLUDING FAR 52.222-6 OR 52.222-41, WHERE WORK IS TO BE PERFORMED, IN WHOLE OR IN PART, IN THE UNITED STATES (THE 50 STATES AND THE DISTRICT OF COLUMBIA.)****

f. FAR Clause **52.222-55, Minimum Wages Under Executive Order 13658** (Jan 2022).

577

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INCLUDING FAR 52.222-6 OR 52.222-41, WHERE WORK IS TO BE PERFORMED, IN WHOLE OR IN PART, IN THE UNITED STATES (THE 50 STATES AND THE DISTRICT OF COLUMBIA.)****

g. FAR Clause **52.222-62, Paid Sick Leave Under Executive Order 13706** (Jan 2022).

578

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

579

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

SECTION J - LIST OF ATTACHMENTS

580

****(USE BELOW IN ALL SOLICITATIONS.)*****

Note: *If an Attachment listed below is NOT appropriate for the Solicitation, do not select it. If an attachment is required in the Solicitation but is NOT listed below, you will need to add it to this listing in the appropriate section.*

The following documents are incorporated into this RFP:

582.1

****(USE BELOW IN ALL SOLICITATIONS.)****

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location

****(USE BELOW IN ALL SOLICITATIONS BY OFFICES OF ACQUISITION THAT CURRENTLY USE THE NIH ELECTRONIC CONTRACT PROPOSALS SUBMISSION (eCPS) WEBSITE.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM

1. The Contract Specialist must specify the applicable clause under Section I.4.a. and must specify the Technical Proposal page limit under Section II.B.
2. It is recommended that you thoroughly read this attachment as it relates to the packaging and delivery of proposals with the NIH Electronic Contract Proposals Submission (eCPS) website.
3. Access this Attachment from the Workform Attachments Page: https://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files under Solicitation Attachments.

Attachment 1:	Packaging and Delivery of Proposals for Use with the NIH electronic Contract Proposal Submission (eCPS) Website

Attachment No.	Title	Location

****(USE BELOW IN ALL SOLICITATIONS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. Fill out the appropriate form from the Attachment Files - Section J: http://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files under Solicitation Attachments.
2. Save the file.
3. Upload this file using the Attachment Manager.

Attachment 2:	Packaging and Delivery of Proposal (2 locations)
Attachment 3:	Packaging and Delivery of Proposal (1 location)

****(USE BELOW IN ALL SOLICITATIONS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. Complete the following fields of the Proposal Intent Response Sheet from the Attachment Files - Section J Page on the OAMP Internet site: https://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files under RFP Attachments:
    - **RFP No.**
    - **RFP Title**
    - Select either a **Receipt Date** or indicate that intent forms are due at **"earliest practical date,"** in the combo box located in the first paragraph of the form.
2. Save the file.
3. Upload this file using the Attachment Manager.

Attachment 4:	Proposal Intent Response Sheet

****(USE BELOW IN ALL SOLICITATIONS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. It is recommended that you convert and save your SOW file into PDF format.
2. Upload the SOW file using the Attachment Manager.

Attachment 5:	Statement of Work

****(USE WHEN THE GOVERNMENT WILL PROVIDE GOVERNMENT FURNISHED PROPERTY TO BE USED IN THE RESULTANT CONTRACT.)****

Attachment 6:	Government Furnished Property

Attachment No.	Title	Location

****(USE BELOW IN ALL SOLICITATIONS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. Access this Form from the Workform Attachments Page: https://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files under RFP Attachments.
2. **Annual Representations and Certifications,** FAR Clause 52.204-8): Fill out subparagraph (c)(2) of this clause.
3. Save the File.
4. Upload this file using the Attachment Manager.

Attachment 7:	Section K - Representations, Certifications, and Other Statements of Offerors

****(USE BELOW WHEN AN OFFEROR WILL REQUIRE ACCESS TO SENSITIVE INFORMATION IN ORDER TO PREPARE AN OFFER.)****

Access this form at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Nondisclosure.pdf.

Attachment 8:	Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement

****(USE FOR A PERFORMANCE BASED (PBA) REQUIREMENT WHERE INCENTIVE IS TIED TO FEE.)****

Access this form from the Workform Attachments Page at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. It is recommended that you convert and save your QASP file into PDF format.
2. Upload the QASP using the Attachment Manager.

Attachment 9:	Quality Assurance Surveillance Plan

Attachment No.	Title	Location

****(USE FOR A PERFORMANCE BASED (PBA) REQUIREMENT USING AN "AWARD TERM" INCENTIVE.)****
Additional information on the Contractor Performance Assessment Reporting System (CPARS) found at: https://www.cpars.gov/documents/CPARS-Guidance.pdf.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. It is recommended that you convert and save the "Contractor Assessment Report/ Performance Indicators and Standards" file into PDF format.
2. Upload using the Attachment Manager.

Attachment 10:	Contractor Assessment Report/Performance Indicators and Standards

582.2

****(USE BELOW IN ALL SOLICITATIONS.)****

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location

****(USE IN ALL SOLICITATIONS THAT INVOLVE HUMAN SUBJECTS IN CLINICAL TRIALS.)****
Access this form at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

Attachment 11:	Inclusion Enrollment Report included in PHS Human Subjects and Clinical Trials Information Form (Study Record Form)

****(USE IN SOLICITATIONS THAT WILL UNDERGO PEER REVIEW.)****
Note: *This form may be included in any other solicitation at the discretion of the Contracting Officer.*
Access this form at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf.

Attachment 12:	Technical Proposal Cost Summary

****(USE IN ALL SOLICITATIONS.)****
Access this form at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf.

Attachment 13:	Summary of Related Activities

Attachment No.	Title	Location

****(USE BELOW IN ALL SOLICITATIONS THAT INVOLVE HUMAN SUBJECTS.)****
Access this form at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

Attachment 14:	Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310)

****(USE BELOW IN R&D SOLICITATIONS INVOLVING LIVE VERTEBRATE ANIMALS (INCLUDING THEIR USE AS A SOURCE OF TISSUES.)****
Access this form at: https://grants.nih.gov/grants/olaw/vascontracts.pdf.

Attachment 15:	Contract Proposal Vertebrate Animal Section (VAS) Worksheet

****(USE BELOW IN SOLICITATIONS IN ACCORDANCE WITH HHSAR 339, WHICH WILL DEVELOP, PURCHASE, MAINTAIN, OR USE ELECTRONIC AND INFORMATION TECHNOLOGY (EIT) PRODUCTS AND SERVICES, INCLUDING EIT DELIVERABLES SUCH AS ELECTRONIC DOCUMENTS AND REPORTS, UNLESS THE EIT PRODUCTS AND/OR SERVICES ARE INCIDENTAL TO THE PROJECT.)****

NOTE: *Other exceptions to this requirement can be found at FAR 39.204.*

IMPORTANT NOTE Regarding Electronic Report Submission requirements:
When the only EIT product required under the contract is the submission of electronic reports/deliverables AND the Contracting Officer and Project Officer have documented in the AP that:

- the required electronic reports/deliverables are considered incidental to the contract in accordance with 36 CFR 1194.3, FAR 39.204(c) and HHS Section 508 policy at 4.3.3; and,
- the contract will require submission in a 508 compliant format.
- Section 508 is not applicable to the contract and this item is not required.

The previous HHS Section 508 Evaluation Template Product Accessibility Template (PAT) was updated. Information and form located at: https://www.section508.gov/sell/vpat/.

Attachment 16:	Voluntary Product Accessibility Template (VPAT)

582.3

****(USE IN ALL SOLICITATIONS.)****

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location

****(USE IN ALL SOLICITATIONS.)
Access this form at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf.

Attachment 17: Proposal Summary and Data Record, NIH-2043

****(USE IN SOLICITATIONS OVER $750,000 (OR $1.5 Million for construction of Public Facilities).)****

Note: An offeror must submit their respective subcontracting plan electronically using the U.S. Department of Health and Human Services (HHS) Small Business Customer Experience (SBCX) system at https://osdbu.hhs.gov. The form will be generated by the portal when the offerors submit their information for each specific proposal. The offeror shall follow the instructions outlined in the SBCX Industry Guide .

Note: This item **DOES NOT APPLY** to Small Businesses.
Access the Industry Guide at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

Attachment 18: Small Business Subcontracting Plan

****(USE IN ALL SOLICITATIONS UNLESS AWARD IS BASED ON ADEQUATE PRICE COMPETITION.)****
See FAR 15.403-1.
Access these forms at: https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee-and-labor-hours and https://oamp.od.nih.gov/sites/default/files/DFASDocs/buscntrctprpslsprdsht08-2014_508.xlsx .

Attachment 19: Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet

****(USE AS DESIRED. THIS FORM IS OPTIONAL.)****
Access this form at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf.

Attachment 20: Offeror's Points of Contact

****(USE WHEN CERTIFIED COST OR PRICING DATA IS REQUIRED.)****
Access this form at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/cert-current-cost.pdf.

Attachment 21: Certificate of Current Cost or Pricing Data

Attachment No.	Title	Location

****(USE WHEN SERVICE CONTRACT LABOR STANDARDS APPLIES AND A WAGE RATE DETERMINATION IS NEEDED.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. To get most current Wage Rate Agreement, go to Wage Determinations on-line at: https://sam.gov/content/wage-determinations. Save the file and upload it here.
2. Make sure to indicate the area covered by the Wage Rate Determination attached.

Attachment 22: Wage Rate Determination

****(USE BELOW IN ALL SOLICITATIONS WITH AN EXPECTED CONTRACT VALUE OVER $100,000.)****

Access this form at: https://www.gsa.gov/forms-library/disclosure-lobbying-activities.

Attachment 23: Disclosure of Lobbying Activities, OMB Form SF-LLL

582.4

****(USE IN ALL SOLICITATIONS.)****

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location

****(USE WHEN RESULTANT CONTRACT USE WORK ASSIGNMENTS.)****

Access this form at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/wkassign.pdf.

Attachment 24: Sample Work Assignment

****(USE AS REQUIRED.)****

Access this form at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

Attachment 25: Invoice/Financing Request Instructions-CR-NIH(RC)-1

****(USE FOR ALL NIDA SOLICITATIONS.)****

Access this form at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

Attachment 26: NIDA Supplemental Billing Instructions, Exhibit A to NIH(RC)-1

Attachment No.	Title	Location

****(USE AS REQUIRED.)****
Access this form at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

Attachment 27: Invoice Instructions for NIH Fixed Price Contracts NIH(RC)-2

****(USE AS REQUIRED.)****
Access this form at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

Attachment 28: Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4

****(USE AS REQUIRED.)****
Access this form at: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2706.pdf.

Attachment 29: Financial Report of Individual Project/Contract NIH 2706

****(USE AS REQUIRED.)****
Access this form at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/instructions2706.pdf.

Attachment 30: Instructions for Completing Form NIH 2706

****(USE AS REQUIRED. MAKE SURE TO INCLUDE THE APPLICABLE SYSTEM OF RECORDS NUMBER IN THE SPACE PROVIDED.)****
Access this form at: https://www.hhs.gov/foia/privacy/sorns/nih-sorns.html.

Attachment 31: Privacy Act System of Records

****(USE WHEN THE RESULTANT CONTRACT WILL INVOLVE HAZARDOUS MATERIALS OR OPERATIONS.)****
Access this form at: https://oamp.od.nih.gov/sites/default/files/DGS/FORMS/hhsar_352.223-70_safety_and_health_508.pdf.

Attachment 32: Safety and Health, HHSAR Clause 352.223-70

Attachment No.	Title	Location

****(USE WHEN THE RESULTANT CONTRACT WILL INVOLVE PATIENT CARE.)****
Access this form at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc11.pdf.

Attachment 33: Research Patient Care Costs, NIH(RC)-11

****(USE WHEN THE RESULTANT CONTRACT WILL INVOLVE HUMAN SUBJECTS.)****
Access this form at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

Attachment 34: PHS Human Subjects and Clinical Trials Information Form

****(USE WHEN THE RESULTANT CONTRACT WILL INVOLVE HUMAN SUBJECTS AND MEETS THE NIH DEFINITION FOR CLINICAL RESEARCH.)****

Access this form at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

Attachment 35: Inclusion Enrollment Report included in PHS Human Subjects and Clinical Trials Information Form (Study Report Form)

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT INVOLVE HUMAN SUBJECTS, INCLUDING RESEARCH INVOLVING HUMAN SPECIMENS, SAMPLES, AND/OR DATA.)****

Access this form at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.
SEE NIH NOTICE NOT-OD-22-001, NIH Implementation of the Revised Common Rule Provision Regarding Public Health Surveillance Activities Deemed Not to Be Research at:
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-001.html.

Attachment 36: Public Health Surveillance Exclusion Request

****(USE AS REQUIRED.)****
To be determined during negotiations.

Attachment 37: Government Property Schedule

Attachment No.	Title	Location

****(USE WHEN THE RESULTANT CONTRACT IS SUBJECT TO IT SECURITY REQUIREMENTS.)****
Access this form at:
https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf.

Attachment 38: Commitment to Protect Non-Public Information Contractor Agreement

****(USE WHEN THE RESULTANT CONTRACT IS SUBJECT TO IT SECURITY REQUIREMENTS.)****

Access this form at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

Attachment 39: Roster of Employees Requiring Suitability Investigations

****(USE WHEN THE RESULTANT CONTRACT IS SUBJECT TO IT SECURITY REQUIREMENTS.)****
Access this form at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf.

Attachment 40: Employee Separation Checklist

****(USE FOR PROJECTS THAT REQUIRE THE USE OF AN EARNED VALUE MANAGEMENT SYSTEM (EVMS).)****
Select the applicable format(s) based on the designated tier for the requirement. Access the forms as follows:
Format 1: Work Breakdown Structure
https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2734-1.pdf.
Format 2: Organizational Categories
http://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2734-2.pdf.
Format 3: Baseline
https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2734-3.pdf.
Format 4: Staffing
https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2734-4.pdf.
Format 5: Explanations and Problem Analyses
https://www.esd.whs.mil/Portals/54/Documents/DD/forms/dd/dd2734-5.pdf.

Attachment 41: Contract Performance Reports (EVM)

Attachment No.	Title	Location

****(USE BELOW IN ALL SOLICITATIONS FOR CONFERENCES WHEN REGISTRATION FEES WILL BE CHARGED AND COLLECTED.)****
Contractor Pre-Conference Expense Offset Worksheet, 1 page. Located at:
https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Pre-Conf-worksheet.pdf.
Post Conference Expense Offset Worksheet, 2 pages. Located at:
https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Post-Conf-worksheet.pdf.

Attachment 42:	Conference Expense Offset Worksheets

**** USE BELOW IN SOLICITATIONS THAT INCLUDE THE SALE OF RESEARCH SUBSTANCES AND/OR LIVING ORGANISMS.)****
Access this form at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

Attachment 43:	The Sale of Research Substances and/or Living Organisms

****(USE BELOW IN ALL SOLICITATIONS THAT INVOLVE HUMAN FETAL TISSUE OBTAINED FROM ELECTIVE ABORTIONS.)****

NIH requires offerors to address Human Fetal Tissue (HFT) requirements by providing a justification for the use of HFT obtained from elective abortions, details regarding procurement and costs, and information about how the offeror will use HFT obtained from elective abortions.
Located at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HUMAN%20FETAL%20TISSUE%20OBTAINED%20FROM%20ELECTIVE%20ABORTIONS%20JUSTIFICATION%20Final.pdf.

Attachment 44:	Human Fetal Tissue Obtained From Elective Abortions Justification

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHERE CONTRACTORS ARE PROPOSED/WORK ON GOVERNMENT FACILITIES.)****
For all onsite contracts as Contractors return to physical workspace or utilize the NIH 2019 Novel Coronavirus (COVID-19) asymptomatic testing program.

1. COVID-19 Return to Work Guidance, located at:
https://oamp.od.nih.gov/sites/default/files/DGS/Return-to-Work-Guidance.pdf.
https://oamp.od.nih.gov/sites/default/files/DGS/Return-to-Work-Guidance.docx.
2. COVID-19 Return to Work Guidance- Appendix I for Contractors, located at:
https://oamp.od.nih.gov/sites/default/files/DGS/Return-to-Work-Guidance%20-%20Appendix%20I%20for%20CTRs_20200616.pdf.
https://oamp.od.nih.gov/sites/default/files/DGS/Return-to-Work-Guidance%20-%20Appendix%20I%20for%20CTRs_20200616.docx.

Attachment No.	Title	Location
Attachment 45:	COVID-19 Return to Work Guidance	

****(USE BELOW IN ALL SOLICITATIONS.)****

1. Electronic Invoicing Instructions Notification to NIH Contractors/Vendors, located at: https://oamp.od.nih.gov/sites/default/files/dgs/Communication%20to%20Vendors%20on%20Deadline%20to%20Stop%20Accepting%20Mailed%20Invoice_%20Final%2011-4-20-508.pdf.
2. Electronic Invoicing Step-by-Step Instructions for NIH Contractors/Vendors, located at: https://oamp.od.nih.gov/sites/default/files/DGS/Electronic Invoicing Step-by-Step Instructions 7-22.pdf.

Attachment 46:	Electronic Invoicing Instructions for NIH Contractors/Vendors

581

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

PART IV - REPRESENTATIONS AND INSTRUCTIONS

582

****(USE BELOW IN ALL SOLICITATIONS.)****

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

583

****(USE BELOW IN ALL SOLICITATIONS.)****

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST:

1. Go to the **System for Award Management (SAM)** and complete the Representations and Certifications. The SAM website may be accessed at: https://www.sam.gov/content/home ; and

2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**

   SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS which is included as an Attachment in Section J-LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation.

   If you are unable to access this SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

3. FAR Clause 52.204-19 **Incorporation by Reference of Representations and Certifications** (December 2014).

   The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

   (End of clause).

584

****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

585

****(USE BELOW IN ALL SOLICITATIONS.)****

1. **GENERAL INFORMATION**

586

****(USE BELOW IN ALL COMPETITIVE SOLICITATIONS.

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. This basic provision states that the Government intends to make award WITHOUT discussions. If the CO intends to establish a competitive range and hold discussions with offerors in that range, use this provision with its Alternate I.
2. In accordance with HHSAR 352.215-1, the subparagraph (e) contained in this item has been substituted for the subparagraph (e) of the provision at FAR 52.215-1.)****

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** FAR 52.215-1 (Nov 2021).

(a) Definitions . As used in this provision-

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

In writing , "writing," or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

Proposal modification is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

Proposal revision is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

Time , if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) Amendments to solicitations . If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) Submission, modification, revision, and withdrawal of proposals.

(1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show-

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) Submission, modification, revision, and withdrawal of proposals.

(i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and-

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5 , Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17 , Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) Restriction on disclosure and use of data. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall-

(1) Mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed-in whole or in part-for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of-or in connection with-the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]; and

(2) Mark each sheet of data it wishes to restrict with the following legend:

Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

(f) Contract award.

(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306 (a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection.

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial products, the make and model of the product to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of provision).

587

****(USE BELOW WITH THE BASIC PROVISION, ABOVE, IF THE CONTRACTING OFFICER INTENDS TO MAKE AWARD AFTER DISCUSSIONS WITH OFFERORS WITHIN THE COMPETITIVE RANGE.)****

Alternate I (*Oct 1997).* As prescribed in FAR 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

588

****(USE BELOW WITH THE BASIC PROVISION IF THE CONTRACTING OFFICER DETERMINES THAT THE SUBMISSION OF ALTERNATE PROPOSALS AND DEVIATIONS FROM THE TERMS AND CONDITIONS OF THE SOLICITATION ARE ACCEPTABLE.)****

Note: *This Alternate allows offerors to propose changes in the terms and conditions as well as the technical requirement. Any proposed alternate to the terms and conditions set forth in SECTIONS A-K of the solicitation could have direct impact on the resultant contract. If it is your intent to allow offerors to submit alternate technical proposals ONLY, note that this is authorized in SECTION L.2.a(5), entitled, "Alternate Proposals," in this workform. Please read both paragraphs carefully to determine exactly which situation you wish to authorize.*

Alternate II *(Oct 1997).* As prescribed in FAR 15.209(a)(2), add a paragraph (c)(9) substantially the same as the following to the basic clause:

(9) Offerors may submit proposals that depart from stated requirements. Such proposals shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the terms and conditions of the solicitation, as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the solicitation to allow all offerors an opportunity to submit revised proposals based on the revised requirements.

589

****(USE BELOW WHEN ISSUING A SOLICITATION FOR INFORMATION OR PLANNING PURPOSES. NOTE: The cover page of the solicitation must be clearly marked indicating that the solicitation is for information or planning purposes.)****

b. **REQUEST FOR INFORMATION OR SOLICITATION FOR PLANNING PURPOSES FAR 52.215-3** (Oct 1997).

(a) The Government does not intend to award a contract on the basis of this solicitation or to otherwise pay for the information solicited except as an allowable cost under other contracts as provided in subsection 31.205-18, Bid and proposal costs, of the Federal Acquisition Regulation.

(b) Although "proposal" and "offeror" are used in this Request for Information, your response will be treated as information only. It shall not be used as a proposal.

(c) This solicitation is issued for the purpose of: _____ [State Purpose]

(End of provision).

590

****(USE BELOW IN SOLICITATIONS INVOLVING TOTAL SMALL BUSINESS SET ASIDES.)****

c. **NOTICE OF SMALL BUSINESS SET-ASIDE**

1. **General.** Offerors are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.
2. **Definitions.** The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the size standards in this solicitation. In addition to meeting these criteria, a small business concern submitting an offer in his own name shall furnish, in the performing the contract, only end items manufactured or produced by small business concerns in the United States or its outlying areas, provided that this additional requirement does not apply in connection with construction or service contracts.

591

****(USE BELOW IF THIS REQUIREMENT IS A COMPETITIVE 8(a) SET-ASIDE.)****

d. **NOTICE OF 8(a) COMPETITIVE SET-ASIDE**

Offers are solicited only from small business concerns expressly certified by the Small Business Administration (SBA) for participation in the SBA's 8(a) Program. Bids or proposals received from others will be considered non-responsive.

592

****(USE BELOW IF THIS REQUIREMENT WILL BE SET-ASIDE UNDER THE SERVICE-DISABLED VETERAN- OWNED SMALL BUSINESS (SDVOSB) PROCUREMENT PROGRAM.)****
See FAR 19.1405 for SDVOSB set-aside procedures.

e. **NOTICE OF SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESS SET-ASIDE**

In accordance with the "Service-Disabled Veteran-owned Small Business (SDVOSB) Procurement Program" authorized by the Veterans Benefit Act of 2003 (15 U.S.C. 657f), offers are solicited only from Service-Disabled Veteran-owned Small Business concerns.

At the time of proposal submission, a service-disabled veteran-owned small business (SDVOSB) concern must represent to the Contracting Officer that it is a SDVOSB concern and is considered small under the North American Industry Classification System (NAICS) code assigned to the solicitation.

Offers received from other than SDVOSB concerns shall not be considered.

593

****(USE BELOW IN ALL SOLICITATIONS (EXCEPT FOREIGN))****

f. **NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is _____ .
2. The small business size standard is _____ .

594

****(INCLUDE FOR ALL SOLICITATIONS WHICH ARE NOT SMALL BUSINESS OR 8(a) SET ASIDES.)****

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

595

****(INCLUDE BELOW, IN ALL SOLICITATIONS. MAKE SURE TO INCLUDE SPECIFIC AWARD INFORMATION IN THE APPROPRIATE PARAGRAPHS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Paragraph 1** : Select the appropriate anticipated number of awards within the brackets. Modify this information if needed.
2. **Paragraph 2** : Select the appropriate information for your solicitation from within the bracketed section. *If incremental funding is NOT being contemplated, adjust the paragraph accordingly.*
3. **Paragraph 3** : Include this paragraph for all solicitations EXCEPT Firm-Fixed Price contracts. Delete this paragraph 3 when the resultant contract will be FFP.

g. **TYPE OF CONTRACT AND NUMBER OF AWARDS**

1. It is anticipated that [one/multiple award(s)] will be made from this solicitation and that the award(s) will be made on/about _____ .
2. It is anticipated that the award(s) from this solicitation will be a multiple-year [Cost-Reimbursement/Fixed-Price] type [Completion/Level of Effort] contract with a [Term of _ Years/Period of Performance of _____], and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).
3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a Contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

596

****(INCLUDE BELOW IN ALL SOLICITATIONS THAT WILL RESULT IN THE AWARD OF MULTIPLE AWARD INDEFINITE DELIVERY CONTRACTS.)****

h. **TASK ORDERS UNDER MULTIPLE AWARD INDEFINITE DELIVERY CONTRACTS**

a. **General**

The Contractor will be required provide services under the resultant contract only in performance of task orders and modifications to task orders signed by the Contracting Officer. Costs not attributed to the performance of a specific task order shall not be allowed without the prior written consent of the Contracting Officer. The Contractor will commence performance upon the receipt of a Task Order signed by the Contracting Officer. Costs for the preparation of Task Order proposals shall not be reimbursed as a direct cost under the resultant contract.

One or more task orders may be issued during the performance period of the resultant

contract. If a Contractor responds to a Task Order Request for Proposal (TORFP) and is the successful offeror, that Contractor will be required to accept and perform the task order issued by the Contracting Officer within the scope of the resultant contract. The government has no obligation to issue any task orders, beyond the minimum identified in SECTION B of the contract. In the event of any inconsistency between any task order and the contract, the contract shall control.

In accordance with the Federal Acquisition Streamlining Act, the Contracting Officer will provide each Contractor a "Fair Opportunity" to be considered for each Task Order awarded in excess of $3,500, unless one of the conditions in FAR 16.505(b)(2) applies.

The competition requirements in FAR Part 6, and the policies in FAR Subpart 15.3, **DO NOT APPLY** to the task ordering process. For each requirement under the resultant contract, the government intends to provide each Contractor a fair opportunity for consideration of a task order. The Contracting Officer shall:

1. Issue a notice of intent to award a task order for services to all resultant Contractors within a technical area covered by the task order requirement. To satisfy this requirement, the Contracting Officer will provide an e-mail notifying all qualified Contractors of the requirement. The e-mail will identify how the details concerning the requirement, including a description of the work and selection criteria, will be provided, i.e. attached to the e-mail, posted on a website. Contractors will be asked to submit a response to the notice of intent, advising the government of their intent to submit a proposal or quote;

2. Afford all Contractors, within the technical area covered by the task order requirement, who are responding to the notice, a fair opportunity to submit an offer and have that offer fairly considered;

3. Consider price and cost under each order as one of the factors in the selection decision;

4. Keep submission requirements to a minimum;

5. Consider past performance on earlier task orders under this contract to the maximum extent possible. Past performance considerations shall include, but not be limited to, the Contractor's performance regarding completeness, accuracy, clarity, timeliness and cost control. If a Contractor has no past performance on any earlier task order, past performance will be considered through other sources, such as the Contractor's original proposal.

In addition to the above, for all orders exceeding $5 million, the Contracting Officer will consider all requirements set forth in FAR 16.505(b)(1)(iv).

b. **Exceptions to Fair Opportunity**

Contractors may not be given an opportunity to be considered for requirements in excess of $3,500 if one of the following conditions applies:

1. The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.
2. Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.
3. The order must be issued on a sole-source basis in the interest of economy and efficiency because it is a logical follow-on to an order already issued under the contract, provided that all awardees were given a fair opportunity to be considered for the original order.
4. It is necessary to place an order to satisfy a minimum guarantee.

c. **Requesting Task Order Proposals**

The Contracting Officer or a designated individual may solicit responses to requirements from Contractors within a technical area covered by a task order requirement in writing.

A Task Order Request for Proposals (TORFP) will be prepared and issued for each task order requirement.
All contract clauses contained the resultant contract shall be incorporated in the TORFP and the resultant task order. If conflicts exist between the contract clauses and the information outlined in the task order, the resultant contract language takes precedence over the information in the task order.

d. **Competitive Ordering Process**

1. All Contractors within a technical area will receive e-mail notification advising of the availability of each proposed task order requirement. All proposed task orders will incorporate all terms of the resultant contract unless otherwise specified in the proposed task order.

2. Contractors will be provided an adequate time to prepare and submit responses based on the Contracting Officer's consideration of the estimated dollar value and complexity of proposed task order. Responses will not be considered a proposal as defined in FAR Part 15. However, the Contractor shall provide information sufficient for consideration in accordance with FAR Part 16. Each TORFP will indicate the criteria for the evaluation of proposals. The responses shall demonstrate capability for each criterion to be evaluated. Generally, the Contractor will be asked to demonstrate the following as appropriate:
    - Understanding of the requirements;
    - Experience and capability on similar tasks;
    - Technical approach, methods and procedures for satisfying the requirements with a discussion of potential problems to be encountered and proposed solutions and/or risk mitigation strategies.
    - Procedures for assuring quality of work, products, and deliverables;

- Plan for managing the task order, including meeting requirements and schedules, and performance measures (if applicable);
- Staffing plan with skill levels and level of effort for each individual proposed. Generally, resumes will be required for proposed personnel (if not previously submitted);
- References to evaluate past performance; and
- Cost/Price to perform the task order.

e. **Evaluation and Award of Task Order Proposals**

The Government will evaluate the Task Order proposals against the requirements of the TORFP. Specifically, the technical evaluation factors, cost/price, past performance and any other factor specifically identified in the TORFP will be used for evaluation of each proposal. In addition, the TORFP will identify the basis for selecting a Contractor for award. Generally, technical factors will be significantly more important than price and other factors. However, each TORFP will specify how the award decision will be made.

Upon completion of evaluations, the Contracting Officer will issue a task order to the Contractor whose proposal is most advantageous to the government.

The Contracting Officer will notify the IDIQ Contractors of the selection decision in writing.

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****(INCLUDE BELOW WHEN THE GOVERNMENT INTENDS TO USE A PERFORMANCE BASED ACQUISITION METHOD IN THE AWARD OF THE CONTRACT.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Third Paragraph(s):** Select the one of the three paragraphs below, that is applicable to your SOLICITATION. If you will be using a different incentive than that defined below, you will need to develop language appropriate to your requirement.

i. **PERFORMANCE BASED ACQUISITION**

The Government intends to use a Performance Based Acquisition method in the evaluation and award of any contract resulting from this SOLICITATION.

The Performance Based contract is designed to motivate the Contractor to perform at a higher standard. Outstanding performance is rewarded through an incentive defined in the contract. The following performance incentive will be used in any contract awarded from this SOLICITATION:

Cost-Plus-Award-Fee (CPAF): The CPAF contract includes an estimated cost and an award fee amount that is paid based upon periodic evaluations of Contractor performance. The Quality Assurance Surveillance Plan (QASP), which is included as an attachment to this SOLICITATION sets forth all the elements required for evaluation and determination of the award fee amount. The award fee determination is made unilaterally by the

Government and is not subject to Disputes clause procedures. The QASP is included in this SOLICITATION and located _____ .

OR

Award Term: The Award Term contract includes one or more extensions of the contract period for which the Contractor is entitled based upon periodic evaluations of Contractor performance. This is not a Government option to extend the contract. Under the Award Term incentive, if the Contractor's evaluated performance meets the Award Term criteria set forth in the Quality Assurance Surveillance Plan (QASP) and funds are available and there is a continuing need for the items or services set forth in the Statement of Work, the Award Term will be issued. The QASP is included in this SOLICITATION and located _____ .

OR

Award Option: The Award Option contract includes one or more options to extend the contract period based upon periodic evaluations of Contractor performance. Under the Award Option incentive, the Contractor's evaluated performance against the criteria set forth in the Quality Assurance Surveillance Plan (QASP) serves as the precursor to the Government exercising its unilateral rights in accordance with FAR Part 17.2. A successful Award Option evaluation precedes the Government's review and determination to exercise or not to exercise the Award Option. The QASP is included in this RFP and located _____ .

598

****(INCLUDE BELOW WHEN A PRE-PROPOSAL CONFERENCE IS SCHEDULED. MAKE SURE TO INCLUDE SPECIFIC CONFERENCE INFORMATION IN THE APPROPRIATE PARAGRAPHS.)****

j. **PRE-PROPOSAL CONFERENCE**

A pre-proposal conference will be held with prospective offerors at _____ on _____ . The pre-proposal conference will be held for the purpose of providing information concerning the Government's requirements which may be helpful in the preparation of proposals and for answering any questions which you have regarding this solicitation.

The success of this type of conference depends largely on the lead-time available to the Government for research in connection with questions submitted by offerors. Therefore, you are requested to mail written questions concerning any areas of uncertainty which, in your opinion, require clarification or correction, in sufficient time to be received on or before _____ at the

address specified in Block 7 of SECTION A - Solicitation/Contract Form of this solicitation.

Your questions should be submitted to the Contract Specialist, _____ and the envelope should be marked, "Pre-proposal conference, RFP No. _____." A set of all questions and answers will be furnished simultaneously to all prospective offerors whether or not they are in attendance.

Because of space limitations, each prospective offeror shall be limited to a total of _ representatives.

Attendance at the pre-proposal conference is recommended; however, attendance is not a prerequisite for proposal submission and will not be considered a factor in proposal evaluation.

599

****(USE BELOW WHEN A COST-REIMBURSEMENT COMPLETION OR A FIXED-PRICE R&D TYPE CONTRACT WILL BE AWARDED FROM THIS SOLICITATIONS. THIS MAY ALSO BE USED IN OTHER SITUATIONS AS THE CO DEEMS APPROPRIATE. MAKE SURE TO COMPLETE INFORMATION IN THE PARAGRAPH.)****

k. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this SOLICITATION. To assist you in the preparation of your proposal, the Government considers the effort to be approximately _____ labor hours. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

600

****(USE BELOW WHEN A COST-REIMBURSEMENT TERM (I.e. LEVEL OF EFFORT) TYPE CONTRACT WILL BE AWARDED FROM THIS SOLICITATION. MAKE SURE TO COMPLETE INFORMATION IN THE PARAGRAPH.)****

l. **LEVEL OF EFFORT**

The Government's requirement for the work set forth in the Statement of Work of this solicitation is _____ direct labor hours. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

Labor Hours

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7

601

****(INCLUDE BELOW WHEN BRAND NAME OR EQUAL PURCHASE DESCRIPTIONS ARE INCLUDED IN THE SOLICITATION.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- This item is for use with Brand Name or EQUAL.
- If your solicitation includes the requirement for acquiring a "Brand Name" item ONLY, you must include a written justification as required by FAR 11.105 with your solicitation. Additionally, in accordance with OFPP Memorandum dated, April 11, 2005, entitled "Use of Brand Name Specifications," this justification must be posted in Contract Opportunities at https://sam.gov/content/home with the SOLICITATION. Therefore, if you require a "Brand Name Specification," do not use this item. However, you should tailor a paragraph to be included with your RFP which either includes the justification for Brand Name Specification or references where the justification is published. If providing the justification is inappropriate because of National Security, Trade Secrets, or similar concerns, a copy of the justification to the file must be provided to the Office of Federal Procurement Policy (OFPP) through the Director, DAPE, OAMP, NIH.

m. **BRAND NAME OR EQUAL,** FAR 52.211-6 (Aug 1999).

a. If an item in this solicitation is identified as "brand name or equal," the purchase description reflects the characteristics and level of quality that will satisfy the Government's needs. The salient physical, functional, or performance characteristics that "equal" products must meet are specified in the solicitation.

b. To be considered for award, offers of "equal" products, including "equal" products of the brand name manufacturer, must-

1. Meet the salient physical, functional, or performance characteristic specified in this solicitation;
2. Clearly identify the item by-
    i. Brand name, if any; and
    ii. Make or model number;
3. Include descriptive literature such as illustrations, drawings, or a clear reference to previously furnished descriptive data or information available to the Contracting Officer; and
4. Clearly describe any modifications the offeror plans to make in a product to make it conform to the solicitation requirements. Mark any descriptive material to clearly show the modifications.

c. The Contracting Officer will evaluate "equal" products on the basis of information furnished by the offeror or identified in the offer and reasonably available to the Contracting Officer. The Contracting Officer is not responsible for locating or obtaining any information not identified in the offer.

d. Unless the offeror clearly indicates in its offer that the product being offered is an "equal" product, the offeror shall provide the brand name product referenced in the solicitation.

(End of provision).

602

****(USE BELOW IN ALL SOLICITATIONS.)****

n. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

603

****(INCLUDE BELOW IN ALL SOLICITATIONS THAT INVOLVE LOGISTICAL SUPPORT SERVICES; INCLUDES THE CONDUCT OF A CONFERENCE OR MEETING, EVEN IF INCIDENTAL TO THE PERFORMANCE OF THE CONTRACT; INVOLVES THE PROCUREMENT OF PROMOTIONAL ITEMS; AND PRINTING AND/OR PUBLICATION SERVICES.)****

o. **PROMOTING EFFICIENT SPENDING**

On September 21, 2011, the Office of Management and Budget issued Memorandum M-11-35 , https://obamawhitehouse.archives.gov/sites/default/files/omb/memoranda/2011/m11-35.pdf entitled, "Eliminating Conference Spending and Promoting Efficiency in Government," emphasizing the President's priority to ensure that the Government operates with the utmost efficiency and eliminates unnecessary or wasteful spending. This was followed by the Executive Order on Delivering an Efficient, Effective, and Accountable Government (EO 13576) and the Executive Order on Promoting Efficient Spending (EO 13589). On January 23, 2015, the Department of Health and Human Services (DHHS) issued the memorandum "HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings Spaces, Food, Promotional Items, and Printing, and Publications" (See http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html).

In support of these directives, the NIH issued a November 1, 2015, Memorandum, entitled, "NIH Guidance Related to the HHS Policies on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meeting Space, Food, Promotional Items, and Printing and Publications." (See https://oamp.od.nih.gov/news/NIH-efficient-spending-policy)

Any contract awarded as a result of this solicitation will:

- Specifically prohibit the use of contract funds for the provision of food for meals, light refreshments and beverages for any NIH funded meeting or conference; and
- Limit the procurement of meeting space, promotional items, printing and publications.

604

****(USE BELOW IN ALL SOLICITATIONS.)****

p. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this SOLICITATIONS. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

605

****(USE BELOW IN ALL SOLICITATIONS.)****

q. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

606

****(USE BELOW WHEN REFERENCE MATERIALS WILL BE MADE AVAILABLE FOR PROSPECTIVE OFFERORS. INCLUDE SPECIFIC INFORMATION IN THE APPROPRIATE PARAGRAPHS)****

r. **REFERENCE MATERIALS**

A "reading room" containing reference materials pertinent to this acquisition is available in Room __ , Address- _____ , from __ Monday through Friday (except Government holidays) through the closing date of the RFP. Use of the reading room is by appointment only; contact _____ , phone _____ , e-mail _____ for arrangements. Failure of offerors to examine the reference materials prior to proposal preparation and submission will be at the offeror's risk.

607

****(INCLUDE BELOW WHEN THE PROJECT HAS NOT UNDERGONE CONCEPT REVIEW AT THE TIME OF SOLICITATION ISSUANCE.)****

s. **CONCEPT REVIEW**

This project has not been reviewed by the Board of Scientific Counselors as required. Such review will occur prior to technical evaluation. Thus potential offerors are cautioned that cancellation of this RFP due to disapproval by the Board of Scientific Counselors is a possibility.

608

****(USE BELOW IN ALL SOLICITATIONS.)****

t. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

609

****(USE BELOW IN ALL SOLICITATIONS.)****
Make sure to complete the address below.

u. **SERVICE OF PROTEST** FAR 52.233-2 (Sep 2006).

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Office of Acquisitions

_____
_____ Room ___
_____ MSC ___
_____ - __

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of provision).

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****(USE BELOW FOR RESEARCH AND DEVELOPMENT PROJECTS WHEN THE HCA DETERMINES THAT USE OF THIS PROVISION IS APPROPRIATE.)****
See HHSAR 315.208.
Note: *IF the project will not require Peer Review, DO NOT use this clause.*

v. **LATE PROPOSALS AND REVISIONS** , HHSAR 352.215-70 (December 2015).

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, the Government may consider a proposal received after the date specified for receipt if it appears to offer significant cost or technical value to the Government and it was received before proposals were distributed for evaluation, or within 5 calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision).

611

****(USE BELOW WHEN ACQUIRING FIP RESOURCES, IF ANY OF THE TERMINOLOGY TO INCORPORATE STANDARDS IN THIS SOLICITATION ARE INCORPORATED BY REFERENCE.)****

w. **AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."**

Copies of the "Federal ADP and Telecommunications Standards Index" can be purchased from the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402.

612

****(NCI Users: USE BELOW WHEN NON-GOVERNMENT PERSONNEL WILL BE UTILIZED IN THE EVALUATION OF TECHNICAL PROPOSALS.
NCI Processes/Procedures - Regulation listed below - Reviewed 9/22)****

x. **USE OF NON-GOVERNMENT PERSONNEL FOR TECHNICAL PROPOSAL EVALUATION**

In accordance with 42 C.F.R. 52h, Non-Government personnel will be utilized as reviewers in the evaluation of Technical Proposals submitted in response to this solicitation. While NIH requires competent, objective, and expeditious evaluation of proposals submitted in response to R&D solicitations, the use of Non-Government reviewers will be strictly controlled. Non-Government reviewers will be utilized in the evaluation of Technical Proposals only and will not have access to Business proposals submitted in response to this solicitation. All proposed Non-Government reviewers will be required to identify any conflicts of interest held with relation to offeror's organizations and/or investigators submitting proposals in response to this solicitation and will be required to ensure the confidentiality of review documents and proceedings.

613

****(USE BELOW IN ALL SOLICITATIONS.)****

2. **INSTRUCTIONS TO OFFERORS**

614

****(USE BELOW IN ALL SOLICITATIONS.)****

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

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****(USE BELOW IN ALL SOLICITATIONS.)****
ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- Select the appropriate contract type from within the bracketed section.

1. **Contract Type and General Clauses**

It is contemplated that a [cost-reimbursement [(completion/level of effort)/fixed price] type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

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****(USE BELOW IN ALL SOLICITATIONS.)****

2. **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper, printed/copied double-sided, on at least 30 percent post-consumer fiber paper, as required by FAR 4.302(b), and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the SOLICITATION should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, UEI No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

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****(USE BELOW FOR NHLBI ONLY
NHLBI Processes/Procedures Reviewed 9/22)****

3. **FEDCONNECT SOLICITATION INSTRUCTIONS**

Interested parties are hereby notified that communications and submissions (e.g., proposals, solicitation questions, amendments, negotiation questions and responses, etc.) will be conducted via the FedConnect web portal (www.fedconnect.net). Vendors can register with FedConnect at https://www.fedconnect.net/FedConnect/default.htm . Offerors are advised that proposal/file submissions must not exceed 25 MB and the total size for all attachments must be less than 100 MB. In accordance with FAR 52.215-1, offerors should plan on submitting proposals no later than 5:00 p.m. one working day prior to the date specified for receipt of proposals.

Please note that FedConnect is used by multiple federal agencies and, therefore, FedConnect assistance will be provided by Compusearch Software Systems, not the NHLBI OA. More information about registration requirements can be found by downloading the FedConnect Ready, Set, Go! Guide at https://www.fedconnect.net/fedconnect/Marketing/Documents/ FedConnect_Ready_Set_Go.pdf . For assistance in registering or for other FedConnect technical questions, please call the FedConnect Help Desk at (800) 899-6665 or email at support@fedconnect.net .

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****(USE BELOW IN ALL SOLICITATIONS.)****

4. **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See SECTION J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

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****(USE BELOW IN ALL SOLICITATIONS.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

This item is written for proposals which will be peer reviewed. These review panels are not given pricing data relating to individual salary information, indirect costs, fee amounts and total costs. If the proposals submitted under your SOLICITATIONS will not undergo peer review, you may want to consider changing the paragraph below to fit your review situation. e.g. you may wish to substitute the Attachment entitled, "Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet," and remove some of the language restricting submission of certain pricing data.

5. **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

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****(NHLBI: USE BELOW IN ALL NHLBI SOLICITATIONS.
NHLBI Processes/Procedures Reviewed 9/22)****

6. **Uniform Resource Locators (URLs) in Contract Proposals**

All proposals must be self-contained within the specific page limitations cited elsewhere in this solicitation. Unless otherwise specified, URLs/Internet addresses shall not be used to provide information necessary to the review because reviewers are under no obligation to review the Internet sites.

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7. **Page and Formatting Limitations**

The Technical Plan (objectives, approach, methods and procedures, and substudy proposal) of the technical proposal shall not exceed 30 single-sided pages or 15 double-sided pages. This page limitation does not include the cover sheet, abstract, table of contents, personnel, facilities, equipment and resources, other considerations, schedule, other support, cost information, and literature cited. The substudy proposal section of the Technical Plan (included within the 30 page limit) shall not exceed 8 single-sided or 4 double-sided pages. Appendices shall not exceed a total of 50 single-sided pages or 25 double-sided pages. Pages in excess of the limitation will be deleted and will be neither read nor evaluated. Each page of the technical proposal must be numbered sequentially. Offerors are encouraged to limit the overall size of the technical proposal, inclusive of appendices, attachments, etc. Although no page limit has been placed on the business proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

Type density and size must be 10 to 12 points. If constant spacing is used, 15 cpi (characters per inch) or fewer shall be used, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be no less than ½ inch around, exclusive of headers and footers.

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****(USE BELOW IN ALL SOLICITATIONS IF THE GOVERNMENT WOULD BE WILLING TO ACCEPT ALTERNATE PROPOSALS.)****

8. **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the terms and conditions of the solicitation, as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the solicitation to allow all offerors an opportunity to submit revised proposals based on the revised requirements.

623

****(USE BELOW IN ALL SOLICITATIONS.)****

9. **Evaluation of Proposals**

The Government will evaluate proposals in accordance with the factors set forth in PART IV, SECTION M of this RFP.

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****(USE BELOW WHEN THE PROVISION AT FAR 52.215-1, Instructions to Offerors - Competitive Acquisition, IS USED WITH ITS ALTERNATE I. THIS PROVISION ADVISES OFFERORS THAT THE GOVERNMENT INTENDS TO MAKE AWARD AFTER CONDUCTING DISCUSSIONS WITH OFFERORS WHOSE PROPOSALS ARE WITHIN THE COMPETITIVE RANGE. THE FOLLOWING MUST BE INCLUDED IN THE SOLICITATION IF THE CONTRACTING OFFICER WISHES TO RESERVE THE RIGHT TO MAKE AWARD WITHOUT DISCUSSIONS NOTWITHSTANDING THE LANGUAGE IN ALTERNATE I.)****

10. **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

625

****(USE BELOW IN ALL SOLICITATIONS.)****

11. **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant

inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

626

****(USE BELOW WHERE THERE MAY BE OFFERS FROM INSTITUTIONS THAT ARE CONSIDERED UNDER THE PRIVACY RULE TO BE "COVERED ENTITIES" (AS DEFINED IN THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 ("HIPAA").)****

12. **Standards for Privacy of Individually Identifiable Health Information**

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply.

Decisions about the applicability and implementation of the Privacy Rule reside with the Contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html .

627

****(USE BELOW IN SOLICITATIONS FOR PERSONAL PROTECTIVE EQUIPMENT (PPE) WHEN THE ACQUISITION IS ABOVE THE MICRO PURCHASE THRESHOLD.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Applicability of Commercial Clauses:**

When the clause at FAR 52.212-5, Contract Terms and Conditions Required To Implement Statutes or Executive Orders-Commercial Products and Commercial Services is included in a solicitation and contract for PPE above the micro purchase threshold, Contracting Officers shall also include the full text of HHSAR 352-225-70 Made in America - Personal Protective Equipment. **(Contracting Officers do not check off paragraphs (b)(48) thru (50) of FAR clause 52.212-5 if HHSAR clause 352.225-70 will apply to the procurement.)** and HHSAR 352.225-71 Made in America Certificate - Personal Protective Equipment.

When the provision at FAR 52.212-3, Offeror Representations and Certifications-Commercial Products and Commercial Services is included in a solicitation for PPE Contracting Officers shall also include the full text of HHSAR 352-225-70 Made in America - Personal Protective Equipment and HHSAR 352.225-71 Made in America Certificate - Personal Protective Equipment.

- **PPE should be obtained through the NIH Supply Center, the VA, and the GSA.**

13. HHSAR **352.225-70, Made in America - Personal Protective Equipment** (February 2023).

(a) *Definitions.* As used in this clause-

Component, as applied to an item described in subsection (b) of this clause, means an article, material, or supply incorporated directly into personal protective equipment.

Domestic personal protective equipment, as applied to an item described in subsection (b) of this clause, means personal protective equipment, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the United States.

Foreign-made domestic personal protective equipment, as applied to an item described in subsection (b) of this clause, means personal protective equipment that is assembled outside the United States containing only materials and components that are grown, reprocessed, reused, or produced in the United States.

Foreign personal protective equipment means personal protective equipment other than domestic personal protective equipment or foreign-made domestic personal protective equipment.

Personal protective equipment, as applied to an item described in subsection (b) of this clause, means surgical masks, respirator masks and powered air purifying respirators and required filters, face shields and protective eyewear, gloves,

disposable and reusable surgical and isolation gowns, head and foot coverings, and other gear or clothing used to protect an individual from the transmission of disease.

United States, as applied to an item described in subsection (b) of this clause, means the 50 States, the District of Columbia, and the possessions of the United States.

(b) The Contractor shall deliver only domestic personal protective equipment, unless it specified delivery of foreign-made domestic personal protective equipment in the provision of the solicitation entitled "Made in America Certificate - Personal Protective Equipment."

(End of clause).

628

****(USE BELOW IN SOLICITATIONS FOR PERSONAL PROTECTIVE EQUIPMENT (PPE) WHEN THE ACQUISITION IS ABOVE THE MICRO PURCHASE THRESHOLD.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Applicability of Commercial Clauses:**

When the clause at FAR 52.212-5, Contract Terms and Conditions Required To Implement Statutes or Executive Orders-Commercial Products and Commercial Services is included in a solicitation and contract for PPE above the micro purchase threshold, Contracting Officers shall also include the full text of HHSAR 352-225-70 Made in America - Personal Protective Equipment. **(Contracting Officers do not check off paragraphs (b)(48) thru (50) of FAR clause 52.212-5 if HHSAR clause 352.225-70 will apply to the procurement.)** and HHSAR 352.225-71 Made in America Certificate - Personal Protective Equipment.

When the provision at FAR 52.212-3, Offeror Representations and Certifications-Commercial Products and Commercial Services is included in a solicitation for PPE Contracting Officers shall also include the full text of HHSAR 352-225-70 Made in America - Personal Protective Equipment and HHSAR 352.225-71 Made in America Certificate - Personal Protective Equipment.

- **PPE should be obtained through the NIH Supply Center, the VA, and the GSA.**

14. HHSAR **352.225-71, Made in America Certificate - Personal Protective Equipment** (February 2023).

(a)(1) The Offeror certifies that each item of personal protective equipment, except those listed in paragraph (b) of this provision, is domestic personal protective equipment.

(2) The Offeror shall list offered foreign-made domestic personal protective equipment items in paragraph (b).

(3) The terms "domestic personal protective equipment," "foreign-made

domestic personal protective equipment," foreign personal protective equipment," and "personal protective equipment," are defined in the clause of this solicitation entitled "Made in America-Personal Protective Equipment."

(b) Foreign-made Domestic Personal Protective Equipment:

Line-Item No.	Country of Origin

[List as necessary.]

(End of provision).

629

****(USE BELOW IN SOLICITATIONS OVER THE MICROPURCHASE THRESHOLD, IN CONNECTION WITH THE IMPLEMENTATION OF HIV/AIDS PROGRAMS UNDER THE PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF; OR WHERE THE CONTRACTOR WILL RECEIVE FUNDING UNDER THE UNITED STATES LEADERSHIP AGAINST HIV/AIDS, TUBERCULOSIS AND MALARIA ACT OF 2003. SEE HHSAR 370.701.)****

15. **Non-discrimination for Conscience, HHSAR 352.270-9** (December 2015).

a. Section 301(d) of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act, as amended, provides that an organization, including a faith-based organization, that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961, under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, or under any amendment to the foregoing Acts for HIV/AIDS prevention, treatment, or care-

1. Shall not be required, as a condition of receiving such assistance, to-
   i. Endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or
   ii. Endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.

2. Shall not be discriminated against under the provisions of law in subparagraph (a) for refusing to meet any requirement described in paragraph (a)(1) in this solicitation.

b. Accordingly, an offeror who believes this solicitation contains work requirements that would require it to endorse or utilize a multisectoral or comprehensive approach to combating

HIV/AIDS, or to endorse, utilize, make referral to, become integrated with, or otherwise participate in a program or activity to which it has a religious or moral objection, shall identify those work requirements it has excluded in its technical proposal.

c. The Government acknowledges that an offeror has specific rights, as cited in paragraph (b) of this provision, to exclude certain work requirements in this solicitation from its proposal. However, the Government reserves the right to not make an award to an offeror whose proposal does not comply with the salient work requirements of the solicitation. Any exercise of that Government right will be made by the Head of the Contracting Activity.

(End of provision).

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****(USE BELOW IF THE GOVERNMENT MAY REQUIRE A DIFFERENT SCOPE OR SPECIAL REQUIREMENTS IN LIEU OF OR IN ADDITION TO THAT DEFINED IN THE GENERAL RIGHTS IN DATA CLAUSE.)****

Note: *This should be handled on a case-by-case basis. For additional guidance, contact the NIH Office of Technology Transfer (OTT) at (301-496-7057).*

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- The Contracting Officer with the assistance of the Project Officer and/or Contracting Officer's Representative (COR) shall select the appropriate sentence within the [brackets] below. If the special requirements are known at the time of the solicitation, they should be stated in the SOLICITATION.)****

16. **Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)**

Under the provisions of the Rights in Data General clause (FAR 52.227-14), contractors must seek permission to establish a copyright for software and associated data generated under a contract. As a general rule, permission is normally granted provided, a paid-up, world-wide, irrevocable, nonexclusive license to the Government is provided. This is to advise offerors that for this project, the Government intends to assert additional copyright permissions under this contract. [The scope of the Government's interest in the copyright will be determined during negotiations. - **OR** - The Government will require: *State specific requirements*].

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****(USE BELOW IN ALL SOLICITATIONS.)****

17. **Privacy Act - Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or

purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this SOLICITATION pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the Government Accountability Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

632

****(USE BELOW IN ALL SOLICITATIONS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Subparagraph a:** For R&D SOLICITATIONS include the language within the brackets. For Non R&D SOLICITATIONS remove the bracketed information in its entirety.
2. **Subparagraphs d and f:** Insert the applicable I/C name in the text box.

18. **Selection of Offerors**

a. The acceptability of the [scientific and] technical portion of each [research] contract proposal will be evaluated by a technical review committee. The committee will evaluate each

proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b. The business portion of each contract proposal found to be technical acceptable will be subjected to a cost and price analysis, management analysis, etc.

c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d. If the Government intends to conduct discussions prior to awarding a contract -

   1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

      Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

   2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

      While it is ___ 's policy to conduct discussions with all offerors in the competitive range, ___ reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR Part 315.

e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.

f. The ___ reserves the right to make a single award, multiple awards, or no award at all to the SOLICITATION. In addition, the SOLICITATION may be amended or canceled as necessary to meet ___ requirements. Synopses of awards exceeding $25,000 will be published in Contract Opportunities at: https://sam.gov/content/home .

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****(USE BELOW FOR ALL R&D REQUIREMENTS EXCEPT THOSE EXPECTED TO BE AWARDED TO A FEDERAL AGENCY.)****

19. **Institutional Responsibility Regarding Investigator Conflicts of Interest**

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any Investigator financial conflicts of interest. The Institution shall comply with all requirements of 45 CFR Part 94 at: https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94.

634

****(USE BELOW IN SOLICITATIONS WHERE THERE IS A CHANCE THAT AN EDUCATIONAL INSTITUTION WILL SUBMIT A PROPOSAL.)****
Note: *The prohibition contained in the FY-97 Appropriations Act is intended to be continuous until it is expressly rescinded.*

20. **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

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****(USE BELOW IN ALL SOLICITATIONS THAT WILL EXCEED $5.5 M)****

21. **Certification Regarding Tax Matters, FAR 52.209-12** (Oct 2020).

(a) This implements section 523 of Division B of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113- 235), and similar provisions, if contained in subsequent appropriations acts.

(b) If the Offeror is proposing a total contract price that will exceed $5.5 million (including options), the Offeror shall certify that, to the best of its knowledge and belief, it

(1) Has [ ] filed all Federal tax returns required during the three years preceding the certification;

(2) Has [ ] been convicted of a criminal offense under the Internal Revenue Code of 1986; and

(3) Has not [ ] , more than 90 days prior to certification, been notified of any unpaid Federal tax assessment for which the liability remains unsatisfied, unless the assessment is the subject of an installment agreement or offer in compromise that has been approved by the Internal Revenue Service and is not in default, or the assessment is the subject of a non- frivolous administrative or judicial proceeding.

(End of provision).

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****(USE BELOW IN ALL SOLICITATIONS INCLUDING COMMERCIAL ITEMS UNDER FAR PART 12)****

22. **Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation, FAR 52.203-18** (Jan 2017).

a. *Definition.* As used in this provision-
Internal confidentiality agreement or statement, subcontract, and subcontractor, are defined in the clause at 52.203-19 , Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements.

b. In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use funds appropriated (or otherwise made available) for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

c. The prohibition in paragraph (b) of this provision does not contravene requirements applicable to Standard Form 312, (Classified Information Nondisclosure Agreement), Form

4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

d. Representation. By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(End of provision).

637

****(USE BELOW IN COMPETITIVE SOLICITATIONS THAT ARE EXPECTED TO EXCEED THE SIMPLIFIED ACQUISITION THRESHOLD UNLESS THE CONTRACTING OFFICER HAS DETERMINED IN WRITING THAT EVALUATION OF PAST PERFORMANCE IS NOT ESSENTIAL TO ENSURING AWARD TO THE OFFEROR MOST CAPABLE OF PERFORMING. NOTE: FOR OPTION CONTRACTS THE ESTIMATED BASE AMOUNT PLUS THE OPTION AMOUNTS ARE TO BE CONSIDERED IN DETERMINING THE TOTAL VALUE OF THE RESULTANT CONTRACT.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Paragraph a:**
  - First sentence:
    - Select BUSINESS proposal from the Drop Down List, if proposals are to be reviewed by non-Government employees. Otherwise, the information may be submitted with either the BUSINESS or TECHNICAL proposal based on the Contracting Officer's discretion.
  - Second paragraph:
    - Indicate the number of past contracts for which you would like to see past performance information. Select the appropriate information for your solicitation from within each of the 2 bracketed sections and complete fill in information as required.
    - The Contracting Officer will define "major subcontract" for individual acquisitions. A major subcontract could be defined, for example, as a subcontract that exceeds a certain dollar threshold.

23. **Past Performance Information**

a. Offerors shall submit the following information as part of their [Business/Technical] proposal.

A list of the last _ contracts completed during the past [One/Two/Three/Four/Five] years and [ALL CONTRACTS/THE LAST _ CONTRACTS AWARDED] currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered

into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as _____ .

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

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****(USE BELOW IN TIME-AND-MATERIAL/LABOR-HOUR SOLICITATIONS FOR NONCOMMERCIAL ITEMS IF THE PRICE IS NOT EXPECTED TO BE BASED ON ADEQUATE PRICE COMPETITION.)****

24. **Time-and-Material/Labor-Hour Proposal Requirements--Non-Commercial Item Acquisitions without Adequate Price Competition, FAR 52.216-30** (Nov 2021).

(a) The Government contemplates award of a Time-and-Materials or Labor-Hour type of contract resulting from this solicitation.

(b) The offeror must specify separate fixed hourly rates in its offer that include wages, overhead, general and administrative expenses, and profit for each category of labor to be performed by--

(1) The offeror;
(2) Each subcontractor; and
(3) Each division, subsidiary, or affiliate of the offeror under a common control.

(c) Unless exempt under paragraph (d) of this provision, the fixed hourly rates for services transferred between divisions, subsidiaries, or affiliates of the offeror under a common control--

(1) Shall not include profit for the transferring organization; but
(2) May include profit for the prime Contractor.

(d) The fixed hourly rates for services that meet the definition of commercial item at 2.101 that are transferred between divisions, subsidiaries, or affiliates of the offeror under a common control may be the established catalog or market rate when it is the established practice of the transferring organization to price interorganizational transfers at other than cost for commercial work of the offeror or any division, subsidiary or affiliate of the offeror under a common control.

(End of provision).

639

****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT LESS THAN $7,008,000.)****

25. **Notice of Buy American Requirement--Construction Materials, FAR 52.225-10** (May 2014).

(a) *Definitions.* "Commercially available off-the-shelf (COTS) item," "construction material," "domestic construction material," and "foreign construction material," as used in this provision, are defined in the clause of this solicitation entitled "Buy American--Construction Materials" (Federal Acquisition Regulation (FAR) clause 52.225-9).

(b) *Requests for determinations of inapplicability.* An offeror requesting a determination regarding the inapplicability of the Buy American statute should submit the request to the Contracting Officer in time to allow a determination before submission of offers. The offeror shall include the information and applicable supporting data required by paragraphs (c) and (d) of the clause at FAR 52.225-9 in the request. If an offeror has not requested a determination regarding the inapplicability of the Buy American statute before submitting its offer, or has not received a response to a previous request, the offeror shall include the information and supporting data in the offer.

(c) *Evaluation of offers.*

(1) The Government will evaluate an offer requesting exception to the

requirements of the Buy American statute based on claimed unreasonable cost of domestic construction material, by adding to the offered price the appropriate percentage of the cost of such foreign construction material, as specified in paragraph (b)(3)(i) of the clause at FAR 52.225-9.

(2) If evaluation results in a tie between an offeror that requested the substitution of foreign construction material based on unreasonable cost and an offeror that did not request an exception, the Contracting Officer will award to the offeror that did not request an exception based on unreasonable cost.

(d) Alternate offers.

(1) When an offer includes foreign construction material not listed by the Government in this solicitation in paragraph (b)(2) of the clause at FAR 52.225-9, the offeror also may submit an alternate offer based on use of equivalent domestic construction material.

(2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer, and a separate price comparison table prepared in accordance with paragraphs (c) and (d) of the clause at FAR 52.225-9 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.

(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of the clause at FAR 52.225-9 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic construction material, and the offeror shall be required to furnish such domestic construction material. An offer based on use of the foreign construction material for which an exception was requested-

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or
(ii) May be accepted if revised during negotiations.

(End of provision).

640

****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW WITH FAR 52.225-10 IF INSUFFICIENT TIME IS AVAILABLE TO PROCESS A DETERMINATION REGARDING THE INAPPLICABILITY OF THE BUY AMERICAN STATUTE PRIOR TO RECEIPT OF OFFERS.)****

Alternate I (May 2014), **FAR 52.225-10, Notice of Buy American Requirement--Construction Materials** (May 2014). As prescribed in 25.1102(b)(2), substitute the following paragraph (b) for paragraph (b) of the basic provision:

(b) Requests for determinations of inapplicability. An offeror requesting a determination regarding the inapplicability of the Buy American statute shall submit the request with its offer, including the information and applicable supporting data required by paragraphs (c) and (d) of the clause at FAR 52.225-9.

641

****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,032,000 OR MORE.)****

26. **Notice of Buy American Requirement--Construction Materials Under Trade Agreements, FAR 52.225-12** (May 2014).

(a) *Definitions* . "Commercially available off-the-shelf (COTS) item," "construction material," "designated country construction material," "domestic construction material," and "foreign construction material," as used in this provision, are defined in the clause of this solicitation entitled "Buy American--Construction Materials Under Trade Agreements" (Federal Acquisition Regulation (FAR) clause 52.225-11).

(b) *Requests for determination of inapplicability.* An offeror requesting a determination regarding the inapplicability of the Buy American statute should submit the request to the Contracting Officer in time to allow a determination before submission of offers. The offeror shall include the information and applicable supporting data required by paragraphs (c) and (d) of FAR clause 52.225-11 in the request. If an offeror has not requested a determination regarding the inapplicability of the Buy American statute before submitting its offer, or has not received a response to a previous request, the offeror shall include the information and supporting data in the offer.

(c) *Evaluation of offers.*

(1) The Government will evaluate an offer requesting exception to the requirements of the Buy American statute based on claimed unreasonable cost of domestic construction materials, by adding to the offered price the appropriate percentage of the cost of such foreign construction material, as specified in paragraph (b)(4)(i) of FAR clause 52.225-11.

(2) If evaluation results in a tie between an offeror that requested the substitution of foreign construction material based on unreasonable cost and an offeror that did not request an exception, the Contracting Officer will award to the offeror that did not request an exception based on unreasonable cost.

(d) *Alternate offers.*

(1) When an offer includes foreign construction material, other than

designated country construction material, that is not listed by the Government in this solicitation in paragraph (b)(3) of FAR clause 52.225-11, the offeror also may submit an alternate offer based on use of equivalent domestic or designated country construction material.

(2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer, and a separate price comparison table prepared in accordance with paragraphs (c) and (d) of FAR clause 52.225-11 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.

(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of FAR clause 52.225-11 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic or designated country construction material, and the offeror shall be required to furnish such domestic or designated country construction material. An offer based on use of the foreign construction material for which an exception was requested —

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or

(ii) May be accepted if revised during negotiations.

(End of provision).

642

****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW WITH FAR 52.225-12,IF INSUFFICIENT TIME IS AVAILABLE TO PROCESS A DETERMINATION REGARDING THE INAPPLICABILITY OF THE BUY AMERICAN ACT PRIOR TO RECEIPT OF OFFERS.)****

Alternate I (May 2014), **FAR 52.225-12, Notice of Buy American Requirement--Construction Materials Under Trade Agreements** (May 2014).

As prescribed in 25.1102(d)(2), substitute the following paragraph (b) for paragraph (b) of the basic provision:

(b) Requests for determination of inapplicability. An offeror requesting a determination regarding the inapplicability of the Buy American statute shall submit the request with its offer, including the information and applicable supporting data required by paragraphs (c) and (d) of FAR clause 52.225-11.

643

****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW WITH FAR 52.225-12, IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,032,000 OR MORE, BUT LESS THAN $12,001,460.)****

Alternate II (June 2009), FAR Clause **52.225-12, Notice of Buy American Requirement-Construction Materials Under Trade Agreements** (May 2014) **.**

As prescribed in 25.1102(d)(3), add the definition of "Bahrainian, Mexican, or Omani construction material" to paragraph (a) and substitute the following paragraph (d) for paragraph (d) of the basic provision:

(d) *Alternate offers.*

(1) When an offer includes foreign construction material, except foreign construction material from a designated country other than Bahrain, Mexico, or Oman that is not listed by the Government in this solicitation in paragraph (b)(3) of FAR clause 52.225-11, the offeror also may submit an alternate offer based on use of equivalent domestic or designated country construction material other than Bahrainian, Mexican, or Omani construction material.

(2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer, and a separate price comparison table prepared in accordance with paragraphs (c) and (d) of FAR clause 52.225-11 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.

(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of FAR clause 52.225-11 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic or designated country construction material other than Bahrainian, Mexican, or Omani construction material. An offer based on use of the foreign construction material for which an exception was requested--

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or

(ii) May be accepted if revised during negotiations.

644

****(WHEN USING RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT LESS THAN $7,032,000.)****

27. **Notice of Required Use of American Iron, Steel, and Manufactured Goods--Buy American Statute--Construction Materials, FAR 52.225-22** (Jan 2021).

(a) *Definitions.* "Construction material," "domestic construction material," "foreign construction material," "manufactured construction material," "steel," and "unmanufactured construction material," as used in this provision, are defined in the clause of this solicitation entitled "Required Use of Iron, Steel, and Manufactured Goods--Buy American Statute--Construction Materials" (Federal Acquisition Regulation (FAR) clause 52.225-21).

(b) *Requests for determinations of inapplicability.* An offeror requesting a determination regarding the inapplicability of section 1605 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act) or the Buy American statute should submit the request to the Contracting Officer in time to allow a determination before submission of offers. The offeror shall include the information and applicable supporting data required by paragraphs (c) and (d) of the

clause at FAR 52.225-21 in the request. If an offeror has not requested a determination regarding the inapplicability of section 1605 of the Recovery Act or the Buy American statute before submitting its offer, or has not received a response to a previous request, the offeror shall include the information and supporting data in the offer.

(c) *Evaluation of offers.* (1) If the Government determines that an exception based on unreasonable cost of domestic construction material applies in accordance with FAR 25.604, the Government will evaluate an offer requesting exception to the requirements of section 1605 of the Recovery Act or the Buy American statute by adding to the offered price of the contract--

(i) 25 percent of the offered price of the contract, if foreign manufactured construction material is incorporated in the offer based on an exception for unreasonable cost of comparable manufactured domestic construction material; and

(ii) 20 percent of the cost of foreign unmanufactured construction material included in the offer based on an exception for the unreasonable cost of comparable domestic unmanufactured construction material.

(2) If the solicitation specifies award on the basis of factors in addition to cost or price, the Contracting Officer will apply the evaluation factors as specified in paragraph (c)(1) of this provision and use the evaluated price in determining the offer that represents the best value to the Government.

(3) Unless paragraph (c)(2) of this provision applies, if two or more offers are equal in price, the Contracting Officer will give preference to an offer that does not include foreign construction material excepted at the request of the offeror on the basis of unreasonable cost of comparable domestic construction material.

(d) *Alternate offers.* (1) When an offer includes foreign construction material not listed by the Government in this solicitation in paragraph (b)(3) of the clause at FAR 52.225-21, the offeror also may submit an alternate offer based on use of equivalent domestic construction material.

(2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer and a separate cost comparison table prepared in accordance with paragraphs (c) and (d) of the clause at FAR 52.225-21 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.

(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of the clause at FAR 52.225-21 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic construction material, and the offeror shall be required to furnish such domestic

construction material. An offer based on use of the foreign construction material for which an exception was requested--

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or

(ii) May be accepted if revised during negotiations.

(End of provision).

645

****(WHEN USING RECOVERY ACT FUNDS, USE BELOW WITH FAR 52.225-22 IF INSUFFICIENT TIME IS AVAILABLE TO PROCESS A DETERMINATION REGARDING THE INAPPLICABILITY OF THE BUY AMERICAN STATUTE PRIOR TO RECEIPT OF OFFERS.)****

Alternate I (May 2014), **FAR 52.225-22, Notice of Required Use of American Iron, Steel, and Manufactured Goods--Buy American Statute--Construction Materials** (Jan 2021).

As prescribed in 25.1102(e), substitute the following paragraph (b) for paragraph (b) of the basic provision:

(b) *Requests for determinations of inapplicability* . An offeror requesting a determination regarding the inapplicability of section 1605 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act) or the Buy American statute shall submit the request with its offer, including the information and applicable supporting data required by paragraphs (c) and (d) of the clause at FAR 52.225-21.

646

****(WHEN USING RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,032,000 OR MORE.)****

28. **Notice of Required Use Of American Iron, Steel, and Manufactured Goods--Buy American Statute--Construction Materials Under Trade Agreements, FAR 52.225-24** (Jan 2021).

(a) *Definitions* . "Construction material," "domestic construction material," "foreign construction material," "manufactured construction material," "Recovery Act designated country construction material," "steel," and "unmanufactured construction material," as used in this provision, are defined in the clause of this solicitation entitled "Required Use of Iron, Steel, and Manufactured Goods--Buy American statute--Construction Materials Under Trade Agreements" (Federal Acquisition Regulation (FAR) clause 52.225-23).

(b) *Requests for determination of inapplicability* . An offeror requesting a determination regarding the inapplicability of section 1605 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act) or the Buy American statute should submit the request to the Contracting Officer in time to allow a determination before submission of offers. The offeror shall include the information and applicable supporting data required by paragraphs (c) and (d) of FAR clause 52.225-23 in the request. If an offeror has not requested a determination regarding the inapplicability of section 1605 of the Recovery Act or the Buy American statute before submitting its offer, or has not received a response to a previous request, the offeror shall include the information and supporting data in the offer.

(c) *Evaluation of offers* . (1) If the Government determines that an exception based on unreasonable cost of domestic construction material applies in accordance with FAR 25.604, the Government will evaluate an offer requesting exception to the requirements of section 1605 of the Recovery Act or the Buy American statute by adding to the offered price of the contract-

(i) 25 percent of the offered price of the contract, if foreign manufactured construction material is included in the offer based on an exception for the unreasonable cost of comparable manufactured domestic construction material; and

(ii) 20 percent of the cost of foreign unmanufactured construction material included in the offer based on an exception for the unreasonable cost of comparable domestic unmanufactured construction material.

(2) If the solicitation specifies award on the basis of factors in addition to cost or price, the Contracting Officer will apply the evaluation factors as specified in paragraph (c)(1) of this provision and use the evaluated cost or price in determining the offer that represents the best value to the Government.

(3) Unless paragraph (c)(2) of this provision applies, if two or more offers are equal in price, the Contracting Officer will give preference to an offer that does not include foreign construction material excepted at the request of the offeror on the basis of unreasonable cost.

(d) Alternate offers. (1) When an offer includes foreign construction material, other than Recovery Act designated country construction material, that is not listed by the Government in this solicitation in paragraph (b)(3) of FAR clause 52.225-23, the offeror also may submit an alternate offer based on use of equivalent domestic or Recovery Act designated country construction material.

(2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer and a separate cost comparison table

prepared in accordance with paragraphs (c) and (d) of FAR clause 52.225-23 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.

(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of FAR clause 52.225-23 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic or Recovery Act designated country construction material, and the offeror shall be required to furnish such domestic or Recovery Act designated country construction material. An offer based on use of the foreign construction material for which an exception was requested--

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or

(ii) May be accepted if revised during negotiations.

(End of provision).

647

****(WHEN USING RECOVERY ACT FUNDS, USE BELOW WITH FAR 52.225-24, IF INSUFFICIENT TIME IS AVAILABLE TO PROCESS A DETERMINATION REGARDING THE INAPPLICABILITY OF THE BUY AMERICAN ACT PRIOR TO RECEIPT OF OFFERS FOR ACQUISITIONS VALUED AT $7,032,000 OR MORE, BUT LESS THAN $12,001,460.)****

Alternate I (May 2014), FAR Clause 52.225-24, Notice of Required Use of American Iron, Steel, and Manufactured Goods-Buy American Statute-Construction Materials under Trade Agreements (Jan 2021).

As prescribed in 25.1102(e), substitute the following paragraph (b) for paragraph (b) of the basic provision:

(b) *Requests for determination of inapplicability* . An offeror requesting a determination regarding the inapplicability of section 1605 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act) or the Buy American statute shall submit the request with its offer, including the information and applicable supporting data required by paragraphs (c) and (d) of FAR clause 52.225-23.

648

****(WHEN USING RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,032,000 OR MORE, BUT LESS THAN $12,001,460.)****

Alternate II (Mar 2009), **FAR Clause 52.225-24, Notice of Required Use of American Iron, Steel, and Manufactured Goods-Buy American Act-Construction Materials under Trade Agreements** (Jan 2021).

As prescribed in 25.1102(e), add the definition of "Bahrainian, Mexican, or Omani construction material" to paragraph (a) and substitute the following paragraph (d) for paragraph (d) of the basic provision:

(d) *Alternate offers.* (1) When an offer includes foreign construction material, except foreign construction material from a Recovery Act designated country other than Bahrain, Mexico, or Oman that is not listed by the Government in this solicitation in paragraph (b)(3) of FAR clause 52.225-23, the offeror also may submit an alternate offer based on use of equivalent domestic or Recovery Act designated country construction material other than Bahrainian, Mexican, or Omani construction material.

(2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer and a separate cost comparison table prepared in accordance with paragraphs (c) and (d) of FAR clause 52.225-23 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.

(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of FAR clause 52.225-23 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic or Recovery Act designated country construction material other than Bahrainian, Mexican, or Omani construction material. An offer based on use of the foreign construction material for which an exception was requested--

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or
(ii) May be accepted if revised during negotiations.

649

****(USE BELOW IN NEGOTIATED FIXED-PRICE REQUIREMENTS(excluding Architect and Engineering, and Construction contracts) WHERE PERFORMANCE-BASED CONTRACT FINANCING WILL BE PROVIDED.)****

29. **Invitation to Propose Performance-Based Payments, FAR 52.232-28** (Mar 2000).

(a) The Government invites the offeror to propose terms under which the Government will make performance-based contract financing payments during contract performance. The Government will consider performance-based payment financing terms proposed by the offeror in the evaluation of the offeror's proposal. The Contracting Officer will incorporate the financing terms of the successful offeror and the FAR clause, Performance-Based Payments, at FAR 52.232-32, in any resulting contract.

(b) In the event of any conflict between the terms proposed by the offeror and the terms in the clause at FAR 52.232-32, Performance-Based Payments, the terms of the clause at FAR 52.232-32 shall govern.

(c) The Contracting Officer will not accept the offeror's proposed performance-based payment financing if the financing does not conform to the following limitations:

(1) The Government will make delivery payments only for supplies delivered and accepted, or services rendered and accepted in accordance with the payment terms of this contract.

(2) The terms and conditions of the performance-based payments must-

(i) Comply with FAR 32.1004;

(ii) Be reasonable and consistent with all other technical and cost information included in the offeror's proposal; and

(iii) Their total shall not exceed 90 percent of the contract price if on a whole contract basis, or 90 percent of the delivery item price if on a delivery item basis.

(3) The terms and conditions of the performance-based financing must be in the best interests of the Government.

(d) The offeror's proposal of performance-based payment financing shall include the following:

(1) The proposed contractual language describing the performance-based payments (see FAR 32.1004 for appropriate criteria for establishing performance bases and performance-based finance payment amounts).

(2) A listing of-

(i) The projected performance-based payment dates and the projected payment amounts; and

(ii) The projected delivery date and the projected payment amount.

(3) Information addressing the Contractor's investment in the contract.

(e) Evaluation of the offeror's proposed prices and financing terms will include whether the offeror's proposed performance-based payment events and payment amounts are reasonable and consistent with all other terms and conditions of the offeror's proposal.

(End of provision)

650

****(USE BELOW, WITH 52.232-28 (above) IN COMPETITIVE NEGOTIATED SOLICITATIONS (excluding Architect and Engineering, and Construction contracts) IF THE GOVERNMENT INTENDS TO ADJUST PROPOSED PRICES FOR PROPOSAL EVALUATION PURPOSES (See FAR 32.1004(e).)****

Alternate I (Mar 2000), **FAR Clause 52.232-28, Invitation to Propose Performance-Based Payments** (Mar 2000).

As prescribed in FAR 32.1005(b)(2), add the following paragraph (f) to the basic provision:

(f) The Government will adjust each proposed price to reflect the cost of providing the proposed performance-based payments to determine the total cost to the Government of that particular combination of price and performance-based financing. The Government will make the adjustment using the procedure described in FAR 32.205(c).

651

****(USE BELOW, IN ALL SOLICITATIONS FUNDED WITH APPROPRIATED BIO-DEFENSE FUNDS.
Note: *At this time, may only be applicable to NIAID projects* .
NIAID Processes/Procedures Reviewed 9/22)****

30. **Prohibition on Contractor Involvement with Terrorist Activities**

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

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****(INCLUDE BELOW IN SOLICITATIONS WHEN IT HAS BEEN DETERMINED THAT:

- CONTRACTOR PERSONNEL MAY REQUIRE ACCESS TO HHS-CONTROLLED FACILITIES AND/OR INFORMATION SYSTEMS, INCLUDING SENSITIVE DATA/INFORMATION, IN ORDER TO PERFORM THE CONTRACT/ORDER SOW/PWS, AND/OR ;
- THE HOMELAND SECURITY PRESIDENTIAL DIRECTIVE'S (HSPD-12) MORE STRINGENT ACCESS PROCEDURES ARE EXPECTED TO APPLY, BECAUSE ACCESS WILL BE ROUTINE AND OF LONG-TERM DURATION, OR IS ROUTINE AND OF SHORT-TERM DURATION, BUT GREATER ACCESS CONTROLS ARE DEEMED NECESSARY.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. For more information, see HHS OCIO Program Policies at: https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/information-security-privacy-program/index.html.
2. The Contract Specialist, Project Officer, I/C Information Systems Security Officer (ISSO), and/or Privacy Officer can assist the acquisition staff in tailoring the language in the below Article. If additional guidance is needed, contact the individual responsible for Contracts (Security Language) - located in the NIH Office of the Chief Information Officer (OCIO) - Phone: 301-496-1168 and Email: nihciocommunications@mail.nih.gov.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- Second paragraph: Select "Technical" or "Business" as appropriate from the drop-down box.

31. **HHS SECURITY AND PRIVACY LANGUGAGE FOR INFORMATION AND IT PROCUREMENTS**

HHS Security and Privacy Language for Information and Information Technology Procurements is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the _____ Technical/Business] Proposal entitled "Information Security."

The Homeland Security Presidential Directive (HSPD)-12 and the Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, Contractor (including subcontractor), or other source.

653

****(USE BELOW IN SOLICITATIONS WHEN IT HAS BEEN DETERMINED THAT:

- CONTRACTOR PERSONNEL MAY REQUIRE ACCESS TO HHS-CONTROLLED FACILITIES AND/OR INFORMATION SYSTEMS, INCLUDING SENSITIVE DATA/INFORMATION, IN ORDER TO PERFORM THE CONTRACT/ORDER SOW/PWS, AND/OR;
- THE HOMELAND SECURITY PRESIDENTIAL DIRECTIVE'S (HSPD-12) MORE STRINGENT ACCESS PROCEDURES ARE EXPECTED TO APPLY, BECAUSE ACCESS WILL BE ROUTINE AND OF LONG-TERM DURATION, OR IS ROUTINE AND OF SHORT-TERM DURATION, BUT GREATER ACCESS CONTROLS ARE DEEMED NECESSARY.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

Subparagraph c: At the time of solicitation, the Contracting Officer (CO) shall specify all known position sensitivity levels based on the recommendation of the ISSO and PO.

If the levels are not known at the time of solicitation, the Contracting Officer shall insert the words "To Be Determined at the Time of Award." (Note: The Contracting Officer must include the definitive position sensitivity levels in the awarded contract/order).

When known, the CO shall check all levels that apply and delete those that do not apply. The CO shall also list the applicable Contractor Position Titles in the text box under the heading, if considered appropriate.

Additional guidance is located for Position Sensitivity Designations. To determine the designation, the Position Designation Tool (PDT) discussion is found at:
https://www.ors.od.nih.gov/ser/dpsac/resources/Pages/investigation-requirements-for-your-position.aspx

The requiring activity representative, in conjunction with Personnel Security, shall use the OPM Position Sensitivity Designation automated tool (https://pdt.nbis.mil/) to determine the sensitivity designation for background investigations. After making those determinations, include all applicable position sensitivity designations.

32. **INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY**

A. **POSITION SENSITIVITY DESIGNATIONS**

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 and 732of Title 5, Code of Federal Regulations (CFR). To determine the designation, the Position Designation Tool (PDT) discussion is found at:
https://www.ors.od.nih.gov/ser/dpsac/resources/Pages/investigation-requirements-for-your-position.aspx and the link to access the tool is found at: https://pdt.nbis.mil/

The following position sensitivity designation levels apply to this solicitation/contract:

[ ] Tier 5: Critical Sensitive and Special Sensitive National Security, including Top Secret, SCI, and "Q" access eligibility.

[ ] Tier 5SR: Reinvestigation.

[ ] Tier 4: High Risk Public Trust (HRPT).

[ ] Tier 4SR: Reinvestigation.

[ ] Tier 3: Non-Critical Sensitive, National Security, including Secret and "L" access eligibility.
[ ] Tier 3SR: Reinvestigation.

[ ] Tier 2S with Subject Interview: Moderate Risk Public Trust (MRPT).
[ ] Tier 2SR: Reinvestigation.

[ ] Tier 1: Low Risk, Non-Sensitive, including HSPD-12 Credentialing.

HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

The Contractor (and/or any subcontractor) and its employees must comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; FIPS 201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; and Executive Order 13467, Part 1 §1.2.
For additional information, see HSPD-12 policy at: https://www.dhs.gov/homeland-security-presidential-directive-12

Roster-

1. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster shall be submitted to the COR and/or CO within fourteen (14) calendar days after the effective date of this contract. Any revisions to the roster as a result of staffing changes shall be submitted within seven (7) calendar days of the change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for C use at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.
2. If the Contractor is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.
3. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.
4. The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.
5. All Contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract. Contractors may begin work after the fingerprint check has been completed.
6. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.

7. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more that the cost of the additional investigation(s).
8. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
9. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.
10. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

B. **Assessment and Authorization (A&A)-** A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) shall work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s) within three (3) months after contract award. The Contractor shall conduct the A&A requirements in accordance with HHS IS2P, NIST SP 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach (latest revision).

For an existing ATO, Contracting Officer Representative must make a determination if the existing ATO provides appropriate safeguards or if an additional ATO is required for the performance of the contract and state as such.
NIH acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the system security and privacy controls are implemented and operating effectively.

C. **A&A Package Deliverables -** The Contractor (and/or any subcontractor) shall provide an A&A package within 30 days of contract award to the CO and/or COR. The following A&A deliverables are required to complete the A&A package.

- **System Security Plan (SSP) -** due within 30 days after contract award. The SSP shall comply with the NIST SP 800-18, Guide for Developing Security Plans for Federal Information Systems, the Federal Information Processing Standard (FIPS) 200, Recommended Security Controls for Federal Information Systems, and NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline requirements, and other applicable NIST guidance as well as HHS and NIH policies and other guidance. The SSP shall be consistent with and detail the approach to IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The SSP shall provide an overview of the system environment and security requirements to protect the information system as well as describe all applicable security controls in place or planned for meeting those requirements. It

should provide a structured process for planning adequate, cost-effective security protection for a system. The Contractor shall update the SSP at least annually thereafter.

- **Security Assessment Plan/Report (SAP/SAR) -** due 30 days after the contract award. The security assessment shall be conducted by the assessor and be consistent with NIST SP 800-53A, NIST SP 800-30, and HHS and NIH policies. The assessor will document the assessment results in the SAR.

  The NIH should determine which security control baseline applies and then make a determination on the appropriateness/necessity of obtaining an independent assessment. Assessments of controls can be performed by contractor, government, or third parties, with third party verification considered the strongest. If independent assessment is required, include statement below.

  Thereafter, the Contractor, in coordination with the NIH shall conduct/assist in the assessment of the security controls and update the SAR at least annually.

- **Independent Assessment -** due 90 days after the contract award. The Contractor (and/or subcontractor) shall have an independent third-party validate the security and privacy controls in place for the system(s). The independent third party shall review and analyze the Security Authorization package, and report on technical, operational, and management level deficiencies as outlined in NIST SP 800-53. The Contractor shall address all "high" deficiencies before submitting the package to the Government for acceptance. All remaining deficiencies must be documented in a system Plan of Actions and Milestones (POA&M).
- **POA&M -** due 30 days after contract award. The POA&M shall be documented consistent with the HHS Standard for Plan of Action and Milestones and NIH policies.
  All findings/weaknesses shall be documented in the POA&M and remediated/mitigated from the date the weaknesses are formally identified and documented by the timelines below:
  - Critical within 30 days;
  - High within 60 days;
  - Medium within 1 year; and
  - Low within 1 year.

  The NIH will determine the risk rating of vulnerabilities. Identified risks stemming from deficiencies related to the security control baseline implementation, assessment, continuous monitoring, vulnerability scanning, and other security reviews and sources, as documented in the SAR, shall be documented and tracked by the Contractor for mitigation in the POA&M document. Depending on the severity of the risks, NIH may require designated POAM weaknesses to be remediated before an ATO is issued. Thereafter, the POA&M shall be updated at least quarterly.

D. **Contingency Plan and Contingency Plan Test** - due 60 days after contract award. The Contingency Plan must be developed in accordance with NIST SP 800- 34, Contingency Planning Guide for Federal Information Systems, and be consistent with HHS and NIH policies. Upon acceptance by the System Owner, the Contractor, in coordination with the System Owner, shall test the Contingency Plan and prepare a Contingency Plan Test Report that includes the test results, lessons learned and

any action items that need to be addressed. Thereafter, the Contractor shall update and test the Contingency Plan at least annually.

- **E-Authentication Questionnaire** - The Contractor (and/or any subcontractor) shall collaborate with government personnel to ensure that an E-Authentication Threshold Analysis (E- auth TA) is completed to determine if a full E- Authentication Risk Assessment (E-auth RA) is necessary. System documentation developed for a system using E-auth TA/E-auth RA methods shall follow OMB 04-04 and NIST SP 800-63, Rev. 2, Electronic Authentication Guidelines.

  Based on the level of assurance determined by the E- Auth, the Contractor (and/or subcontractor) must ensure appropriate authentication to the system, including remote authentication, is in- place in accordance with the assurance level determined by the E-Auth (when required) in accordance with HHS policies.

E. **Reporting and Continuous Monitoring**

Following the initial ATOs, the Contractor (and/or any subcontractor) must perform the minimum ongoing continuous monitoring activities specified below, submit required deliverables by the specified due dates, and meet with the system/ service owner and other relevant stakeholders to discuss the ongoing continuous monitoring activities, findings, and other relevant matters. The CSP will work with the agency to schedule ongoing continuous monitoring activities.

- **Information Security Continuous Monitoring-** Upon the government issuance of an Authority to Operate (ATO), the Contractor (and/or subcontractor)- owned/operated systems that input, store, process, output, and/ or transmit government information, shall meet or exceed the Information Security Continuous Monitoring (ISCM) requirements in accordance with FISMA and NIST SP 800- 137, Information Security Continuous Monitoring (ISCM) for Federal Information Systems and Organizations, and HHS IS2P. The following are the minimum requirements for ISCM:
- **Annual Assessment/ Pen Test -** Assess the system security and privacy controls (or ensure an assessment of the controls is conducted) at least every two (2) years on high- risk systems, to determine the implemented security and privacy controls are operating as intended and producing the desired results. This may involve penetration testing conducted by the agency or independent third- party. In addition, review all relevant A& A documentation (SSP, POA& M, Contingency Plan, etc.) and provide updates by specified due date provided by the Contracting Officer Representative.
- **Asset Management -** Using any available Security Content Automation Protocol (SCAP)- compliant automated tools for active/ passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing HHS- owned information/ data. It is anticipated that this inventory information will be required to be produced at least 60 days after contract award. IT asset inventory information shall include IP address, machine name, operating system level, security patch level, and SCAP- compliant format information. The Contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.
- **Configuration Management -** Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and

process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The Contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP- compliant automated tools.

- **Vulnerability Management -** Use SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process gove rnment information. Contractors shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS policy. Automated tools shall be compliant with NIST-specified SCAP standards for vulnerability identification and management. The Contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP- compliant automated tools and report to the agency at least within 30 days of the contract award.
- **Patching and Vulnerability Remediation -** Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeframes.
- **Secure Coding -** Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
- **Boundary Protection -** The Contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).
- A security control assessment must be conducted by a FedRAMP third- party assessment organization (3PAO) for the initial ATO and annually thereafter or whenever there is a significant change to the system's security posture in accordance with the FedRAMP Continuous Monitoring Plan.
- At a minimum, the Contractor must provide the following artifacts/ deliverables on a monthly basis as directed by the Contracting Officer/ Contracting Officer's Representative.
    1. Operating system, database, Web application, and network vulnerability scan results;
    2. Updated POA& Ms;
    3. Any updated authorization package documentation as required by the annual attestation/ assessment/ review or as requested by the NIH System Owner or AO; and
    4. Any configuration changes to the system and/ or system components or CSP's cloud environment, that may impact HHS/ NIH's security posture. Changes to the configuration of the system, its components, or environment that may impact the security posture of the system under this contract must be approved by the agency.

F. **Configuration Baseline**

The Contractor shall certify that applications are fully functional and operate correctly as intended on systems using the US Government Configuration Baseline (USGCB), DISA Security Technical Implementation Guides (STIGs), Center for Information Security (CIS) Security Benchmarks or any other HHS- identified configuration baseline. The standard installation, operation, maintenance, updates, and/ or patching of software shall not alter the configuration settings from the approved HHS/NIH.

- The Contractor shall configure its computers that contain HHS data with the latest applicable United States Government Configuration Baseline (USGCB) and/or other approved HHS IT Security Configurations. (See: https://usgcb.nist.gov/). Note: Approved security configurations include, but are not limited to, those published by the Department, the NIH, and the National Institute of Standards and Technology (NIST) . NIH may have security configurations that are more stringent than the minimum baseline set by the Department or NIST. When incorporating such security configuration requirements in solicitations and contracts, the NIH CISO and/or Information System Security Officer (ISSO) shall be consulted to determine the appropriate configuration reference for a particular system or services acquisition.)
- The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS and must adhere to all NIH configuration standards and policies (See: https://ocio.nih.gov/InfoSecurity/Policy/Pages/CM.aspx.
- The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP) - validated tools with USGCB Scanner capability to ensure its products operate correctly with USGCB configurations and do not alter USCGB settings - (See: http://scap.nist.gov/validation). The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest USGCB major version and subsequent major versions.
- The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.
- The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.
- The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (See: http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.
- The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.
- The Contractor shall use Security Content Automation Protocol (SCAP) validated tools with configuration baseline scanner capability to certify their products operate correctly with HHS and NIST defined configurations and do not alter these settings.

G. **Standard for Encryption**

The Contractor (and/or any subcontractor) shall:

1. Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.
2. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-3 validated encryption solution.
3. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and NIH- specific encryption standard requirements.

Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).

4. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-3. The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer Technical Representative within 15 days of the validation.
5. Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys. Encryption keys shall be provided to the COR upon request and at the conclusion of the contract.

H. **Applicability**

The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:

1. A (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.
2. Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.

I. **Safeguarding Information and Information Systems**

In accordance with the Federal Information Processing Standards Publication (FIPS) 199, Standards for Security Categorization of Federal Information and Information Systems, the Contractor (and/or any subcontractor) shall protect government information and information systems in order to ensure:

- **Confidentiality,** which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;
- **Integrity**, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
- **Availability**, which means ensuring timely and reliable access to and use of information.
    - Provide security for any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor on behalf of HHS regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or Contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, within one (1) hour or less, bring the situation to the attention of the other party.

- Adopt and implement the policies, procedures, controls, and standards required by the HHS Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the HHS Information Security Program security requirements, outlined in the HHS Information Security and Privacy Policy (IS2P), by contacting the CO/COR or emailing fisma@hhs.gov
- Comply with the Privacy Act requirements.

J. **Information Security Categorization** - In accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800- 60, Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories, Contractor Non-Disclosure Agreement and based on information provided by the ISSO, CISO, or other security representative, the risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

Confidentiality: [ ] Low [ ] Moderate [ ] High
Integrity: [ ] Low [ ] Moderate [ ] High
Availability: [ ] Low [ ] Moderate [ ] High
Overall Risk Level: [ ] Low [ ] Moderate [ ] High

Based on information provided by the ISSO, Privacy Office, system/data owner, or other security or privacy representative, it has been determined that this solicitation/contract involves:

[ ] No PII [ ] Yes

Personally Identifiable Information (PII). Per the Office of Management and Budget (OMB) Circular A-130, "PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: social security number, date and place of birth, mother's maiden name, biometric records, etc.

Confidentiality Impact Level has been determined to be: [ ] Low [ ] Moderate [ ] High

K. **Contract Initiation and Expiration**

1. **General Security Requirements-** The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the Contractor shall follow the HHS EPLC framework and methodology or and in accordance with the HHS Contract Closeout Directive (2018) located at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HHS-Closeout-Directive-2018.pdf . HHS Enterprise Architecture (EA) requirements are located at: https://www.hhs.gov/sites/default/files/eplc-policy-dec-2016.pdf

2. **System Documentation-** Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-160, Systems Security Engineering: Considerations for a Multidisciplinary Approach in the Engineering of Trustworthy Secure Systems, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.
3. **Sanitization of Government Files and Information-** As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation in accordance with the NIH Media Sanitization and Disposal Policy to the CO and/ or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800- 88, Guidelines for Media Sanitization.
4. **Notification-** The Contractor (and/or any subcontractor) shall notify the CO and/ or COR and system ISSO within fifteen days before an employee stops working under this contract.
5. **Contractor Responsibilities Upon Physical Completion of the Contract-** The Contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non- government- owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or NIH policies.
6. The Contractor (and/or any subcontractor) shall perform and document the actions identified in the Employee Separation
7. Checklist https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf when an employee terminates work under this contract within 2 days of the employee's exit from the contract. All documentation shall be made available to the CO and/or COR upon request.

L. TRAINING

1. Mandatory Training for All Contractor Staff- All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable HHS/ NIH Contractor Information Security Awareness, Privacy, and Records Management training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, the employees shall complete NIH Information Security Awareness, Privacy, and Records Management training at least annually, during the life of this contract. All provided training shall be compliant with HHS training policies.
2. Role- based Training- All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role- based training annually commensurate with their role and responsibilities in accordance with HHS policy and the HHS Role- Based Training (RBT) of Personnel with Significant Security Responsibilities Memorandum. Read further guidance about the NIH Role- based Training: https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/index.html
3. Training Records- The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS policy. A copy of the

training records shall be provided to the CO and/or COR within 30 days after contract award and annually thereafter or upon request.

M. **RULES OF BEHAVIOR**

1. The Contractor (and/ or any subcontractor) shall ensure that all employees performing on the contract comply with the HHS Information Technology General Rules of Behavior, and comply with the NIH Information Technology General Rules of Behavior https://ocio.nih.gov/aboutus/publicinfosecurity/securitytraining/Pages/NIH_IT_GeneralRulesofBehavior.aspx , which are contained in the NIH Information Security Awareness Training Course http://irtsectraining.nih.gov
2. All Contractor employees performing on the contract must read and adhere to the Rules of Behavior before accessing Department data or other information, systems, and/ or networks that store/ process government information, initially at the beginning of the contract and at least annually thereafter, which may be done as part of annual NIH Information Security Awareness Training. If the training is provided by the contractor, the signed Rules of Behavior must be provided as a separate deliverable to the CO and/ or COR per defined timelines above.

N. **INCIDENT RESPONSE**

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams within one(1) hour of discovery, whether the response is positive or negative.

FISMA defines an incident as " an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cyber security and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines a breach as "a suspected or confirmed incident involving PII".

1. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-3 validated encryption.

2. DO NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send NIH approved notifications to affected individuals in accordance with https://wiki.ocio.nih.gov/wiki/index.php/US-CERT_Federal_Incident_Notification_Guidelines.
3. Report all suspected and confirmed information security and privacy incidents and breaches to the NIH Incident Response Team (IRT) via email at IRT@mail.nih.gov , COR, CO, the NIH Office of the SOP (or his or her designee), and other stakeholders, including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable NIH and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contract information, impact classifications/ threat vector, and the type of information compromised. In addition, the Contractor shall:
    - cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
    - not include any sensitive information in the subject or body of any reporting e-mail; and
    - encrypt sensitive information in attachments to email, media, etc.
    - Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.
4. Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.
5. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to Contractor facilities during a breach/ incident investigation within an hour of discovery.

O. **Vulnerability Scanning Reports-**

The Contractor shall report the results of the required monthly special vulnerability scans no later than 10 days following the end of each reporting period. If required monthly, this report may be included as part of the Technical Progress Report. Otherwise, this report shall be submitted under a separate cover on monthly basis.

P. **Confidentiality and Nondisclosure of Information-**

Any information provided to the Contractor (and/ or any subcontractor) by HHS or collected by the Contractor on behalf of HHS shall be used only for the purpose of carrying out the provisions

of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any HHS records may be made available or disclosed shall be notified inwriting by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein. The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and NIH policies. Unauthorized disclosure of information will be subject to the HHS/ NIH sanction policies and/ or governed by the following laws and regulations:

18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);

18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and

44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

Each employee, including subcontractors, having access to non- public Department information under this acquisition shall complete the " Commitment to Protect Non- Public Information - Contractor Employee Agreement" located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf . A copy of each signed and witnessed Non- Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

654

****(USE IN ALL SOLICITATIONS)****

33. **Electronic and Information Technology Accessibility Notice,** HHSAR 352.239-73 (December 2015).

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

b. Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508 . The complete text of the Section 508 Final Provisions can be accessed at https://www.access-board.gov/ict.html .

c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility. In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508

accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://www.hhs.gov/web/508. In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision).

The "HHS Section 508 Product Assessment Template" is included in SECTION J - List of Attachments, of this solicitation.

655

****(USE BELOW IN ALL SOLICITATIONS.)****

34. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1** (Feb 1998).

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

656

****(USE BELOW IN ALL SOLICITATIONS EXCEPT AS PROVIDED IN FAR 4.1102 (a).)****
ADDITIONAL INFORMATION TO COMPLETE THIS ITEM.

- **Alternate I:** Include for contracts to support unusual or compelling needs (FAR 4.1102(a)(5).

a. System for Award Management, FAR Provision 52.204-7 (Oct 2018).

Alternate I (Oct 2018) [is/is not] applicable to this solicitation.

657

****(USEBELOW IN ALL SOLICITATIONS THAT DO NOT CONTAIN THE PROVISION AT FAR 52.204-7, System for Award Management (See FAR 4.1102(a) for additional information.) OR MEET A CONDITION AT FAR 4.605(c)(2).)****

b. Unique Entity Identifier, FAR Provision 52.204-6 (Oct 2016).

658

****(USE BELOW WHEN THE TRADE AGREEMENT ACT OR THE NORTH AMERICAN FREE TRADE AGREEMENT ACT (NAFTA) APPLIES TO THIS REQUIREMENT. THE FOLLOWING CLAUSE MAY ALSO BE INCLUDED IF THE CO DECIDES THAT THEY ARE NECESSARY.)****

c. Submission of Offers in the English Language, FAR Clause 52.214-34, (Apr 1991).

659

****(USE BELOW WHEN THE TRADE AGREEMENT ACT OR THE NORTH AMERICAN FREE TRADE AGREEMENT ACT (NAFTA) APPLIES TO THIS REQUIREMENT. THE FOLLOWING CLAUSE MAY ALSO BE INCLUDED IF THE CO DECIDES THAT THEY ARE NECESSARY.)****

d. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (Apr 1991).

660

****(USE BELOW ONLY IF FACSIMILE PROPOSALS ARE AUTHORIZED.)****

Note: *Careful consideration should be given before allowing facsimile proposals. They SHOULD NOT be used for R&D proposals or any proposal that requires submission to more than one destination. Also, the anticipated size of the proposal should be considered. Large proposals may not be appropriate for faxing.* **IMPORTANT:** MAKE SURE TO INCLUDE THE FAX NUMBER ON THE FACE PAGE OF THE SOLICITATION IF FACSIMILE PROPOSALS ARE AUTHORIZED.

e. Facsimile Proposals, FAR Clause 52.215-5, (Oct 1997).

661

****(USE BELOW IN SOLICITATIONS WHICH MAY RESULT IN CONTRACTS WITH COMMERCIAL ORGANIZATIONS.)****

f. Facilities Capital Cost of Money, FAR Clause 52.215-16, (June 2003).

662

****(USE BELOW IN ALL SOLICITATIONS.)****

g. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (Oct 1997).

663

****(USE BELOW IN ALL SOLICITATIONS WHEN THE ESTIMATED CONTRACT OR ORDER VALUE IS EXPECTED TO EXCEED THE SIMPLIFIED ACQUISITION THRESHOLD **AND** THE CONTEMPLATED CONTRACT TYPE IS EXPECTED TO BE A COST-REIMBURSEMENT CONTRACT. THIS PROVISION SHALL ALSO BE USED IN ALL OTHER SOLICITATIONS WHERE FAR CLAUSE 52.215-23, Limitations on Pass-Through Charges, IS INCORPORATED.)****

h. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22, (Oct 2009).

664

****(USE BELOW IN SOLICITATIONS FOR INDEFINITE-QUANTITY CONTRACTS THAT MAY RESULT IN MULTIPLE CONTRACT AWARDS.)****

i. Single or Multiple Awards, FAR Clause 52.216-27, (Oct 1995).

665

****(USE THE PROVISION BELOW IN SOLICITATIONS FOR NON-COMMERCIAL ITEMS CONTEMPLATING USE OF A TIME-AND-MATERIALS OR LABOR-HOUR TYPE OF CONTRACT IF THE PRICE IS EXPECTED TO BE BASED ON ADEQUATE PRICE COMPETITION.)****

j. Time-and-Materials/Labor-Hour Proposal Requirements-Non-Commercial Item Acquisitions with Adequate Price Competition, FAR Clause 52.216-29, (Nov 2021).

666

****(USE THE PROVISION BELOW IN SOLICITATIONS CONTEMPLATING USE OF A COMMERCIAL TIME-AND-MATERIALS OR LABOR-HOUR TYPE OF CONTRACT.)****

k. Time-and-Materials/Labor-Hour Proposal Requirements-Commercial Item Acquisition, FAR Clause 52.216-31, (Nov 2021).

667

****(USE BELOW IN ALL SOLICITATIONS EXPECTED TO RESULT IN A CONTRACT OF $10,000,000 OR OVER.)****

l. Preaward On-Site Equal Opportunity Compliance Evaluation, ($10,000,000 or Over), FAR Clause 52.222-24, (Feb 1999).

668

****(USE BELOW IN SOLICITATIONS FOR NEGOTIATED CONSTRUCTION CONTRACTS.)****

m. Notice of Requirement for Affirmative Action to Ensure Equal Employment Opportunity for Construction, FAR 52.222-23, (Feb 1999).

669

****(USE BELOW IN ALL SOLICITATIONS ASSOCIATED WITH LARGE SCALE (OVER $25 MILLION) CONSTRUCTION PROJECTS, WHEN IT IS DETERMINED THAT A PROJECT LABOR AGREEMENT WILL BE REQUIRED. See FAR Subpart 22.5.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Alternate I:** Include when the submission of a project labor agreement from only the apparent successful offeror will be required.
2. **Alternate II:** Include when the submission of a project labor agreement will be allowed after contract award.

n. Notice of Requirement for Project Labor Agreement, FAR Clause 52.222-33 (May 2010).

Alternate I (May 2010) [is/is not] applicable to this solicitation.

Alternate II (May 2010 [is/is not] applicable to this solicitation.

670

(USE BELOW IN SOLICITATIONS WHEN IT IS POSSIBLE THAT AT LEAST $500,000 OF THE VALUE OF THE CONTRACT PERFORMED OUTSIDE THE UNITED STATES HAS AN ESTIMATED VALUE THAT EXCEEDS $550,000; AND THE ACQUISITION IS NOT ENTIRELY FOR COMMERCIALLY AVAILABLE OFF-THE-SHELF ITEMS.)

o. Certification Regarding Trafficking in Persons Compliance Plan, FAR Provision 52.222-56 (Oct 2020)

671

****(USE BELOW IN SOLICITATIONS FOR NEGOTIATED CONSTRUCTION CONTRACTS.)****

p. Preparation of Proposals--Construction, FAR Clause 52.236-28, (Oct 1997).

672

****(USE BELOW IN SOLICITATIONS OVER THE SIMPLIFIED ACQUISITION THRESHOLD FOR PROFESSIONAL OR TECHNICAL SERVICES TO BE ACQUIRED ON THE BASIS OF THE NUMBER OF HOURS TO BE PROVIDED, I.E. LEVEL OF EFFORT.)****

q. Identification of Uncompensated Overtime, FAR Clause 52.237-10, (Mar 2015).

673

****(USE THIS PROVISION WHEN IT IS QUESTIONABLE WHETHER OR NOT THIS REQUIREMENT INVOLVES ANTI-TERRORIST TECHNOLGY PRODUCT(S) OR SERVICES WHICH MAY BE APPROPRIATE FOR SAFETY ACT PROTECTIONS AND:

1. AFTER CONSULTATION WITH DEPARTMENT OF HOMELAND SECURITY (DHS), THE AGENCY HAS DETERMINED THAT SAFETY ACT PROTECTIONS ARE NOT APPLICABLE; OR
2. DHS HAS DENIED APPROVAL OF A PRE-QUALIFICATION DESIGNATION NOTICE.)****

r. SAFETY Act Coverage Not Applicable, FAR Clause 52.250-2, (Feb 2009).

674

****(USE THIS PROVISION WHEN THE DEPARTMENT OF HOMELAND SECURITY (DHS) HAS ISSUED A BLOCK DESIGNATION/CERTIFICATION FOR THE SOLICITED TECHNOLOGIES.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Alternate I:** Use with Alternate I when contingent offers are authorized in accordance with FAR 50.205-3.
2. **Alternate II:** Use with Alternate II when offers presuming SAFETY Act designation or certification are authorized in accordance with FAR 50.205-4. If this alternate is used, the Contracting Officer may alter the number of days within which offerors must submit their SAFETY Act designation or certification application.

s. SAFETY Act Block Designation/Certification, FAR Clause 52.250-3, (Feb 2009).

Alternate I (Feb 2009) [is/is not] applicable to this solicitation.

Alternate II (Feb 2009) [is/is not] applicable to the solicitation.

[Note to Offerors: The DHS SAFETY Act block designation or block certification is attached to this solicitation and contains essential information. Offerors should read this information carefully to make sure they comply with its terms if they plan to take advantage of SAFETY Act coverage for their technology(ies).]

675

****(USE THIS PROVISION IN A SOLICITATION FOR WHICH THE DEPARTMENT OF HOMELAND SECURITY (DHS) HAS ISSUED A PRE-QUALIFICATION DESIGNATION NOTICE.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Alternate I:** Use with Alternate I when contingent offers are authorized in accordance with FAR 50.205-3.
2. **Alternate II:** Use with Alternate II when offers presuming SAFETY Act designation or certification are authorized in accordance with 50.205-4. If this Alternate is used, the Contracting Officer may alter the number of days within which offerors must submit their SAFETY Act designation or certification application.

t. SAFETY Act Pre-qualification Designation Notice, FAR Clause 52.250-4, (Feb 2009).

Alternate I (Feb 2009) [is/is not] applicable to this solicitation.

Alternate II (Feb 2009) [is/is not] applicable to the solicitation.

[Note to Offerors: The DHS SAFETY Act block pre-qualification designation notice is attached to this solicitation and contains essential information. Offerors should read this information carefully to make sure they comply with its terms if they plan to take advantage of SAFETY Act coverage for their technology(ies).]

676

**** (USE BELOW IF THE PROVISION AT 52.250-3 IS USED WITH ITS ALTERNATE II OR THE PROVISION AT 52.250-4 IS USED WITH ITS ALTERNATE II. See previous two items above.) ****

u. SAFETY Act--Equitable Adjustment, FAR Clause 52.250-5, (Feb 2009).

677

****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a

clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

Note to Offerors: Beginning May 25, 2008, the offeror shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

678

****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

1. **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

679

****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

a. **Statement of Work**

1. Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

2. Approach

The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. Proposals which merely restate the requirements of the Government's scope of work will not be eligible for award.

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

3. Methods

Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you

anticipate.

4. Schedule

Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments of work, as applicable, by contract year as well as for the overall contract. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

680

****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

b. **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

681

****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

1. Single Principal Investigator/Project Director

List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project

Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

682

****(USE BELOW WHEN THE SOLICITATION HAS BEEN SELECTED TO INCLUDE THE OPTION FOR PROPOSING MULTIPLE PRINCIPAL INVESTIGATORS UNDER THE CONTRACT.)****

2. Multiple Principal Investigators

The NIH now provides offerors the opportunity to propose a multiple Principal Investigator (PI) model on research and development contracts. The multiple PI model is intended to supplement, and not replace, the traditional single PI model. The NIH chose this RFP as a candidate for the multiple PI model. Ultimately, the decision to submit a proposal using the multiple PI versus single PI is the decision of the investigators and their institutions. The decision should be consistent with and justified by the scientific goals of the project.

It is essential that organizations consider all aspects of this approach before submitting a proposal. While there are some projects that clearly are appropriate for the multiple PI model, the "fit" of other projects may not be so clear. Offerors should base the selection of either the single PI or multiple PI option on the research proposed, to ensure optimal facilitation of the science. Projects suitable for the multiple PI model could include as few as two PIs who are jointly responsible for the scientific and technical direction of the project. The multiple PI option is based on the proposed project, not on the number of performance sites or the number of participating institutions.

Multiple PIs under research contracts shall use the Subcontract Model. In this approach, offerors submit a single proposal, and a single award is made to the prime contractor. The prime contractor, when appropriate, will award subcontracts to fund the components of the project at the other institutions. The relationship between the Contractor and subcontractors must be designed to support all components of the project.

To facilitate communication with the NIH, the offeror must designate a Contact PI at the time of proposal submission. The Contact PI must be employed at the prime contractor's organization. The designation of the Contact PI may rotate on an annual basis. However, this rotation is restricted to PIs located at the prime contractor's organization. The Contact PI is responsible for: relaying communications between all of the PIs and the NIH, and coordinating progress reports for the project.

Being named Contact PI does not confer any special authority for the project.

Leadership Plan

Offerors proposing multiple PIs will need to submit a Leadership Plan as part of the Technical Proposal. The Leadership Plan shall describe the governance and organizational structure of the research project including communication plans, process for making decisions on scientific direction, allocation of resources, publications, intellectual property issues, and procedures for resolving conflicts.
The Leadership Plan shall follow the Table of Contents provided below:

I. Rationale
   Include a discussion of how the project will be enhanced by the multiple PI approach.
II. Identification of all proposed PIs
   Identify the proposed PIs, their point of contact information and affiliated organizations, and the percentages of time proposed for this project. Identify the Contact PI and plans for rotation of that role, if any.
III. Roles and Responsibilities
   Identify both the scientific and administrative roles and responsibilities of all named PIs.
IV. Approach to Fiscal and Management Coordination
   Describe how the project will be performed and monitored from a fiscal and management perspective. Discuss organizational administrative coordination and support.
V. Project Direction and Resource Allocation
   Address how decisions will be made regarding scientific direction, and, how resources will be allocated and redistributed if needed during performance. Address plans for shared resources such as IT or other shared data considerations. If joint standard operating procedures will be developed, describe this process.
VI. Communication and Lines of Authority
   Address communication and lines of authority within and among PIs and within and among organizations.
VII. Data sharing, Intellectual Property, Publication, and other Proprietary Considerations
   Data sharing plans, intellectual property considerations, publication agreements, and any other proprietary or confidential information sharing should be addressed in this section.
VIII. Conflict Resolution
   Address how conflicts will be avoided, identified, and resolved.
IX. Other
   Address any other information relative to the leadership approach to Multiple PI projects.

Offerors submitting single PI proposals do not need to submit a Leadership Plan.

683

****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

3. Other Investigators

   List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

684

****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

4. Additional Personnel

   List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

   1. The specific items or expertise they will provide.
   2. Their availability to the project and the amount of time anticipated.
   3. Willingness to act as a consultant.
   4. How rights to publications and patents will be handled.

685

****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

5. Resumes

   Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

686

****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

2. **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
d. Other factors you feel are important and support your proposed research.
e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

687

****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

3. **Technical Evaluation**

Proposals will be technically evaluated in accordance with SECTION M - Evaluation Factors for Award of this solicitation.

688

****(USE BELOW WHEN HUMAN SUBJECTS WILL BE INVOLVED IN THE PROJECT. BY DEFINITION THIS INCLUDES INTERVIEWS AS WELL AS STUDIES AND TRIALS.)****

Note: *This item consists of the subparagraphs a. through l. that should be selected as appropriate for the SOLICITATION.*

4. **Human Subjects**

IMPORTANT NOTE TO OFFERORS: The following subparagraphs shall be addressed, as applicable, in a SEPARATE FILE of the Technical Proposal entitled, "HUMAN SUBJECTS."

689

****(INCLUDE IN ALL SOLICITATIONS THAT INVOLVE HUMAN SUBJECTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM :

Alternate I: Use when the agency is prescribing a date later than the proposal submission by which the offeror must have an approved FWA. Delete if this is not needed.

a. **Notice to Offerors of Requirements, Protection of Human Subjects, HHSAR 352.270-4(a)** (December 2015).

(a)The Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR part 46, are available on the Office for Human Research Protections (OHRP) Web site at: http://www.hhs.gov/ohrp/index.html .These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of human subjects participating in research activities supported or conducted by HHS.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable public information through intervention or interaction with the individual, or identifiable private information. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. 45 CFR part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.

(c) Activities which involve human subjects in one or more of the categories set forth in 45 CFR 46.101(b)(1)-(6) are exempt from complying with 45 CFR part 46. See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal.

(e) In accordance with 45 CFR part 46, offerors considered for award shall file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board shall ensure that: The risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46 .111 for additional requirements regarding initial and continuing review. HHS

regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP Web site (at http://www.hhs.gov/ohrp/assurances/index.html).

(f) Offerors may consult with OHRP only for general advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. ONLY the contracting officer may offer information concerning a solicitation.

(g) The offeror shall document in its proposal the approved FWA from OHRP, related to the designated Institutional Review Board (IRB) reviewing and overseeing the research. If the offeror does not have an approved FWA from OHRP, the offeror must obtain an FWA before the deadline for proposal submission. When possible, the offeror shall also certify the IRB's review and approval of the research. If the offeror cannot obtain this certification by the time of proposal submission they must include an explanation in their proposal. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.

(End of provision).

Alternate I (Dec 2015).

As prescribed in HHSAR 370.303(a), the Contracting Officer shall substitute the following paragraph (g) for paragraph (g) of the basic clause.

(g) The offeror's proposal shall document that it has an approved or active FWA from OHRP, related to the designated IRB reviewing and overseeing the research. When possible the offeror shall also certify the IRB has reviewed and approved the research. If the offeror cannot make this certification at the time of proposal submission, its proposal must include an explanation. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB. If the offeror does not have an active FWA from OHRP, the offeror shall take all necessary steps to obtain an FWA prior to the deadline for proposal submission. If the offeror cannot obtain an FWA before the proposal submission date, the proposal shall indicate the steps/actions the offeror will take to obtain OHRP approval within(Contracting Officer must insert a time period in which the FWA must be obtained). Upon obtaining FWA approval, submit the approval notice to the Contracting Officer.

690

****(USE BELOW WHEN HUMAN SUBJECTS WILL BE INVOLVED IN THE PROJECT. BY DEFINITION THIS INCLUDES INTERVIEWS AS WELL AS STUDIES AND TRIALS.)****

Note: *The requirements in this Paragraph (6), may be supplemented when necessary, based on the specific requirements of the solicitation.*

b. **Instructions to Offerors Regarding Protection of Human Subjects**

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

a. Risks to the subjects
    1. Human Subjects Involvement, Characteristics, and Design :
        i. Briefly describe the overall study design in response to the solicitation.
        ii. Describe the subject population(s) to be included in the study; the procedures for assignment to a study group, if relevant; and the anticipated numbers of subjects for each study group.
        iii. List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research.
    2. Study Procedures, Materials, and Potential Risks
        i. Describe all planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data, and/or records, will be obtained; and whether any private identifiable information will be collected in the proposed research project.
        ii. For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials.
        iii. Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects.
        iv. Where appropriate, describe alternative treatments and procedures, including their risks and potential benefits. When alternative treatments or procedures are possible, make the rationale for the proposed approach clear.
b. Adequacy of Protection Against Risks
    1. Recruitment and Informed Consent:

i. Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent. The informed consent document for the Contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the Contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

1. For research involving children: If the proposed studies will include children, describe the process for meeting HHS regulatory requirements for parental permission and child assent (45 CFR 46.408). See the HHS page on Research with Children FAQs and the NIH page on Requirements for Child Assent and Parent/Guardian Permission.
2. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver.

2. Protection Against Risk:
   i. Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
   ii. Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
   iii. In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.
3. **Vulnerable Subjects, if relevant to your study** - Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. 'Prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers).
   i. Pregnant Women, Fetuses, and Neonates or Children - If the study involves vulnerable subjects subject to additional protections under Subparts B and D (pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements.

1. HHS' Subpart B - Additional Protections for Pregnant Women, Fetuses, and Neonates
2. HHS' Subpart D - Additional Protections for Children
3. OHRP Guidance on Subpart D Special Protections for Children as Research Subjects and the HHS 407 Review Process

c. Potential Benefits of the Proposed Research to the Subjects and Others

1. Discuss the potential benefits of the research to the subjects and others.
2. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
3. Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

Note: Financial compensation of subjects should not be presented as a benefit of participation in research.

d. Importance of the Knowledge to be Gained

1. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
2. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note : If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

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****(USE BELOW WHEN HUMAN SUBJECTS WILL BE INVOLVED IN THE PROJECT. BY DEFINITION THIS INCLUDES INTERVIEWS AS WELL AS STUDIES AND TRIALS.)****

c. **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 and amended September 24, 2010, at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html .

Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH Office of Extramural Research (OER) on-line tutorial, entitled "Protecting Human Research Participants" at: https://phrptraining.com/ . This course is also available in Spanish under the title "Protección de los participantes humanos de la investigación" at: https://phrptraining.com/ . You may take the tutorials on-line or download the information in PDF form at no cost. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual, entitled, "Protecting Study Volunteers in Research," can be obtained through CenterWatch, Inc.
at: https://www.centerwatch.com/products/category/1060-training-guides
.

If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

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d. **Inclusion of Women and Minorities in Research Involving Human Subjects**

NIH-conducted and supported clinical research must conform to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research in accord with Public Health Service Act sec. 4928 U.S.C. sec 289a-2. The policy requires that women and members of minority groups and their subpopulations must be included in all NIH-conducted or supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant NIH Institute/Center (IC) Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an IC Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended November 2017," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research."

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for

selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report" (see Section J, Attachments)

NOTE 1 : *For all proposals, use the ethnic and racial categories and complete the "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report" in accordance with the Office of Management and Budget (OMB) for all Application Packages after January 25, 2018, which may be found at* : https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm .

NOTE 2 : *If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in FAR 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.*

Standards for Collecting Data . When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in Appendix A- Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity at: https://nces.ed.gov/programs/handbook/data/pdf/Appendix_A.pdf . The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity

first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials *** require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect ((see NIH Guide:

https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm, Glossary/Definitions - Significant Difference). *The definition of an " **NIH-Defined Phase III clinical trial** " can also be found at this website.) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups,

  OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups,

  OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form entitled, "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report," when preparing your response to the solicitation requirements for inclusion of women and minorities. (See Section J-List of Documents, Exhibits and Other Attachments of the RFP)

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the form entitled, "PHS Human Subjects and Clinical Trials Information Form/Cumulative Inclusion Enrollment Report," for reporting in the resultant contract .

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e. **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are clear and compelling reasons not to include them. (See examples of Justifications for Exclusion of Children below). For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 18 years.

All Offerors proposing research involving human subjects should read the "Inclusion of Children in Clinical Research: Change in NIH Definition " which was published in the NIH guide notice on October 13, 2015 and is available at the following URL address:

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-010.html

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

1. The objective of the solicitation is not relevant to children.
    a. There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
    b. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
    c. A separate, age-specific study in children is warranted and preferable. Examples include:
        i. The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
        ii. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
        iii. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive,

developmental, or disease stages of different age-related metabolic processes); or

iv. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or

v. Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);

vi. Other special cases justified by the offeror and found acceptable to the review group and the Institute Director.

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 18 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 18) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

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f. **Research Involving Prisoners as Subjects**

A. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as

required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: http://www.hhs.gov/ohrp/policy/prisoner.html.

B. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.
The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:
    a. to describe the prevalence or incidence of a disease by identifying all cases, or
    b. to study potential risk factor associations for a disease, and
2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2 7) and determined and documented that:
    a. the research presents no more than minimal risk, and
    b. no more than inconvenience to the prisoner subjects, and
    c. prisoners are not a particular focus of the research.

For more information about this Waiver see
http://www.gpo.gov/fdsys/pkg/FR-2003-06-20/html/03-15580.htm.

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****(USE BELOW WHEN HUMAN FETAL TISSUE WILL BE INVOLVED IN THE SOLICITATION)****
The Contracting Officer shall submit an HFT justification, HFT Compliance Assurance, and a draft Informed Consent form from each from all offerors still being considered for award to the Ethics Advisory Board for review and recommend whether, in light of ethical consideration, NIH should fund the research project.

g. **Research Involving Human Fetal Tissue**

Research involving Human Fetal Tissue (HFT) must be conducted in accordance with applicable Federal, State and local laws, regulations, and policies. Selected Federal statutes, regulations, and policies are provided below:

42 U.S.C. 289g-1 a 289g-2 set forth specific requirements and prohibitions on research involving human fetal tissue. For example, among other prohibitions, 42 U.S.C. 289g-2 provides:

"Prohibitions regarding Human Fetal Tissue

a. Purchase of tissue

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."

The full text of 42 U.S.C. 289g-1 is available at: http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap6A-subchapIII-partH-sec289g-1.htm.

The full text of 42 U.S.C. 289g-2 is available at: http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap6A-subchapIII-partH-sec289g-2.htm.

Research involving HFT is also subject to the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B). The following provisions may be specifically relevant:

§ 46.204 Research involving pregnant women or fetuses.
~ (a) - (g)

h. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
i. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
j. Individuals engaged in the research will have no part in determining the viability of a neonate.

§ 46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

a. Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.
b. If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

The full text of the HHS Regulations for the Protection of Human Subjects is available at: http://www.hhs.gov/ohrp/policy/ohrpregulations.pdf.

Furthermore, per NOT-OD-16-033 at: https://grants.nih.gov/grants/guide/notice-files/not-od-16-033.html, when obtaining primary HFT for research purposes, NIH expects offerors to maintain appropriate documentation, such as an attestation from the health care provider or a third- party supplier, that informed consent was obtained at the time of tissue collection.

Non-Transplantation Research on Fetal Tissue Obtained from Elective Abortions

a. By signing the face page of the proposal, the offeror (authorized institutional official) certifies that the research involving HFT is in compliance with applicable federal, state, or local laws, regulations, and policies, including 42 USC 289g-1 and g-2, the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B), and NOT-OD-16-033.

Human Fetal Tissue Obtained from Elective Abortions

Offerors shall include a justification for its use as a separate attachment (see Section J. for a link to the template used for the justification) and include an HFT Compliance Assurance and draft Informed Consent form as described below. Offerors shall address HFT requirements as outlined in NOT- OD-19-128. Offerors who fail to include a justification for the use of HFT obtained from elective abortions, an HFT Compliance Assurance, and a draft Informed Consent form, will be non- responsive to the solicitation and withdrawn from further consideration.

Offerors shall include the following information in the justification package:

o Use the specific heading: "Human Fetal Tissue Obtained from Elective Abortions Justification".

o The Offeror must include the following in the justification:

1. Indicate why the research goals cannot be accomplished using an alternative to HFT (including, but not limited to, induced pluripotent cells not developed from HFT, organoids not developed from HFT, neonatal human tissue, human tissue obtained from adults, HFT not derived from elective abortion, animal models, and *in vitro* models that are not developed from HFT, and computational models).
2. Indicate the methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments).
3. Describe results from a literature review used to provide justifications.
4. Describe plans for the treatment of HFT and the disposal of HFT when research is complete.

5. Describe planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained. Include a draft informed consent form for planned use under the proposed research. The informed consent for donation of HFT for use in research requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and to be signed by both the woman and the person who obtains the informed consent.
6. Budget Justification: Describe and document the quantity, type, and source of the HFT, and include a line item cost for the acquisition of HFT or indicate the cost is $0 if using donated or existing HFT. The line item cost shall also be included in the offeror's separate Business proposal.
7. HFT Compliance Assurance: Offeror shall provide a letter signed by the Program Director/Principal Investigator assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration.

Research using HFT shall be in compliance with all applicable federal, state, or local laws, regulations, and policies, including 42 USC 289g-1 and g-2, the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B), NOT-OD-16-033, and NOT-OD-19-128.

Research on Transplantation of Human Fetal Tissue

Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) contain additional requirements for research on the transplantation of human fetal tissue for therapeutic purposes conducted or supported by NIH. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as the following NIH guidance.

Under section 498A, the official who signs the application is certifying that the research on transplantation of human fetal tissue will adhere to the following provisions. The woman who donates the fetal tissue must sign a statement declaring that the donation is being made:

- for therapeutic transplantation research
- without any restriction regarding the identity of individuals who may receive the transplantation, and
- without the donor knowing the identity of the recipient.

The attending physician must sign a statement that they have:

- obtained the tissue in accordance with the donor's signed statement and
- fully disclosed to the donor their intent, if any, to use the tissue in research and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks associated with the woman's medical care.

In the case of tissue obtained pursuant to an induced abortion, the physician's statement also must state that they:

- obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used;
- did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and
- performed the abortion in accordance with applicable State and local laws.

The Program Director/Principal Investigator (PD/PI) must sign a statement certifying that they are aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The PD/PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information. The PD/PI must certify in writing that they have had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

In submitting an application to NIH, the individual that signs the application is certifying that, if research on the transplantation of human fetal tissue is conducted under the grant-supported project, the organization will make available for audit by the HHS Secretary or designee, the physician statements, the PD/PI's statements, and informed consents required by subsections 498A(b)(2) and (c) of the PHS Act or will ensure HHS access to those records, if maintained by an entity other than the recipient. This requirement is in addition to the requirements concerning human subjects in research.

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****(USE BELOW IN ALL SOLICITATIONS THAT INVOLVE HUMAN SUBJECTS, INCLUDING RESEARCH INVOLVING HUMAN SPECIMENS, SAMPLES, AND/OR DATA.)****
SEE NIH NOTICE NOT-OD-22-001, NIH Implementation of the Revised Common Rule Provision Regarding Public Health Surveillance Activities Deemed Not to Be Research at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-001.html)

h. **Public Health Surveillance Exclusion**

An Offeror may request an exclusion from applicability of the "revised Common Rule"[1] if it believes that NIH-funded or -conducted activities associated with this solicitation should be considered "public health surveillance activities deemed not to be research" for the purposes of the revised Common Rule. All requests for the public health surveillance exclusion from the revised Common Rule for NIH-funded research-whether conducted or supported-must receive NIH approval, as per the process outlined below, to be considered a public health surveillance activity deemed not to be research under the revised Common Rule's Sections §46.102(k), Public health authority, and §46.102(l)(2), Public health surveillance activities. NIH expects that NIH-supported or -conducted research will be determined to be a public health surveillance activity only in extremely rare cases. **Please note that NIH will not consider any NIH-defined clinical trials for a public health surveillance exclusion request. In addition, NIH will not consider studies that contain any activity that does not meet the requirements for an exclusion for a public health surveillance determination, including any intent to store specimens and/or data for future use.**

Requesting a Determination that NIH-Funded or -Conducted Activities be Considered Public Health Surveillance:

Offerors shall provide a compelling justification as to why NIH-funded or -conducted activities should be considered public health surveillance activities deemed not to be research for the purposes of the revised Common Rule. Refer to the attached template in Section J. All activities for which approval of the exclusion will be sought must be disclosed and described.

The justification shall include information that demonstrates **all three (3)** of the following:

a) The proposed activity is strictly limited to only that necessary for NIH to identify, monitor, assess, or investigate:

i. Potential public health signals; or

ii. Onsets of disease outbreaks; or

iii. Conditions of public health importance (including trends, signals, risk factors, or patterns in diseases).

AND

b) The activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

AND

c) The activities will directly inform NIH public health decision-making or action.

Note: An Offeror shall submit its compelling justification for exclusion with its technical proposal as a separate attachment, so that the justification can be detached from and evaluated apart from the Offeror's technical proposal. The Government reserves the right to not consider any public health surveillance exclusion requests if the justification is not provided at the time of original proposal submission.

Offerors shall complete and submit the PHS Human Subjects and Clinical Trials Information Form, following instructions in the solicitation, as applicable. Offerors should not assume that approval of an exclusion will be granted when completing the PHS Human Subjects and Clinical Trials Information Form.

Note that the proposed budget in the proposal must reflect all necessary/required costs for the full and proper conduct of research involving human subjects, in complete compliance with all applicable laws, protocols, rules, and/or regulations at all levels, without approval of any exclusion. Offerors should not assume that approval of an exclusion will be granted when considering the costs to include in any proposed budget and therefore, must respond and price accordingly.

Notice of Approval or Disapproval of Request for Exclusion

Exclusion requests will be considered separate from the NIH peer review of technical proposals. Offerors will be issued written notification of approval or denial by the NIH Contracting Officer of any request(s) for exclusion prior to award. Any decision by NIH on an Offeror's request for a Public Health Surveillance Exclusion shall be final.

The award budget may then be adjusted accordingly if approval of an exclusion is granted by NIH.

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[1] Code of Federal Regulations (CFR) Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects, Revised 19 January 2017, Effective 19 July 2018, with a General Compliance Date of 21 January 2019 (45 CFR part 46)), and not its predecessor, the Pre-2018 Common Rule (Common Rule). The revised Common Rule is also known or referred to as the "2018 Requirements" or the "2018 Rule."

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****(USE BELOW WHEN RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES WILL BE ADMINISTERED TO HUMAN SUBJECTS.)****

i. **Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Including Human Gene Transfer Research)**

All research projects (both NIH-funded and non-NIH-funded) involving recombinant or synthetic nucleic acid molecules that are conducted at or sponsored by an entity in the U.S. that receives any support for recombinant or synthetic nucleic acid research from NIH shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*) (see http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines). All NIH-funded projects conducted abroad that involve research with recombinant or synthetic nucleic acid molecules must also comply with the NIH Guidelines. In addition to biosafety and containment requirements, the *NIH Guidelines* delineate points to consider in the development and conduct of human gene transfer clinical trials, including ethical principles and safety reporting requirements.

Prior to beginning any clinical trial involving the transfer of recombinant or synthetic nucleic acid molecules into humans, the trial must be registered with the NIH Office of Science Policy (OSP) and, if applicable, reviewed by the NIH Recombinant DNA Advisory Committee (RAC). If this contract involves a human gene transfer trial raising unique and/or novel issues, the trial may be discussed by the RAC in a public forum (see Appendix M-I-B of the *NIH Guidelines* for the specific criteria for the selection of protocols for RAC review and discussion). Approval of an Institutional Biosafety Committee (IBC) and the Institutional Review Board (IRB) are necessary before the Contracting Officer's Representative (COR) and Contracting Officer (CO) may approve the protocol prior to the start of the research. IBC approval may not occur until the protocol registration process with NIH is complete. If the trial is reviewed by the RAC, IBC approval may not occur before the RAC has concluded its review of the protocol and the protocol registration process with NIH is complete.

For human gene transfer research, Appendix M-I-C-4 of the NIH Guidelines requires any serious adverse events (SAEs) that are both unexpected and possibly associated with the human gene transfer product to be reported to NIH OSP and an IBC within 15 days, or within 7 days if the event was life-threatening or resulted in a death. A copy of the report must also be filed with the COR and CO. SAE reports must also be submitted within their mandated time frames to the IRB, Food and Drug Administration (FDA), and, if applicable, the Health and Human Services (HHS) Office for Human Research Protections (OHRP). In addition, annual reports must be submitted

to NIH OSP covering certain information about human gene transfer protocols. Further information about the content of these reports can be found in Appendix M-I-C-3 of the NIH Guidelines. Additional information on the requirements that pertain to human gene transfer can be found in a series of Frequently Asked Questions at: https://osp.od.nih.gov/biotechnology/nih-guidelines-faqs/.

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of the contract for any work related to recombinant or synthetic nucleic acid research or a requirement for the CO to approve any or all recombinant or synthetic nucleic acid molecule projects under this contract. This includes the requirement for the institution to have an IBC registered with NIH OSP that complies with the requirements of the *NIH Guidelines* . Further information about compliance with the *NIH Guidelines* can be found on the NIH OSP website at: https://osp.od.nih.gov/biotechnology/nih-guidelines/.

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****(USE BELOW WHEN HUMAN SUBJECTS WILL BE INVOLVED IN THE PROJECT.)****

j. **Human Stem Cell Research**

On March 9, 2009, the President issued Executive Order (EO) 13505: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells. The NIH has published Guidelines on Human Stem Cell Research at: https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research . The Guidelines implement EO 13505 with regard to extramural NIH-funded human stem cell research, establish policy and procedure under which the NIH will fund such research, and help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.

To facilitate research using human embryonic stem cells, the NIH has established a Human Embryonic Stem Cell Registry ("the NIH Registry") that lists the human embryonic stem cells that are currently eligible for use in NIH-funded research. This registry is available at: https://grants.nih.gov/stem_cells/registry/current.htm . Proposed human embryonic stem cell line(s) must be on the NIH Registry at the time of proposal submission. Any possible changes to the proposed cell line must be discussed in the proposal. Offerors wishing to have Human Embryonic Stem Cell Lines added to the NIH Human Embryonic Stem Cell Registry must submit the request on Form NIH 2890 through the following website: https://hescregapp.od.nih.gov/NIH_Form_2890_Login.htm .

See Section H of this solicitation for more details.

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****(USE BELOW FOR ALL RFPs THAT WILL RESULT IN THE CONDUCT OF CLINICAL TRIALS.)****
NOTE: The following language may be modified to incorporate an IC's alternate and comparable approach to expressing the NIH policy regarding Data and Safety Monitoring in Clinical Trials.

k. **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Contracting Officer Representative (COR).

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and

specific data and safety monitoring plan must be submitted as part of the proposal.

For any proposed clinical trial, NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial, its size, and its complexity. Provide a description of the DSMP, including:

- The overall framework for safety monitoring and what information will be monitored.
- The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
- The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), will be managed and reported, as required, to the IRB, the person or group responsible for monitoring, the awarding IC, the NIH Office of Biotechnology Activities, and the Food and Drug Administration.
- The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the DSMP will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:
    - PD/PI: While the PD/PI must ensure that the trial is conducted according to the approved protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PD/PI to also be responsible for carrying out the DSMP.
    - Independent safety monitor/designated medical monitor: a physician or other expert who is independent of the study.
    - Independent Monitoring Committee or Safety Monitoring Committee: a small group of independent experts.
    - Data and Safety Monitoring Board (DSMB): a formal independent board of experts including investigators and biostatisticians. NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally, for all Phase III clinical trials, although Phase I and Phase II clinical trials may also need DSMBs. If a DSMB is used, please describe the general composition of the Board without naming specific individuals.

The NIH Policy for Data and Safety Monitoring at: http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB- approved monitoring plan as part of the proposal submission.

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****(USE BELOW IN RFPs FOR HIV ANTIRETROVIRAL TREATMENT TRIALS THAT WILL TAKE PLACE IN WHOLE OR IN PART IN DEVELOPING COUNTRIES - Defined as the Low-and-Middle Income Economies, using WORLD BANK CLASSIFICATIONS.)****

l. **HIV Antiretroviral Treatment Trials**

The NIH is committed to conducting HIV/AIDS research in an effort to improve the health of people living with this disease, particularly people in countries most affected by the epidemic. It is important that individuals who volunteer to participate in NIH funded HIV antiretroviral trials be given the option to continue to receive antiretroviral treatment following their completion of the trial. In order to accomplish this, the Contractor must work with the host countries' authorities and other stakeholders to identify sources available, if any, in the country for the provision of such treatment. It is noted that NIH cannot provide this treatment following the completion of the research. See NIH Guide Notice, " Guidance for Addressing the Provision of Antiretroviral Treatment for Trial Participants Following Their Completion of NIH Funded HIV Antiretroviral Treatment Trials in Developing Countries ," located at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-038.html.

The offeror's proposal must address a plan that describes the following:

- A description of available sources, if any (e.g., name of source, location, contact person of facility/organization) for the provision of antiretroviral treatment and care following the completion of the trial;
- A summary of the offeror's interaction with the providers;
- Documents, if any, from available sources/ providers regarding plans for implementation; and
- A description of how this information will be conveyed to the trial participants.

If there are no sources for antiretroviral treatment in or available to the country in which the treatment trials will take place, the offeror must provide:

1. A statement confirming that at the time of the offer, no sources of antiretroviral treatment could be identified;

2. A description of how this information will be conveyed to the trial participants; and
3. A commitment to continue to explore potential sources as the trial proceeds.

This plan or the documentation provided regarding the lack of available sources of antiretroviral treatment will be evaluated by the Contracting Officer Representative (COR) as a part of the overall review of the proposal. While an offeror's documentation of the lack of available sources for antiretroviral treatment will not, of itself, constitute denial of a contract award, priority for contract awards may be given to those offerors who identify sources for the provision of antiretroviral treatment following the completion of the trial.

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****(USE BELOW IN SOLICITATIONS FOR APPLICABLE CLINICAL TRIALS AS FOLLOWS:)****
ADDITIONAL INFORMATION ABOUT THIS ITEM:

- For information about how to determine "applicable clinical trials," see Step 1 of the following link: http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm#whatsteps

Note: *The Contracting Officer should consult with the Project Officer and/or Contracting Officer Representative (COR) to assist in making this determination .*

m. **Registration of and Results Reporting for Applicable Clinical Trials in ClinicalTrials.gov**

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf ,Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov (https://www.clinicaltrials.gov/) and imposes new requirements that apply to certain applicable clinical trials, including those supported in whole or in part by NIH funds. FDAAA requires:

a. The registration of certain "applicable clinical trials" in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
b. The reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

The resultant contract will support one or more applicable clinical trial subject to FDAAA.

The "responsible party" is the entity responsible for registering and reporting trial results in ClinicalTrials.gov.

1. Where the Contractor is the IND/IDE holder, the Contractor will be considered the Sponsor, therefore the "Responsible Party."
2. Where there is no IND/IDE holder or where the Government is the IND/IDE holder, the Government will generally be considered the "Sponsor" and may designate the Contractor's Principal Investigator (PI) as the "Responsible Party."
3. For Multi-Center trials where there is no IND/IDE holder or where the Government is the IND/IDE holder, the "Responsible Party" will be designated at one site (generally the lead clinical site) and all other sites will be responsible for providing necessary data to the "Responsible Party" for reporting in the database.

Additional information is available at https://prsinfo.clinicaltrials.gov/.

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****(USE BELOW INSTRUCTIONS IN SOLICITATIONS AND CONTRACTS THAT INCLUDE WHOLLY OR PARTIALLY FUNDED NIH-FUNDED CLINICAL TRIALS.)****

Note: When reviewing a contract proposal funding a new clinical trial in whole or in part, an award cannot be issued until a plan for the dissemination of clinical trial information has been submitted by the offeror, and the Contracting Officer (CO) has approved the plan. Offerors are required to submit a plan for the dissemination of NIH-funded clinical trial information in the proposal submitted on or after January 18, 2017, that addresses how the policy expectations will be met. If a plan is not included in the proposal, the CO shall request the plan from the offeror prior to award. An award cannot be made until the plan is accepted and approved by the CO. Once approved, the plan is incorporated as a term and condition of award.

n. **PLAN FOR THE DISSEMINATION OF INFORMATION OF NIH-FUNDED CLINICAL TRIAL**

Offerors are required to submit a plan for the dissemination of NIH-funded clinical trial information in the proposal. At a minimum, the plan must contain sufficient information to assure that:

1. The Contractor shall register and submit results information to https://clinicaltrials.gov/ as outlined in the NIH policy on the Dissemination of NIH-Funded Clinical Trial Information and according to the specific timelines stated in the policy (this can be a brief statement);
2. Informed consent documents for the clinical trial(s) shall include a specific statement relating to posting of clinical trial information at https://clinicaltrials.gov/ ; and
3. The Contractor has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with NIH policy on the Dissemination of NIH-Funded Clinical Trial Information requirements.

If the Offerors plan does not meet these minimum standards, or is otherwise not acceptable as determined by the Contracting Officer, the contract award cannot be issued until an approved plan has been submitted.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHERE MORE THAN ONE DOMESTIC SITE WILL CONDUCT THE SAME PROTOCOL INVOLVING NON-EXEMPT HUMAN SUBJECTS RESEARCH.)****
SEE NIH NOTICE- NOT-OD-16-094.

o. **PLAN FOR SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)**

Offerors are required to submit a plan for the Single Institutional Review Board (sIRB) information in the technical proposal for each protocol involving more than one domestic site. At a minimum, the plan shall:

1. Participating sites will adhere to the sIRB Policy;
2. Sites and the sIRB will adhere to the communication plan described in the authorization/reliance agreement; and
3. If, in the case of restricted-award, a sIRB has not yet been identified, include a statement that the offeror will follow the sIRB Policy and communicate plans to select a registered IRB of record. This information must be provided to the Contracting Officer prior to initiating recruitment for a multi-site study.

The Offeror may request direct cost funding for the additional costs associated with the establishment and review of the multi-site study by the sIRB, with appropriate justification; all such costs must be reasonable and consistent with cost principles, in accordance with the Federal Acquisition Regulation Part 31 as applicable to your contract.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHERE MORE THAN ONE DOMESTIC SITE WILL CONDUCT THE SAME PROTOCOL INVOLVING NON-EXEMPT HUMAN SUBJECTS RESEARCH.)****
SEE NIH NOTICE- NOT-OD-16-094.

p. **EXCEPTIONS TO THE SINGLE INSTITUTIONAL REVIEW BOARD (sIRB) POLICY**

In the technical proposal, Offerors may request an exception to the sIRB policy for one or more studies.

1. For sites for which Federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions):

a. The Offeror shall identify any site that meets the requirements for the Single IRB policy but is required to have local IRB review because of a federal, state, or tribal law, regulation or policy; and
b. The Offeror shall provide specific citation for policy-based exceptions.

2. Time Limited Exception: ancillary studies to ongoing research without a sIRB- new multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use the sIRB of record until the parent study is expected to comply with the sIRB policy. The Offeror shall provide the parent contract number to request an exception.
3. *Other exceptions* when Offeror believes that one or more research sites should be exempt from use of the single IRB of record to conduct local IRB review based on compelling justification:
    a. Offerors should request an exception in the sIRB plan attachment within the contract proposal (section 3.2 in the Study Record: PHS Human Subjects and Clinical Trials Information form).
    b. Offerors must include the name of the site(s) for which an IRB other than the sIRB of record is proposed to review the study for the sites(s).
    c. Offerors must substantiate their exception request with sufficient information that demonstrates a compelling justification for *other exceptions* to the sIRB policy. The rationale should include why the sIRB of record cannot serve as the reviewing IRB for the site(s), and why the local IRB is uniquely qualified to be the reviewing IRB for the specific site(s).
    - For instance, the justification may consider ethical or human subjects protections issues, population needs, or other compelling reasons that IRB review for the site(s) cannot be provided by the single IRB of record.
    d. Note that the proposed budget in the proposal must reflect all necessary sIRB costs without an approved *other exception* . The Offerors should not assume that *another exception* will be granted when considering what sIRB costs to include in the budget.

Post-Award Exception Requests

For any post-award changes that necessitate an exception request, such as the addition of a new domestic site that may be unable to use the sIRB Contractor shall contact their Contracting Officer (CO). For policy-based exceptions, the Contractor shall provide the appropriate citation to verify the requirement for local IRB review for the newly added site(s) to the CO. For *other exceptions* , the Contractor shall provide compelling justification to the CO to be reviewed by the NIH Exceptions Review Committee (ERC) (see **Steps to Request an *Other Exception* to the sIRB Policy** above). For time limited exceptions, Contractor shall provide the parent contract number to the CO.

Notice of Approval or Disapproval of *Other Exception* Requests

The sIRB exception requests will be considered after peer review for proposals in the competitive range. All requests for *other exceptions* must be reviewed by the NIH ERC. The decision of NIH ERC is final. Offerors will be notified of the final decision by their CO prior to award. Approved exceptions will be incorporated as a term and condition in the contract award. Also, any exception requests submitted after award must be submitted to the CO and reviewed by the NIH ERC. No further revisions of the exception request will be accepted.

The award budget may need to be adjusted if an exception is granted.

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****(USE BELOW INSTRUCTIONS IN ALL SOLICITATIONS THAT INVOLVE HUMAN SUBJECTS, INCLUDING RESEARCH INVOLVING HUMAN SPECIMENS AND/OR DATA).****

q. **PHS HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM**

Offerors shall submit the "PHS Human Subjects and Clinical Trials Information Form" with each technical proposal for work involving human subjects.

FORM SUBMISSION INSTRUCTIONS

1. The PHS Human Subjects and Clinical Trials Information Form must be submitted with your technical proposal.
2. Offerors must use the form and follow the associated instructions posted on the website at: https://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT INVOLVE HUMAN SUBJECTS).****

r. **INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS**

Section 2038 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions requiring NIH to address the consideration of age as an inclusion variable in research involving human subjects, to identify criteria for justification for any age-related exclusions in NIH research, and to provide data on the age of participants in clinical research studies. The NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects applies to all NIH conducted or supported research involving human subjects, including research that is

otherwise "exempt" in accordance with Sections 101(b) and 401(b) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects.

Effective on all solicitations issued on or after January 25, 2019, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

The proposal for research involving human subjects must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. The Offeror must include a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the Offeror must provide acceptable justification for the exclusion in the proposal.

The Contractor must submit cumulative data as prescribed in the Age Enrollment Report template on participant age at enrollment in monthly progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual level participant data on sex/gender, race, ethnicity, and age at enrollment may be provided in progress reports.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE HUMAN SUBJECTS. BY DEFINITION THIS INCLUDES INTERVIEWS AS WELL AS STUDIES AND TRIALS.)****

s. **POSTING CLINICAL TRIAL INFORMED CONSENT FORMS TO CLINICALTRIALS.GOV**

The Revised Common Rule sections 46.102(b) and 46.116(h) requires Contractors with to post one IRB-approved version of an Informed Consent Form that has been used to enroll participants on a public federal website designated for posting such Consent Forms. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database https://clinicaltrials.gov/. Note: ClinicalTrials.gov only accepts Informed Consent Forms written in English; non-English language forms must be submitted to https://www.regulations.gov/.

1. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database https://clinicaltrials.gov/

2. The Informed Consent Form must be posted after recruitment closes, and no later than 60 days after the final study visit.
3. The Contracting Officer (CO) and/or Contracting Officer's Representative (COR) may permit or require redactions as appropriate.
4. Informed Consent Forms for the clinical trial(s) shall include a specific statement relating to posting of clinical trial information at https://clinicaltrials.gov/
5. Informed Consent Forms must be compliant with the HHS Policy for the Protection of Human Research Subjects (45 CFR 46).

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****(USE BELOW IN SOLICITATIONS THAT INVOLVE LIVE VERTEBRATE ANIMALS.)****

5. **Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, HHSAR 352.270-5(a)** (December 2015).

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, MD 20892-6910 (Email: olaw@od.nih.gov ; Phone: 301-496-7163).

The PHS Policy is available on the internet at: https://olaw.nih.gov/.

(End of provision).

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****(USE BELOW IN R&D SOLICITATIONS INVOLVING LIVE VERTEBRATE ANIMALS (INCLUDING THEIR USE AS A SOURCE OF TISSUES.)****

6. **Research Involving Live Vertebrate Animals**

It is intended that live vertebrate animals will be used during performance of this contract. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (authority derived from the Health Research Extension Act of 1985) specifies that certain information is required from offerors in contract proposals submitted to the NIH that will use live vertebrate animals.

The following criteria must be addressed in a separate section of the Technical Proposal titled "Vertebrate Animal Section" (VAS):

1. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
2. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
3. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
4. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

A concise (no more than 1-2 pages), complete description addressing these criteria must be provided. The description must be cohesive and include sufficient information to allow evaluation by reviewers and NIH staff. For more discussion regarding the VAS, see NIH Guide Notice NOT-OD-16-006 at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html.

The Contract Proposal VAS Worksheet is provided as an Attachment in SECTION J of this solicitation to assist in the preparation of the VAS as part of the Technical Proposal. It can be accessed at: https://grants.nih.gov/grants/olaw/vascontracts.pdf.

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****(USE BELOW IN ALL NIAID SOLICITATIONS AND/OR WHEN CONTRACT PERFORMANCE WILL INVOLVE POSSESSION, USE OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS.
NIAID Processes/Procedures Reviewed 9/22)****

7. **Possession, Use and Transfer of Select Biological Agents or Toxins**

Notice to Offerors of Requirements of Select Agents Regulations - August 25, 2020 (https://www.selectagents.gov/regulations/index.htm): 42 CFR Part 73, Possession , Use, and Transfer of Select Agents and Toxins (relating to public health and safety): 7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins (relating to plant health or plant products) (and, 9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins (relating to human and animal health, animal health or animal products)

These regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the Agricultural Bioterrorism Protection Act of 2002. They are designed to improve the ability of the United States Government to prevent, prepare for, and respond to bioterrorism and other public health emergencies. These regulations establish requirements regarding registration, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications.

Listings of HHS and USDA Select Agents and Toxins, and overlap Select Agents or Toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at https://www.selectagents.gov/ and https://www.selectagents.gov/sat/list.htm. For foreign institutions, see the NIAID Select Agent Award information at: https://www.niaid.nih.gov/grants-contracts/select-agent-terms-award-niaid-grants .

If the proposed contract will not involve the possession, use or transfer Select Agents or Toxins, the offeror must include a statement in its technical proposal that the work does not now nor will it in the future (i.e. throughout the life of the award) involve the possession, use or transfer Select Agents or Toxins.

Domestic Institutions

For prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, the domestic institution must:

i Include details about the Select Agent in their technical proposal, including the quantity proposed to be used during contract performance.

ii Describe the proposed use of the Select Agent or Toxin, including any restricted experiments.

iii Comply with 42 CFR part 73, 7 CFR part 331 and/or 9 CFR part 121 at: https://www.selectagents.gov/regulations/index.htm , as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

Foreign Institutions

For prime or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, the foreign institution must:

i Include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.

ii Describe the proposed use of the Select Agent or Toxin, including any restricted experiments.

iii When requested during negotiations, provide information satisfactory to the NIAID/NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: https://www.selectagents.gov/regulations/index.htm for U.S. institutions are in place and will be administered on behalf of all Select Agent work under the resulting contract. The process for making this determination includes a site visit to the foreign laboratory facility by an NIAID representative. During this visit, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. Laboratory site visits are conducted every three years for the life of the contract.

An NIAID chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the site visit , the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: https://www.selectagents.gov/regulations/index.htm . The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime Contractor of the approval status of the foreign institution. No NIH funds can be used for research involving a Select Agent or Toxin at a foreign institution until NIAID grants this approval.

711

****(USE BELOW IN ALL SOLICITATIONS INVOLVING RESEARCH AND DEVELOPMENT INCLUDING SBIRs.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- Under Relevant Biological variables, variables may be added, but sex cannot be deleted unless justified by the IC.

8. **Enhancing Reproducibility through Rigor and Transparency**

The offeror shall demonstrate compliance with the NIH Policy on enhancing Reproducibility through Rigor and Transparency as described in NIH Guide Notice NOT- OD-15-103 . Specifically, the offeror shall describe in its technical proposal the information described below:

712

****(USE PARAGRAPH a. BELOW IN ALL BROAD AGENCY ANNOUNCEMENTS UNLESS SCIENTIFIC PREMISE WAS ADDRESSED DURING CONCEPT REVIEW.)****

For RFPs, Program staff need to determine if the scientific premise has been addressed by the Government in formulating the contract requirement(s) or if it should be addressed by the Offerors and evaluated in peer review. IF NOT USING PARAGRAPH a., RENUMBER PARAGRAPH b. THROUGH d. AS APPROPRIATE.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- In paragraph c. insert additional variables as needed.

a. Compliance Factors

1. Describe the scientific premise for the Technical Proposal. The scientific premise is the research that is used to form the basis for the proposed research. Offerors should describe the general strengths and weaknesses of the prior research being cited by the offeror as crucial to support the proposal. It is expected that this consideration of general strengths and weaknesses could include attention to the rigor of the previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources.
2. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.
3. Explain how relevant biological variables, including sex, [if deemed necessary by the IC, additional variables may be included here] are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for proposals proposing to study only one sex. If your proposal involves human subjects, the sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion and justify the proposed proportions of individuals (such as males and females) in the sample.

Refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.

4. If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposal. Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.

   Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals. If the Technical Proposal does not propose the use of key biological and/or chemical resources, a plan for authentication is not required, and the offeror should so state in its proposal.

713

****(USE BELOW IN SOLICITATIONS WHEN CONTRACT PERFORMANCE INVOLVES AN AGENT OR TOXIN THAT IS LISTED IN THE UNITED STATES GOVERNMENT POLICY FOR INSTITUTIONAL OVERSIGHT OF LIFE SCIENCES DUAL USE RESEARCH OF CONCERN (DURC).)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- For a list of applicable agents or toxins, refer to Section 6 of the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern: http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf.

9. **Dual Use Research of Concern**

The offeror shall demonstrate compliance with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) or "DURC" policy. Additional National Institutes of Health information is found at: https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research . The offeror shall provide in its technical proposal each of the following items:

a. Identification of the agents or toxins subject to the DURC policy.
b. A description of the categories of experiments in which the identified agents or toxins produces or aims to produce or can be reasonably anticipated to produce one or more of the effects identified in Section 6 of the DURC policy.
c. For projects involving any of the agents listed in the DURC policy and that involve or are anticipated to involve any of the categories of experiments listed in the DURC policy, an indication of whether or not the project meets the definition of "dual use research of concern" in Section 4C of the policy.

d. For projects meeting the definition of "dual use research of concern," a draft risk mitigation plan.
e. Certification that the offeror is or will be in compliance with all aspects of the DURC policy prior to use of pertinent agents or toxins.

The Government shall not award a contract to an offeror who fails to certify compliance or whose draft risk mitigation plan is unsatisfactory to the Government. If selected for award, an approved risk mitigation plan shall be incorporated into the contract.

714

****(USE BELOW IN R&D CONTRACTS OR NON R&D CONTRACTS THAT INVOLVE BIOMEDICAL RESOURCES, SUCH AS A REPOSITORY OR STORAGE FACILITY OF MATERIALS, OR A DATABASE CONTAINING BIOMEDICAL INFORMATION.)****

10. **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guidelines for Recipients of NIH Research Grants and Policy," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf.

715

****(USE BELOW IN ALL SOLICITATIONS WHERE RESEARCH DATA, INCLUSIVE OF GENOMIC DATA, WILL BE GENERATED. IN ACCORDANCE WITH "FINAL NIH POLICY FOR DATA MANAGEMENT AND SHARING," NOTICE NOT-OD-21-013 WITH A RELEASE DATE OF 29 OCTOBER 2020 AND AN EFFECTIVE DATE OF 25 JANUARY 2023, NOT-OD-22-189, IMPLEMENTATION DETAILS FOR THE NIH DATA MANAGEMENT AND SHARING PLAN, AND NOT-OD-22-198, IMPLEMENTATION CHANGES FOR GENOMIC DATA SHARING PLANS INCLUDED WITH APPLICATIONS DUE ON OR AFTER JANUARY 25, 2023, AS APPLICABLE, INCLUDE THE FOLLOWING IN ALL SOLICITATIONS RELEASED AFTER 01 JULY 2022 WITH AN ORIGINAL PROPOSAL RECEIPT DATE OF 25 JANUARY 2023 OR LATER, AND ANY CONTRACTS RESULTING FROM THESE SOLICITATIONS WITH RESEARCH DATA GENERATION REQUIREMENTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Last Paragraph:** Include this bracketed ("[…]") paragraph for Multi-Center Clinical Trials or Epidemiological Studies. Make sure to delete this paragraph if it is not applicable.

a. **Management and Sharing of Research Data**

[Note: This policy applies to **all** NIH contracts, regardless of dollar value or level or type of funding, degree of funding (whole or partial), or type of NIH funding mechanism, that are expected to generate research data. **]**

NIH encourages, to the maximum extent practicable, the sharing of final research data to expedite the translation of research results into knowledge, products, services, and/or procedures to improve the human health condition. This contract is anticipated to generate such research data. Therefore, the Offeror shall submit a plan in its technical proposal for data management and sharing or state why such data sharing is not possible. If data sharing is limited, the Offeror shall explain the rationale and nature of such limitations in its Data Management and Sharing Plan. NIH's Data Management and Sharing Policy may be found at the following Web site:

NOT-OD-21-013: Final NIH Policy for Data Management and Sharing.

NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources are found at: https://grants.nih.gov/policy/sharing.htm.

[If the resultant contract is part of a collaborative program involving multiple sites, all data management and sharing shall be governed by a data management, sharing, and dissemination plan to be jointly developed prior to award. A Coordinating Center's proposal shall describe the methods by which to coordinate such data management, sharing, and dissemination planning and implementation efforts. In its proposal the Coordinating Center shall include a budget with all proposed costs and justification for/of any costs of such collaborative effort(s). **]**

716

****(USE BELOW IN SOLICITATIONS THAT INVOLVE BIOMEDICAL RESEARCH ON MODEL ORGANISMS.)****

Note: *Model Organisms include but are not restricted to Mammalian Models, such as the mouse and rat; and Non-Mammalian Models, such as budding Yeast, social amoebae, round worm, fruit fly, zebra fish, and frog.*

THIS PROVISION SHOULD BE USED IN CONJUNCTION WITH "OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES."

b. **Sharing of Model Organisms for Biomedical Research**

The NIH Research Tools Policy (https://grants.nih.gov/policy/sharing.htm) also referred to as NIH Principles and Guidelines for Sharing of Biomedical Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042 at: (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html), dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066 at: (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html), the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Offerors must include in their technical proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR provide appropriate reasons why such sharing is restricted or not possible. A reasonable time frame for periodic disposition of material and associated data must be specified in the proposal. In addition, the plan must address if, or how, offerors will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following:

1. Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) at: https://www.ott.nih.gov/sites/default/files/documents/pdfs/slaform.pdf ; for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (https://autm.net/surveys-and-tools/agreements/material-transfer-agreements/mta-toolkit/uniform-biological-material-transfer-agreement)

2. How will inappropriate "reach-through" requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?
3. How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

Offerors may request funds in their cost proposal to defray reasonable costs associated with sharing materials or data or transfer of model organisms and associated data to appropriate repositories.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INVOLVING NIH -FUNDED RESEARCH THAT GENERATES LARGE-SCALE HUMAN GENOMIC DATA ON OR AFTER JANUARY 25, 2015.)****

c. **Data Sharing Policy for Large-Scale Human Genomic Data**

1. Pursuant to the NIH Genomic Data Sharing Policy located at: https://sharing.nih.gov/, all offerors proposing NIH-funded research that generates large-scale human genomic data shall provide:
    a. a plan for submission of genomic data to the NIH-designated data repository, and
    b. an Institutional Certification.

As an alternative, Contractors may provide an appropriate justification on why submission to the repository is not possible with the proposal submission to the Contracting Officer for approval.

2. Pursuant to the NIH Genomic Data Sharing Policy located at: https://sharing.nih.gov/, Contractors who request access to controlled-access genomic data in the NIH repository for proposed research will be reviewed by the NIH Data Access Committees (DACs). NIH DACs will accept requests for proposed research uses beginning one month prior to the anticipated data release date. The access period for all controlled-access data is one year; at the end of each approved period, data users can request an additional year of access or close out the project. Additionally, Contractors requesting access to the data shall abide by the database of Genotypes and Phenotypes (dbGaP) Approved User Code of Conduct (https://dbgap.ncbi.nlm.nih.gov/aa/GWAS_Code_of_Conduct.html). Large-scale data include genome-wide association studies, single nucleotide polymorphisms arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism.

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****FOR USE IN ALL SOLICITATIONS AND CONTRACTS THAT INCLUDE HeLa CELL WHOLE GENOME SEQUENCE DATA****

d. **Sharing HeLa Cell Whole Genome Sequence Data and Family Acknowledgement**

1. Offerors proposing to generate HeLa Cell Whole Genome Sequence Data shall include a plan for submission of this data with the proposal pursuant to the HeLa Whole Genome Sequence Data guidance in NIH Guide Notice NOTOD-13-099, available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-099.html
2. Offerors who have generated and submitted HeLa cell whole genome sequence data from DNA or RNA to dbGaP must submit a data access request if they plan to use these data in any analyses. The process for accessing these data is outlined on the HeLa Cell Genome Sequencing Studies page (available at https://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs000640.v10.p1).
3. The following acknowledgment, or a variation of it that has been reviewed by the HeLa Genome Data Access Working Group, shall be made in any dissemination of research findings:

> "The genome sequence described/used in this research was derived from a HeLa cell line (URL to dbGaP). Henrietta Lacks, and the HeLa cell line that was established from her tumor cells without her knowledge or consent in 1951, have made significant contributions to scientific progress and advances in human health. We are grateful to Henrietta Lacks, now deceased, and to her surviving family members for their contributions to biomedical research. This study was reviewed by the NIH HeLa Genome Data Access Working Group."

Contact helagenome@nih.gov for acknowledgement variation requests.

719

****(USE BELOW IN SOLICITATIONS ABOVE THE MICROPURCHASE THRESHOLD WHEN THE ACQUISITION UTILIZES A PRODUCT OR SERVICE CODE DESIGNATED BY HHS AS HAVING SUSTAINABLE ACQUISITION ATTRIBUTES.)****

11. **Instructions to Offerors-Sustainable Acquisition,** HHSAR Provision **352.223-71** (December 2015).

Offerors must include a Sustainable Acquisition Plan in their technical proposals. The Plan must describe their approach and the quality assurance mechanisms in place for applying FAR 23.1 Sustainable Acquisition Policy (and other Federal Laws, regulations and Executive Orders governing sustainable acquisition purchasing) to this acquisition. the Plan shall clearly identify those products and services included in Federal sustainable acquisition preference programs by categorizing them along with their respective price/cost in the following eight groups: Recycled Content,

Energy Efficient, Biobased, Environmentally Preferable, Electronic Product Environment Assessment Tool, Water-Efficient, Non-Ozone Depleting Substances, and Alternative Fuels.

(End of provision).

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****(USE BELOW IN SOLICITATIONS THAT INVOLVE THE ACQUISITION OF COMMUNICATIONS PRODUCTS AND SERVICES, INCLUDING CONTENT IN ANY FORMAT, SUCH AS REPORTS, DOCUMENTS, CHARTS, POSTERS, PRESENTATIONS, OR VIDEO MATERIAL THAT IS SPECIFICALLY INTENDED FOR PUBLICATION ON, OR DELIVERY VIA, AN HHS-OWNED OR FUNDED WEB SITE. See HHSAR 311.7000.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

Text Box: Include the Section 508 accessibility standards which apply to the content or communications material identified in the Statement of Work or Performance Work Statement.

Notes:

1. In accordance with HHSAR Part 311, the Project Officer shall list the applicable accessibility standards of the Access Board Final Rule (36 CFR Part 1194) (e.g., "36 CFR 1194.21(a)-(j).")
2. Most Web-based text and communication must meet the accessibility standards in 36 CFR 1194.22, "Web-based intranet and Internet information and applications."
3. Additionally, 36 CFR 1194.41, "Information, documentation and support," and 36 CFR 1194.24 "Video and multimedia products" apply to all written, graphical, or broadcast video materials or products produced for HHS, including training.

36 CFR 1194.41(c) specifies that support services for products shall accommodate the communication needs of end-users with disabilities.

12. **Section 508 accessibility standards for HHS Web Site Content and Communications Materials**

Regardless of format, all Web content or communications materials specifically produced for publication on, or delivery via, HHS Web sites, including text, audio, or video, under this contract shall conform to applicable Section 508 accessibility standards. Remediation of any materials that do not comply with the applicable accessibility standards of 36 CFR Part 1194 as set forth herein shall be the responsibility of the Contractor.

The following Section 508 accessibility standards apply to the content or communications material identified in this Statement of Work Performance Work Statement:

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****(USE BELOW IN ALL SOLICITATIONS. THE RESULTING BASIC COST/PRICE INFORMATION WILL BE USED FOR SUCH PURPOSES AS ENSURING THAT THE OFFEROR FULLY UNDERSTANDS THE REQUIREMENT AND FOR DETERMINING THAT THE INDIRECT RATE(S) ARE BEING APPLIED CORRECTLY. IT DOES NOT PRECLUDE OBTAINING MORE COMPREHENSIVE INFORMATION, INCLUDING COST OR PRICING DATA, IN APPROPRIATE CIRCUMSTANCES.)****

c. **BUSINESS PROPOSAL INSTRUCTIONS**

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****(USE BELOW IN ALL SOLICITATIONS.)****

1. **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

723

****(USE BELOW FOR SOLICITATIONS THAT WILL NOT REQUIRE THE SUBMISSION OF CERTIFIED COST OR PRICING DATA (SEE FAR 15.403-3). NOTE: This item should also be used in situations where award WILL be based on adequate price competition and that it will not be necessary for the offeror to submit any additional price information (See FAR 15.402). In this case, this Proposal Cover Sheet will constitute the cost/price portion of the business proposal.)****

2. **Proposal Cover Sheet**

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when

certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with FAR 15.406-2.

724

****(USE BELOW WHEN DATA OTHER THAN CERTIFIED COST OR PRICING DATA IS REQUIRED TO SUPPORT PRICE REASONABLENESS OR COST REALISM (SEE FAR 15.403-3). THIS INCLUDES BUT IS NOT LIMITED TO SITUATIONS WHERE:

1. Proposals will be BELOW $2,000,000 AND Adequate Price Competition IS NOT expected;
2. Proposals will be BELOW $2,000,000 AND Adequate Price Competition IS expected BUT The CO concludes that unusual circumstances make it necessary to obtain Data Other Than Certified Cost or Pricing Data to determine Price Reasonableness;
3. Proposals will EXCEED $2,000,000 AND the CO obtains a waiver from the Certified Cost or Pricing Data Requirement in accordance with FAR 15.403-1(b)(4).)****

Note: *It will be necessary for the Contracting Officer to determine the level of data other than certified cost or pricing data required based on the needs and expectations of each solicitation.*

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Last sentence (in Brackets):**
  INCLUDE: Normally, the offeror should be allowed to submit this information in their own format. In this case the bracketed sentence should be INCLUDED in the SOLICITATION.
  DELETE: If the Contracting Officer deems that a specific format for the submission of this information is in the best interest of the Government, DELETE the bracketed sentence below and set forth the necessary format as the final sentence/paragraph of this item.

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3. **Data Other than Certified Cost or Pricing Data**

   a. Data submitted shall be sufficient to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., data to support an analysis of material costs (when sufficient data on labor and overhead rates is already available), or data on prices and quantities at which the offeror has previously sold the same or similar items.

   Data submitted must support the price proposed. The offeror shall include sufficient detail or cross references to clearly establish the relationship of the data provided to the price proposed. The offeror shall support any data provided with explanations or supporting rationale, as needed, to permit the Contracting Officer and authorized representative to evaluate the documentation.

   [Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

726

****(USE BELOW WHEN THE CONTRACTING OFFICER WANTS TO SPECIFY THE LEVEL OF DETAIL OF DATA OTHER THAN CERTIFIED COST AND PRICING DATA.)****

Note: *The information below may NOT be appropriate for all solicitations. The CO should evaluate each requirement individually, determine the level of detail the offeror should provide, and modify the paragraphs below based on the needs of the solicitation .*

b. The data submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $750,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional

guidelines.

7. **Indirect Costs**

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

9. **Travel**

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

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****(USE BELOW WHEN SUBMISSION OF CERTIFIED COST OR PRICING DATA IS REQUIRED.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Paragraph 3:** If you plan to use one of the formats set forth in Table 15.2 of FAR 15.408, delete this paragraph and replace it with the appropriate language from Table 15.2. Also, if you use the language contained in Table 15.2, you will not need to add Alternate I of clause 52.215-20, immediately following this item.

4. **Certified Cost or Pricing Data**
   a. **General Instructions**
      A. You must provide the following information on the first page of your pricing proposal:
         1. Solicitation, contract, and/or modification number;
         2. Name and address of offeror;
         3. Name and telephone number of point of contact;
         4. Name of contract administration office (if available);
         5. Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
         6. Proposed cost; profit or fee; and total;

7. Whether you will require the use of Government property in the performance of the contract, and, if so, what property. See Item 16. Other Administrative Data, subparagraph a.2. Government Property of this Section L.2.c of this solicitation;
8. Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
9. The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403 5(b)(1) and Table 15 2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
10. Date of submission; and
11. Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the certified cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.
C. As part of the specific information required, you must submit, with your proposal, certified cost or pricing data (as defined at FAR 2.101). You must clearly identify on your cover sheet that certified cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including
    1. The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
    2. The nature and amount of any contingencies included in the proposed price.
D. You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries'' section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.
E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406 2, submit a Certificate of Current Cost or Pricing Data.

b. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services** . Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when certified cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own certified cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor certified cost or pricing data as part of your own certified cost or pricing data as required in paragraph A.2. below. These requirements also apply to all subcontractors if required to submit certified cost or pricing data.

1. *Adequate Price Competition* . Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205 26(e)).
2. *All Other* . Obtain certified cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of certified cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $12.5 million or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. Also submit any information reasonably required to explain your estimating process (including the judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data, and the nature and amount of any contingencies included in the price). The Contracting Officer may require you to submit certified cost or pricing data in support of proposals in lower amounts. Subcontractor certified cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date

agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime Contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the certified cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's certified cost or pricing data is required as described in this paragraph, it must be included, along with your own certified cost or pricing data submission, as part of your own certified cost or pricing data. You must also submit any other certified cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor** . Provide a time phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs** . Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. **Other Costs** . List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties** . If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

1. Name and address of licensor.
2. Date of license agreement.
3. Patent numbers.
4. Patent application serial numbers, or other basis on which the royalty is payable.
5. Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
6. Percentage or dollar rate of royalty per unit.
7. Unit price of contract item.
8. Number of units.
9. Total dollar amount of royalties.
10. If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.202 and 31.205-37).

F. **Facilities Capital Cost of Money** . When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB CMF and show the calculation of the proposed amount (see FAR 31.205 10).

c. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of**

Proposed Estimated Cost (plus fee) and Labor Hours (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

d. **General Information**

A. There is a clear distinction between submitting certified cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of certified cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of certified cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

B. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

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****(USE BELOW IN SOLICITATIONS IF IT IS REASONABLY CERTAIN THAT CERTIFIED COST OR PRICING DATA OR DATA OTHER THAN CERTIFIED COST OR PRICING DATA WILL BE REQUIRED.)****

5. **Requirements for Certified Cost or Pricing Data and Data Other than Certified Cost or Pricing Data, FAR Clause 52.215-20** (Nov 2021).

(a) Exceptions from certified cost or pricing data.

(1) In lieu of submitting certified cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following paragraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) *Identification* of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) *Commercial product and commercial service exception.* For a commercial product and commercial service exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include:

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) *Requirements for certified cost or pricing data.* If the offeror is not granted an exception from the requirement to submit certified cost or pricing data, the following applies:

(1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and

the Contractor agree to a different format and change this clause to use Alternate I.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision).

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****(USE BELOW IF CERTIFIED COST AND PRICING DATA WILL BE REQUIRED TO BE SUBMITTED USING THE FORMAT SPECIFIED SECTION L.2.c.4. Certified Cost or Pricing Data, subparagraph 3. OF THIS WORKFORM.)****

Note: *If you will be requiring the submission of Certified Cost or Pricing Data in a format other than the format specified in Section L.2.c.4. Certified Cost or Pricing Data, subparagraph 3. of this workform, the language in Alternate I, below, should be modified to be consistent with the format you require.*

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- Make sure to check that the paragraph numbering within the brackets in paragraph (b)(1) below is consistent with your SOLICITATION. Change if necessary.

Alternate I (October 2010) of FAR Clause **52.215-20, Requirements for Certified Cost or Pricing Data and Data Other than Cost or Pricing Data** (Nov 2021).

As prescribed in 15.408(l)(and see 15.403-5(b)(1)), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in the following format:

[Insert description of the data and format that are required, and include access to records necessary to permit an adequate evaluation of the proposed price in accordance with 15.408 *,* Table 15-2 *, Note 2. The description may be inserted at the time of issuing the solicitation, or the* Contracting Officer *may specify that the offeror's format will be acceptable, or the description may be inserted as the result of negotiations.]*

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****(USE BELOW IN ALL SOLICITATIONS WHEN A COST-REIMBURSEMENT, FIXED-PRICE LEVEL OF EFFORT, TIME-AND-MATERIALS, OR LABOR HOUR CONTRACT IS CONTEMPLATED.)****

6. **Salary Rate Limitation**

Offerors are advised that no NIH funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II*. The Executive Schedule, Level II* annual salary rate limitation also applies to individuals proposed under subcontracts and to consultants. **LINK TO EXECUTIVE SCHEDULE RATES OF PAY:**

https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/
(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

***Note to Offerors** : The current Fiscal Year Executive Level II Salary Rate shall be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year Executive Level II Salary rates.

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****(USE BELOW IN ALL SOLICITATIONS THAT WILL RESULT IN THE AWARD A MULTI-YEAR CONTRACT THAT WILL NOT BE FULLY FUNDED (FAR 17.1).)****

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

1. **Subparagraph c:** Include estimated amount of the cancellation ceiling.
   Note: *In establishing cancellation ceilings, the Contracting Officer should estimate nonrecurring costs which would be incurred by an average Contractor and would be applicable to the products/services furnished under the contract.*
   Nonrecurring costs are those costs which are generally incurred on a one-time basis and include such costs as preproduction or startup, plant or equipment relocation, special tooling and special test equipment, preproduction engineering, and specialized workforce training.
   In most cases, when procuring professional services, the nonrecurring costs (i.e., the cancellation ceiling) will be $0.00.

7. **Multi-year Contract**

a. **General**

The Government intends to award any contract resulting from this solicitation under the terms and conditions of Federal Acquisition Regulation (FAR) Subpart 17.1, Multi-year Contracting. A multi-year contract may provide that performance under the contract during the second and subsequent years of the contract is contingent upon the appropriation of funds. It also may provide for a cancellation payment to be made to the Contractor if appropriations are not made.

Funding will be obligated to cover performance of the first program year plus cancellation liability, if any. Thereafter, performance will be funded as specified in Section B of the contract.

b. **Proposal Preparation and Evaluation**

In accordance with FAR 17.106-2, contract award will not be made on less than the requirements of the first program year; therefore, the offeror's proposal shall specifically identify the costs for the first program year, each subsequent program year, and the total multi-year contract.

Proposals will be evaluated in accordance with the evaluation factors set forth in Section M of this solicitation. The evaluation will consider the offeror's price and ability to perform the first program year as well as the total multi-year requirement. Award will be made based on the best overall value to the government.

If the Government determines before award that only the first program year requirements are needed, the Government's evaluation of the price or estimated cost and fee, if applicable, shall consider only the first year.

c. **Cancellation Ceiling**

In accordance with FAR Subpart 17.1, Multi-year Contracting, cancellation ceiling established for this contract is $ _____ . This amount, which is negotiable, will be reduced at the conclusion of each program year to reflect the contractor's recovery of non-recurring costs as performance progresses.

The first program year is not subject to cancellation. Cancellation dates for each succeeding program year will be included in the resultant contract and will indicate the specific calendar date by which funding for these requirements will be established. The cancellation dates will generally be the last day of each program year.

Offerors shall submit detailed estimates, by program year as well as for the total multi-year

requirement, for any preproduction or startup, labor learning, and other nonrecurring costs that will be incurred in the execution of the proposed contract (see FAR 17.106-1). This information shall be provided in a format similar to below, and shall be included in a clearly identified section of the business proposal. The Government may use the offeror's proposed estimates to revise the cancellation ceiling established by the Government. The cancellation ceiling will not be an evaluation factor for award.

FORMAT FOR SUBMISSION OF PROPOSED CANCELLATION CEILING

The total proposed cancellation ceiling for this contract is $ _____ . After completion of Program Year 1, the proposed ceiling amount is $ _____ ; after completion of Program Year 2, the proposed ceiling amount is $ _____ ; after the completion of Year 3, the proposed ceiling amount is $ _____ ; and after completion of Program Year 4, the proposed ceiling amount is $ _____ .

Instructions:

1. **Adjust accordingly for the number of years proposed.**
2. **Provide basis and support for all costs proposed.**

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****(USE BELOW IN ALL SOLICITATIONS THAT WILL RESULT IN THE AWARD OF A **FULLY FUNDED** MULTI-YEAR CONTRACT (FAR 17.1).)****

Note: *The Government does not create a "cancellation liability" when a multi-year contract is fully funded at award. Cancellation of a fully funded multi-year contract is handled using standard termination for convenience procedures.*

8. **Fully Funded Multi-year Contract**

a. **General**

The Government intends to award a contract resulting from this solicitation in accordance with Federal Acquisition Regulation (FAR) Subpart 17.1, Multi-year Contracting. It is the Government's intention to fully fund this multi-year contract. In this case, cancellation payments will not apply. If needed, cancellation will be handled in accordance with the Termination for Convenience clause incorporated in SECTION I of the contract. Within the context of FAR Subpart 17.1, "program year" has the same meaning as "contract year."

b. **Proposal Preparation and Evaluation**

In accordance with FAR 17.106-2, contract award will not be made on less than the requirements of the first program year, therefore, the offeror's proposal shall specifically identify the costs for the first program year, each subsequent contract year, and the total multi-year requirement.

Proposals will be evaluated in accordance with the evaluation factors set forth in Section M of this solicitation. The evaluation will consider the offeror's price and ability to perform the first program year as well as the total multi-year requirement. Award will be made based on the best overall value to the government.

If the Government determines before award that only the first program year requirements are needed, the Government's evaluation of the offeror's price and ability to perform shall consider only the first year.

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****(USE BELOW WHEN A CONTRACT REQUIRES A SUBCONTRACTING PLAN (All Contracts OVER $750,000 - OR $1.5 million for construction of Public Facilities) EXCEPT SMALL BUSINESS CONTRACTS.)****

NOTE: An offeror must submit their respective subcontracting plan electronically using the U.S. Department of Health and Human Services (HHS) Small Business Customer Experience (SBCX) system at https://osdbu.hhs.gov. The offeror must follow the instructions outlined in the SBCX Industry Guide at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- Last Paragraph: This paragraph identifies the minimum subcontract plan goals for the SOLICITATION and MUST be filled in for EVERY SOLICITATION that requires submission of a Subcontract Plan.

9. **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $750,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation. In accordance with FAR 19.704 and FAR Clause 52.219-9, the submission of a subcontracting plan by other than small business offeror(s) is a requirement as a part of the proposal submission process and is to be submitted separately from the technical and cost proposals. An offeror's subcontracting plan must be determined to be acceptable, by the Contracting Officer, prior to the contract award.

1. An offeror is to submit their respective subcontracting plan electronically using the U.S. Department of Health and Human Services (HHS) Small Business Customer Experience (SBCX) system at https://osdbu.hhs.gov . The offeror must follow the instructions outlined in the SBCX Industry Guide instructions outlined in the SBCX Industry Guide at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j to successfully submit their subcontracting plan by the proposal submission deadline.

2. The official point of receipt for determining timely submission of an offeror's subcontracting plan is the SBCX system and/or email notification. Once the subcontracting plan is successfully submitted in the SBCX system the offeror should receive an email notification and confirmation message of completion upon submission.

3. If an offeror's subcontracting plan is not confirmed as received within the SBCX system by the proposal submission date specified in the solicitation, it will be considered late in accordance with subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offeror-Competition Acquisition. Disposition of late submittals of a subcontracting plan by an offeror via the SBCX system is at the discretion of the Contracting Officer.

4. Any technical questions regarding the use of the SBCX system may be submitted via email message to the SBCX help desk at client.support@apexlogic.com . The client support hours of operation are Monday - Friday, 6:00 a.m. - 8:00 p.m. Eastern Standard Time (EST). Note: help desk tickets can be submitted 24 hours a day / 7 days a week and a representative will respond within the presented client support hours of operation for assistance.

    a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
    b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
    c. The offeror understands that:
        i. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
        ii. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
        iii. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early

enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

iv. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

v. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

vi. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:

i Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

ii A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

iii A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

iv A description of the method used to develop the subcontracting goals.

v A description of the method used to identify potential sources for solicitation purposes.

vi A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

vii The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

viii A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

ix Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than

small businesses, in excess of $750,000 adopt a plan similar to the plan agreed upon by the offeror.

x Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government.

xi List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

32% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

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****(USE BELOW IN ANY SOLICITATION THAT INCLUDES THE FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN.)****

10. **Mentor-Protégé Program, HHSAR 352.219-70** (December) 2015.

a. Large business prime Contractors serving as mentors in the HHS Mentor-Protege Program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU) approved mentor-protege agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protege firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at https://www.esrs.gov/ . The mentor firm and protege firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a $10,000 subcontract awarded to a protege firm and provision of $5,000 of developmental assistance as $15,000 of subcontracting plan credit.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.

b. The program consists of--

1. Mentor firms--large businesses that:
   (i) Demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and
   (ii) Have a Mentor-Protege agreement approved by HHS' OSDBU;
2. Protege firms--firms that:
   (i) Seek developmental assistance;
   (ii) Qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned small businesses; and
   (iii) Have a Mentor-Protege agreement approved by HHS' OSDBU; and
3. Mentor-Protege agreements--joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision).

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****(USE BELOW IN ALL FULL AND OPEN COMPETITIVE SOLICITATION OVER THE SIMPLIFIED ACQUISITION THRESHOLD.)****

11. **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone .

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****(USE BELOW FOR SOLICITATIONS WHICH WILL RESULT IN A CONTRACT FOR SERVICES WHICH WILL EXCEED $700,000 AND THE SERVICE TO BE PROVIDED WILL REQUIRE MEANINGFUL NUMBERS OF PROFESSIONAL EMPLOYEES.)****

12. **Total Compensation Plan**
    a. **Instructions**
       1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. **Evaluation**

1. **Total Compensation Plan (Professional Employees)**

   In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. **Cost (Professional Compensation)**

   Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3. **Other (Labor Relations)**

   An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4. **Federal Acquisition Regulation Clauses incorporated by Reference**

   FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees.

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****(USE BELOW IN SOLICITATIONS FOR CONTRACTS THAT WILL REQUIRE THE CONTRACTOR TO USE AN EARNED VALUE MANAGEMENT SYSTEM (EVMS), WHETHER FULL OR PARTIAL, WHEN THE GOVERNMENT REQUIRES AN INTEGRATED BASELINE REVIEW (IBR) PRIOR TO AWARD.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- EVM IS APPLICABLE TO SOLICITATIONS FOR CONTRACTS THAT USE DEVELOPMENT, MODERNIZATION AND ENHANCEMENT (DME) FUNDS.

Note: *Funds used to develop, plan, modernize, or enhance an IT system are considered DME. DME does not include maintenance of existing IT Systems (including technology refreshment hardware and software.* For more information about EARNED VALUE MANAGEMENT (EVM) See HHSAR Subpart 334.2.

13. **Notice of Earned Value Management System - Pre-Award IBR**

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Business Proposal entitled, "Earned Value Management System."

a. The offeror shall provide documentation that its proposed Earned Value Management System (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard-748 (current version at time of solicitation).
b. If the offeror proposes to use a system that currently does not meet the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the guidelines.
    1. The plan shall:
        i. Describe the EVMS the offeror intends to use in performance of the contract;
        ii. Distinguish between the offeror's existing management system and modifications proposed to meet the guidelines;
        iii. Describe the management system and its application in terms of the EVMS guidelines;
        iv. Describe the proposed procedure for application of the EVMS requirements to subcontractors;
        v. Provide documentation describing the process and results, including Government participation if applicable, of any third- party evaluation or self- evaluation of the system's compliance with the EVMS guidelines; and
        vi. Provide a schedule of events leading up to formal validation and Government acceptance of the offeror's EVMS, if the value of the offeror's proposal, including options, is $25 million or more.
    2. The offeror shall provide information and assistance, as required by the Contracting Officer, to support review of the plan.
    3. The Contracting Officer will review the offeror's EVMS implementation plan prior to contract award.

4. The offeror's EVMS plan must provide milestones indicating when the offeror anticipates that the EVMS will be compliant with the ANSVEIS Standard - 748 guidelines.

c. The offeror shall identify in its offer the subcontractors, or subcontracted effort if subcontractors have not been identified, to which the requirements of EVMS will be applied. Prior to contract award, the offeror and HHS shall agree on the subcontractors, or subcontracted effort, subject to the EVMS requirement.

d. HHS will conduct an Integrated Baseline Review (IBR) prior to contract award. The offeror shall be compensated as set forth elsewhere in this solicitation for its preparation for and participation in the IBR.

Offerors **[ ] Will**, **[ ] Will Not** be directly compensated for the costs of participating in a pre-award IBR.

738

****(USE BELOW IN SOLICITATIONS FOR CONTRACTS THAT WILL REQUIRE THE CONTRACTOR TO USE AN EARNED VALUE MANAGEMENT SYSTEM (EVMS), WHETHER FULL OR PARTIAL, WHEN THE GOVERNMENT REQUIRES AN IBR AFTER CONTRACT AWARD.

EVM APPLIES TO CONTRACTS THAT USE DEVELOPMENT, MODERNIZATION AND ENHANCEMENT (DME) FUNDS).)****

Note: *For more information about Earned Value Management (EVM) see HHSAR Subpart 334.2.*

14. **Notice of Earned Value Management System - Post-Award IBR**

a. The offeror shall provide documentation that its proposed Earned Value Management System (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard-748 (current version in effect at time of solicitation).

b. If the offeror proposes to use a system that currently does not meet the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the guidelines.

1. The plan shall:

i. Describe the EVMS the offeror intends to use in performance of the contract;

ii. Distinguish between the offeror's existing management system and modifications proposed to meet the guidelines;

iii. Describe the management system and its application in terms of the EVMS guidelines;

iv. Describe the proposed procedure for application of the EVMS requirements to subcontractors;

v. Provide documentation describing the process and results, including Government participation if applicable, of any third-party evaluation or self-evaluation of the system's compliance with the EVMS guidelines; and

vi. Provide a schedule of events leading up to formal validation and Government acceptance of the offeror's EVMS, if the value of the offeror's proposal,

including options, is $25 million or more.

2. The offeror shall provide information and assistance, as required by the Contracting Officer, to support review of the plan.

3. The Contracting Officer will review the offeror's EVMS implementation plan prior to contract award.

4. The offeror's EVMS plan must provide milestones indicating when the offeror anticipates that the EVM system will be compliant with the ANSI/EIA Standard-748 guidelines.

c. The offeror shall identify in its offer the subcontractors, or subcontracted effort if subcontractors have not been identified, to which the requirements of EVMS will be applied. Prior to contract award, the offeror and HHS shall agree on the subcontractor's) subcontracted effort, subject to the EVMS requirement.

739

****(USE BELOW IN ALL SOLICITATIONS.)****

15. **Other Administrative Data**

740

a. **Property**

741

****(USE BELOW IN ALL SOLICITATIONS.)****

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below , the proposal must include a comprehensive justification addressing the following items:
    a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.

    b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

742

****(USE BELOW IN ALL SOLICITATIONS.)****

2. Government Property

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);

b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;

c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and

d. A description of the offeror's property management system, plan, and any customary commercial practices, voluntary consensus standards, or industry-leading practices and standards to be used in the offeror in managing Government property.

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from an offeror or Contractor possessing Government property. This will be done by adjusting the offers by applying, for evaluation purposes only, a rental equivalent evaluation factor, as specified in FAR 52.245-9.

743

****(USE BELOW IN ALL SOLICITATIONS.
ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:
- Select the appropriate statement from the drop down box.)****

3. Government-Furnished Property
[No Government Furnished Property is offered for this acquisition/A Listing of Government Furnished Property is provided in Section J - Solicitation Attachments of this solicitation]

744

****(USE BELOW IN ALL SOLICITATIONS.)****

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "Appendix Q, HHS Contracting Guide for Contract of Government Property," which can be found at:

https://oamp.od.nih.gov/sites/default/files/DGS/HHS Contracting Guide for Contract of Government Property-Appendix Q.pdf.

745

****(USE BELOW WHEN IT IS ANTICIPATED THAT ROYALTIES MAY BE PAID IN CONNECTION WITH CONTRACT WORK.)****

b. **Royalties**

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

746

****(USEBELOW IN ALL SOLICITATIONS.)****

c. **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (Jul 2013).

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232 34, Payment by Electronic Funds Transfer Other than System for Award Management.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

(End of provision).

747

****(USE BELOW IN ALL SOLICITATIONS.)****

d. **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

748

****(USE IN ALL SOLICITATIONS EXCEPT THOSE THAT WILL RESULT IN A FIRM-FIXED-PRICE CONTRACT.)****

e. **Adequate Accounting System**

FAR Part 16 sets forth the requirements and limitations for consideration of contract type. As stated in Section L.1., General Instructions of this solicitation, the resultant contract will not be Firm-Fixed Price. Therefore, the offeror's/contractor's accounting system and practices must be adequate and suitable for accumulating costs under government contracts.

To be considered for an award under this solicitation, the offeror shall include, in the Business Proposal, the following Certification:

"By submission of its signed offer, the Offeror certifies that its accounting system:

1. Complies with Generally Accepted Accounting Principles (GAAP).
2. Provides for:
   a. Proper segregation of direct costs from indirect costs.
   b. Identification and accumulation of direct costs by contract.
   c. A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
   d. Accumulation of costs under general ledger control.
   e. A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
   f. A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
   g. Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
   h. Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions.

i. Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.
j. Segregation of preproduction costs from production costs, if applicable.

3. Accounting system provides financial information:
   a. Required by contract clause concerning limitation of cost (FAR 52.232-20) or limitation on payments (FAR 52.216-16).
   b. Required to support requests for progress payments.
4. Accounting system was designed, and records are maintained in such a manner that adequate, reliable data are developed for use in pricing follow-on acquisitions.
5. Accounting system is currently in full operation.

The Contracting Officer reserves the right to request, with the Final Proposal Revision (FPR), a current (within 18 months) CPA opinion confirming that the Offeror's accounting system is compliant as certified above.

749

****(USE BELOW IF THE RESULTANT CONTRACT WILL BE INCREMENTALLY FUNDED.)****

f. **Incremental Funding**

An incrementally funded contract is a contract in which funds are obligated, as they become available, to cover specific periods of performance.

750

****(USE BELOW WHEN A COST-REIMBURSEMENT CONTRACT FOR SEVERABLE SERVICES USING INCREMENTAL FUNDING IS CONTEMPLATED.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- Insert the appropriate period or increment of performance in the text box.

Incremental Funding, HHSAR 352.232-70 (December 2015).

The Government intends to negotiate and award a cost-reimbursement contract using incremental funding as described in the clauses at FAR 52.232-22, "Limitation of Funds." The initial obligation of funds under the contract is expected to cover _____ . The Government intends to obligate additional funds up to and including the full estimated cost of the contract for the remaining years of performance by unilateral contract modification. However, the Government is not required to reimburse the Contractor for costs incurred in excess of the total amount obligated, nor is the Contractor required to perform beyond the level supported by the total amount obligated.

(End of provision).

751

****(USE BELOW IF COMMERCIAL ORGANIZATIONS MIGHT RESPOND TO THE SOLICITATION.)****

g. **Facilities Capital Cost of Money, FAR 52.215-16,** (Jun 2003).

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision).

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] Fac Cap Cost of Money (Has) The prospective Contractor **has** specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] Fac Cap Cost of Money (Has Not) The prospective Contractor **has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

752

****(USE BELOW IN ALL SOLICITATIONS.)****

16. **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a. **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b. **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c. **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d. **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

753

****(USE BELOW IN ALL SOLICITATIONS.)****

17. **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a. Willingness to perform as a subcontractor for specific duties (list duties).
b. What priority the work will be given and how it will relate to other work.
c. The amount of time and facilities available to this project.
d. Information on their cognizant field audit offices.
e. How rights to publications and patents are to be handled.
f. A complete cost proposal in the same format as the offeror's cost proposal.

754

****(USE BELOW IN ALL SOLICITATIONS.)****

18. **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

755

****(USE BELOW IN ALL SOLICITATIONS.)****

19. **Travel Costs/Travel Policy**

756

****(USE BELOW, IF COMMERCIAL ORGANIZATION(S) ARE EXPECTED TO RESPOND TO THIS SOLICITATION.)****

a. **Travel Costs - Commercial**

Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

757

****(USE BELOW IN ALL SOLICITATIONS.)****

b. **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

758

****(USE BELOW IN ALL SOLICITATIONS FUNDED WITH APPROPRIATED BIO-DEFENSE FUNDS.
Note: *At this time, may only be applicable to NIAID projects* .
NIAID Processes/Procedures Reviewed 9/22)****

20. **Certification of Visas for Non-U.S. Citizens**

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

759

****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

SECTION M - EVALUATION FACTORS FOR AWARD

760

****(THE ITEM BELOW SHOULD BE USED WHEN THE CONTRACTING OFFICER HAS DETERMINED THAT PAST PERFORMANCE SHOULD NOT BE EVALUATED AND THE CONTRACT IS EXPECTED TO BE VALUED AT LESS THAN $650,000. Further, this paragraph gives paramount consideration to technical proposals and considers all evaluation factors other than cost/price, when combined, significantly MORE important than cost/price. The paragraph also describes the selection process when the evaluation reveals two or more offerors are approximately equal in combined non-price/cost evaluation factors. If this does not describe your intent, FAR Part 15 allows cost/price to be EQUAL TO or significantly MORE important than combined non-cost/price evaluation factors. If your intent is other than the paragraph below, you should coordinate revised language with your Section Chief or his/her Deputy prior to incorporation into the SOLICITATION.)****

1. **GENERAL**

The technical proposal will receive paramount consideration in the selection of the Contractor(s) for this acquisition. All evaluation factors, other than cost or price, when combined are significantly more important than cost or price. However, cost/price may become a critical factor in source selection in the event that two or more offerors are determined to be essentially equal following the evaluation of all factors other than cost or price. The Government intends to make an award(s) to that offeror(s) whose proposal provides the best overall value to the Government.

761

****(USE BELOW WHEN PAST PERFORMANCE IS TREATED AS A "STAND ALONE" FACTOR. NOTE THAT PARAMOUNT CONSIDERATION IS GIVEN TO TECHNICAL PROPOSALS, WITH COST/PRICE BEING MORE IMPORTANT THAN PAST PERFORMANCE. IF THIS IS NOT CONSISTENT WITH YOUR REQUIREMENT, CHANGE THE NARRATIVE TO APPROPRIATELY REFLECT THE RELATIONSHIP OF PAST PERFORMANCE TO TECHNICAL AND COST FACTORS.)****

Note: *If the evaluation of Past Performance is waived, it will be necessary to modify the text below. In any event, please carefully review this paragraph and make any changes necessary to assure that the language used accurately reflects the evaluation/award process that you deem necessary for your requirement.*

2. **GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are [significantly more important than cost/price/approximately equal to cost/price/significantly less important than cost or price] . The

Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

762

****(USE BELOW WHEN PAST PERFORMANCE IS A TECHNICAL EVALUATION FACTOR WHICH WILL BE EVALUATED AND SCORED BY GOVERNMENT REVIEWERS ON THE TECHNICAL EVALUATION PANEL.

DO NOT USE IF A PEER REVIEW IS TO BE CONDUCTED.

IN THIS EXAMPLE, TECHNICAL PROPOSALS (INCLUDING PAST PERFORMANCE INFORMATION) ARE MORE IMPORTANT THAN COST/PRICE. IF THIS IS NOT CONSISTENT WITH YOUR REQUIREMENT, CHANGE THE NARRATIVE TO APPROPRIATELY REFLECT THE RELATIONSHIP OF COST TO TECHNICAL FACTORS.)****

Note: *Please carefully review this paragraph and make any changes necessary to assure that the language used accurately reflects the evaluation/award process that you deem necessary for your requirement.*

3. **GENERAL**

The major evaluation factors for this solicitation include technical (which encompasses experience and past performance factors), and cost/price factors. Although technical factors are of paramount consideration in the award of the contract and cost/price is also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are [significantly more important than cost/price/approximately equal to cost/price/significantly less important than cost or price] . The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

763

****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the SOLICITATION. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the SOLICITATION. Offerors must submit information sufficient to evaluate their proposals based on the detailed factors listed below.

764

****(USE BELOW IN ALL SOLICITATIONS.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **Second and Third Paragraphs [within brackets]:** If the contract will contain cost-reimbursement line items (other than Other Direct Costs) remove the brackets and include the two paragraphs within the brackets. Otherwise, remove these paragraphs and this item will consist of only the first paragraph.

4. **COST/PRICE EVALUATION**

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in FAR 15.404.

[Cost Realism: The specific elements of each offeror(s) proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in the offeror(s) technical proposal.

Cost Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal. Cost realism analysis will be conducted in accordance with FAR 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value tradeoff decision.]

765

****(USE BELOW IN ALL SOLICITATIONS THAT WILL RESULT IN THE AWARD OF A MULTI-YEAR CONTRACT.)****

5. **MULTI-YEAR CONTRACT**

The evaluation will consider the offeror's price and ability to perform the first program year as well as the total multi-year requirement to assess whether the contractor's anticipated costs are unbalanced and to ensure that the proposed costs are consistent with the proposed effort across all program years. Within the context of FAR Subpart 17.1, "program year" has the same meaning as "contract year."

If the Government determines before award that only the first contract year requirements are needed, the Government's evaluation of the offeror's price and ability to perform shall consider only the first year.

766

****(USE BELOW FOR ANY MULTI-YEAR CONTRACT THAT WILL BE AWARDED USING A LOW PRICE/TECHNICALLY ACCEPTABLE SELECTION PROCESS.)****

The evaluated price will be determined by comparing the lowest priced proposal for the first program year to the lowest priced proposal for the entire multi-year period of performance. If the lowest priced proposal for the first program year is also the lowest priced proposal for the entire multiyear period of performance, then that proposal is the lowest priced proposal. If the lowest priced proposal for the first program year is not the same as the lowest priced proposal for the entire multiyear period, the lowest priced proposal will be determined by assessing the probability that the contract will continue for the entire multiyear period together with the magnitude of the price difference between the proposals. For example, if the Government determines that it is nearly certain that the contract will continue for the entire multiyear period, the proposal with the lowest price over the entire multiyear period will most probably be considered to be the low priced proposal.

767

****(USE BELOW IN STUDIES THAT WILL INVOLVE HUMAN SUBJECTS.)****

6. **HUMAN SUBJECT EVALUATION**

This research project involves human subjects. NIH Policy requires:

768

****(USE BELOW IN ALL SOLICITATIONS THAT INVOLVE HUMAN SUBJECTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Subparagraph a:** Identify applicable I/C in the text box provided.

a. **Protection of Human Subjects from Research Risks**

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by ___ that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to

this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

769

b. **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm, Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups,

OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged),

OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup)

when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
    - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
    - overriding factors dictate selection of subjects); or
    - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.
- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
    - inclusion of those groups would be inappropriate with respect to their health; or
    - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal.

The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

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c. **Children**

Children (i.e. individuals under the age of 18) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in

accordance with NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

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****(USE BELOW FOR SOLICITATIONS THAT WILL RESULT IN THE CONDUCT OF A CLINICAL TRIAL(S).)****

d. **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers will rely on the Statement of Work and Section L in the solicitation, as well as any further technical evaluation factors in this Section M, as applicable, for the solicitation's specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will consider the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for data and

safety monitoring is still found to be unacceptable, then your proposal may not be considered further for award.

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****(USE BELOW IN SOLICITATIONS FOR HIV ANTIRETROVIRAL TREATMENT TRIALS THAT WILL TAKE PLACE IN WHOLE OR IN PART IN DEVELOPING COUNTRIES - Defined as the Low-and-Middle Income Economies, using WORLD BANK CLASSIFICATIONS.)****

e. **HIV Antiviral Treatment Trials**

The offeror's proposal must address a plan to have host countries authorities and/or other stakeholders identify sources available, if any, to provide antiretroviral treatment to HIV affected populations that have participated in the contract funded HIV antiretroviral treatment trial, OR describe why the offeror believes that there are no such sources available. The information provided must be in accordance with Section L.2.b. Technical Proposal Instructions.

The Project Officer (PO) and/or the Contracting Officer's Representative (COR) will evaluate the documentation provided. While an offeror's documentation of the lack of available sources for antiretroviral treatment will not, of itself, constitute denial of a contract award, priority for contract awards may be given to those offerors who identify sources for the provision of antiretroviral treatment following the completion of the trial.

773

****(USE BELOW FOR R&D SOLICITATIONS INVOLVING LIVE VERTEBRATE ANIMALS [INCLUDING THEIR USE AS A SOURCE OF TISSUES.])****

7. **LIVE VERTEBRATE ANIMALS EVALUATION**

The offerors proposal must include, as a separate section of the Technical Proposal titled "Vertebrate Animal Section," (VAS) a complete, concise (no more than 1-2 pages) description addressing the following criteria. (See NIH Guide Notice NOT-OD-16-006 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html):

a. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
b. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
c. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

d. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

As part of the overall technical evaluation of proposals, the reviewers will consider the acceptability of the offeror's description in the VAS of the technical proposal. The discussion of all criteria will be addressed and evaluated. Based on the evaluation of this Section, the VAS may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the description addressing each of the criteria, or no discussion can be found regarding the VAS), or "acceptable." If the reviewers find that this Section of the technical proposal is "unacceptable" they will provide a narrative supporting their findings.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed description under the VAS is still found to be unacceptable, then your proposal may not be considered further for award.

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****(INCLUDE BELOW WHEN MANDATORY QUALIFICATION CRITERIA ARE NECESSARY.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. The documentation which supports that the qualification criterion has been met MUST be contained in the offerors proposal. The Contracting Officer should decide and indicate below whether the offeror will be required to either put all the qualification information into one area of the proposal or to provide an index in the proposal that will direct reviewers to the specific area of the proposal that addresses a particular mandatory qualification. Additionally, if the mandatory criteria must be met at some time other than at the time of Final Proposal Revisions, the CO should modify the language below.
2. **For Solicitations that include SECTION 508 COMPLIANCE requirements:** See HHSAR 315.304. A solicitation for EIT products and services (including EIT deliverables such as electronic documents and **reports** , unless the EIN products and/or services are incidental the project) shall include a separate technical evaluation factor (which may be in the form of a technical evaluation criterion or a **mandatory qualification criterion (but not both)** , as appropriate) developed by the CO, PO, and OPDIV Section 508 Coordinator to determine vendor compliance with applicable Section 508 accessibility standards. For a list of Section 508 Coordinators see: https://ocio.nih.gov/ITGovPolicy/NIH508/Pages/Section508Coordinators.aspx Section 508 Coordinators at NIH ICs.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **First Paragraph:** Select from the bracketed information, that which best describes the way the Contracting Officer would like to see the qualification information presented in the proposal. Delete the sentence that does not apply.
2. **Second Paragraph:** If it is anticipated that the contract will be awarded WITHOUT discussions, make sure that you select the phrase "Technical Proposals" from the drop-down box.
3. **Text Box:**
   - Include the specific qualification criterion that must be met.
   - When the Contracting Officer determines that **SECTION 508 COMPLIANCE** will be evaluated as a Mandatory Qualification Criterion, the HHS Section 508 Product Assessment Template should be used for evaluation purposes.

8. **MANDATORY QUALIFICATION CRITERIA**

Listed below are mandatory qualification criteria. THE OFFEROR SHALL [INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS TECHNICAL PROPOSAL. / PROVIDE AN INDEX WITHIN ITS TECHNICAL PROPOSAL WHICH DIRECTS THE REVIEWER(S) TO THE SPECIFIC AREA(S) OF THE TECHNICAL PROPOSAL THAT ADDRESS A PARTICULAR MANDATORY QUALIFICATION.]
The qualification criteria establishes conditions that must be met at the time of receipt of [Final Proposal Revisions (FPRs)/Technical Proposals] by the Contracting Officer in order for your proposal to be considered any further for award.

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****(USE BELOW WHEN THE RFP CONTAINS AN OPTION CLAUSE, THE OPTION IS NOT TO EXERCISED AT THE TIME OF AWARD, AND THERE IS A REASONABLE LIKELIHOOD THAT THE OPTION WILL BE EXERCISED.)****

Note: *This item can be modified for use when the resultant contract will be performance based and will include Award Term(s) as the performance incentive as follows: Remove the referenced FAR Clause and all references to the word "Option(s)" and replace with the words "Award Term(s)" and add or modify the language below to be consistent with your requirement.*

9. **EVALUATION OF OPTIONS**

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

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****(USE BELOW FOR SOLICITATIONS INVOLVING RESEARCH AND DEVELOPMENT, INCLUDING SBIR.)****

10. **EVALUATION OF AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES**

If the offeror has proposed the use of key biological and/or chemical resources, the offeror's plan for authentication will be reviewed for adequacy.

Any concerns associated with key biological and/or chemical resource authentication raised during the review process will need to be resolved prior to award.

777

****(USE BELOW WHEN THE RESULTANT CONTRACT WILL GENERATE RESEARCH DATA AND MANAGEMENT AND SHARING OF THAT DATA MUST BE ADDRESSED BY EITHER PROPOSING A DATA MANAGEMENT AND SHARING PLAN OR PROVIDING A JUSTIFICATION FOR NOT SHARING DATA. IN ACCORDANCE WITH "FINAL NIH POLICY FOR DATA MANAGEMENT AND SHARING," NOTICE NOT-OD-21-013 WITH A RELEASE DATE OF 29 OCTOBER 2020 AND AN EFFECTIVE DATE OF 25 JANUARY 2023, INCLUDE THE FOLLOWING IN ALL SOLICITATIONS RELEASED AFTER 01 JULY 2022 WITH AN ORIGINAL PROPOSAL RECEIPT DATE OF 25 JANUARY 2023 OR LATER, AND ANY CONTRACTS RESULTING FROM THESE SOLICITATIONS WITH RESEARCH DATA MANAGEMENT AND GENERATION REQUIREMENTS.)****

Note: *The plan or documentation as to the rationale for not providing a plan shall be evaluated by program staff and shall not be scored. However, weaknesses in a plan or in the rationale for not permitting the sharing of research data may be part of discussions.*

11. **EVALUATION OF DATA MANAGEMENT AND SHARING PLAN OR ANY EXCEPTIONS**

The Offeror's plan for the management and sharing of final research data, or, if data sharing is not possible, the Offeror's documentation of its inability to share research data, with justified limitations or exceptions, shall be assessed for appropriateness, adequacy, and reasonableness.

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****(INCLUDE BELOW WHEN THE CONTRACT WILL GENERATE RESEARCH DATA AND SHARING OF THAT DATA IS REQUIRED. IN ACCORDANCE WITH "FINAL NIH POLICY FOR DATA MANAGEMENT AND SHARING," NOTICE NOT-OD-21-013 WITH A RELEASE DATE OF 29 OCTOBER 2020 AND AN EFFECTIVE DATE OF 25 JANUARY 2023, INCLUDE THE FOLLOWING IN ALL SOLICITATIONS RELEASED AFTER 01 JULY 2022 WITH AN ORIGINAL PROPOSAL RECEIPT DATE OF 25 JANUARY 2023 OR LATER, AND ANY CONTRACTS RESULTING FROM THESE SOLICITATIONS WITH RESEARCH DATA MANAGEMENT AND GENERATION REQUIREMENTS.)****

Note: *The plan shall be evaluated by Program staff and shall not be scored. However, weaknesses in a plan should be part of discussions and shall be resolved before award.*

12. **EVALUATION OF DATA MANAGEMENT AND SHARING PLAN**

An Offeror's plan for the management and sharing of final research data (Data Management and Sharing Plan) shall be assessed for appropriateness, adequacy, and reasonableness.

If an Offeror's proposal does not include a Data Management and Sharing Plan (Plan) or if the Plan in an Offeror's proposal is considered "unacceptable," and the Government includes Offeror's proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), the Offeror will be afforded the opportunity to further discuss, clarify, and/or modify its Plan during discussions and in its Final Proposal Revision (FPR). However, if the Plan is still considered "unacceptable" by the Government after discussions, the Offeror may not be further considered for award.

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****(USE BELOW FOR SOLICITATIONS THAT INVOLVE BIOMEDICAL RESEARCH OF MODEL ORGANISMS.)****

13. **EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH**

The offeror's proposal must address the plans for sharing model organisms, OR state appropriate reasons why such sharing is restricted or not possible. Offerors must also address as part of the sharing plan if, or how, they will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. The discussion areas regarding intellectual property outlined in Section L should be addressed.

If your proposal does not include a plan, appropriate reasons for restricting sharing, or, if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan for sharing model organisms during discussions and in your Final Proposal Revision (FPR). If your plan for sharing model organisms is still considered "unacceptable," or your justification for restricting sharing is still considered inappropriate by the Government after discussions, your proposal may not be considered further for award.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INVOLVING GENOME-WIDE ASSOCIATION STUDIES (GWAS) CONDUCTED ON OR AFTER JANUARY 25, 2008.)****

14. **EVALUATION OF PLAN FOR SUBMISSION OF GENOME-WIDE ASSOCIATION STUDY (GWAS) DATA**

The Offeror's plan for the submission of genome-wide association study (GWAS) data to the NIH-designated GWAS data repository will be assessed for appropriateness and adequacy. Proposals submitted for GWAS in which the data submission expectation cannot be met will be considered for award on a case-by-case basis.

Additional information for GWAS is found at: https://www.genome.gov/about-genomics/fact-sheets/Genome-Wide-Association-Studies-Fact-Sheet and at the NIH/National Human Genome Research Institute website: https://www.genome.gov/.

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****(USE BELOW IF THE USE OF OTHER THAN A SPECIFIED CURRENCY IS PERMITTED IN THE SOLICITATION. THE CO MUST INSERT THE SOURCE OF THE RATE TO BE USED IN THE EVALUATION OF OFFERS.)****

15. **EVALUATION OF FOREIGN CURRENCY OFFERS** , FAR 52.225-17, (FEB 2000).

If the Government receives offers in more than one currency, the Government will evaluate offers by converting the foreign currency to United States currency using [Contracting Officer to insert source of rate] in effect as follows:

a. For acquisitions conducted using sealed bidding procedures, on the date of bid opening.
b. For acquisitions conducted using negotiation procedures.
    1. On the date specified for receipt of offers, if award is based on initial offers; otherwise
    2. On the date specified for receipt of proposal revisions.

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****(INCLUDE BELOW IN ALL SOLICITATIONS.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- **For Solicitations that include SECTION 508 COMPLIANCE requirements:** See HHSAR 315.304. A solicitation for EIT products and services (including EIT deliverables such as electronic documents and reports, unless the EIN products and/or services are incidental the project) shall include a separate technical evaluation factor (which may be in the form of a technical evaluation criterion or a mandatory qualification criterion (but not both), as appropriate) developed by the CO, PO, and OPDIV Section 508 Coordinator to determine vendor compliance with applicable Section 508 accessibility standards. For a list of Section 508 Coordinators see: https://ocio.nih.gov/ITGovPolicy/NIH508/Pages/Section508Coordinators.aspx Section 508 Coordinators at NIH ICs.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Last Sentence:**
    - When unweighted subfactors will be used, select the appropriate evaluation scheme from the drop- down box,
    - When no subfactors will be used, delete the last sentence.

16. **TECHNICAL EVALUATION FACTORS**

The evaluation factors are used by the technical evaluation committee when reviewing the technical proposals. The factors below are listed in the order of relative importance with weights assigned for evaluation purposes. Subfactors are [listed in order of relative importance/considered to be of equal importance] .

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****(USE BELOW FOR SOLICITATIONS INVOLVING RESEARCH AND DEVELOPMENT, INCLUDING SBIR, INCLUDE THE PARAGRAPH ON ROBUST APPROACH AND RELEVANT BIOLOGICAL VARIABLES AS A SUBCRITERION UNDER THE TECHNICAL PLAN/APPROACH CRITERION. THE FIRST SENTENCE REGARDING SCIENTIFIC PREMISE SHOULD BE INCLUDED FOR BROAD AGENCY ANNOUCEMENTS UNLESS SCIENTIFIC PREMISE WAS ADDRESSED DURING CONCEPT REVIEW

For RFPs, Program staff need to determine if the scientific premise has been addressed by the government in formulating the contract requirement(s) or if it should be addressed by the Offerors and evaluated in peer review. THE SUBCRITERION MAY OR MAY NOT BE INDIVIDIAULLY SCORED, AS DEEMED APPROPRIATE BY THE COR AND CO.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- Insert additional variables in the text box below. Delete if this is not needed.

a. **DEMONSTRATION OF A STRONG SCIENTIFIC PREMISE FOR THE TECHNICAL PROPOSAL**

Sufficiency of proposed strategy to ensure a robust and unbiased approach, as appropriate for the work proposed. Adequacy of proposed plan to address relevant biological variables, including sex, [*if deemed necessary by the IC, additional variables may be included here]* for studies in vertebrate animals and/or human subjects.

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****(USE BELOW IN SOLICITATIONS THAT INVOLVE THE DEVELOPMENT, ACQUISITION, MAINTAINANCE, OR USE ELECTRONIC AND INFORMATION TECHNOLOGY (EIT) PRODUCTS AND SERVICES SUBJECT TO SECTION 508 OF THE REHABILITATIONS ACT OF 1973 AS AMENDED, INCLUDING EIT DELIVERABLES SUCH AS ELECTRONIC DOCUMENTS AND REPORTS.)****

Note: *Exceptions to this requirement can be found in FAR 39.204.*

17. **EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY - SECTION 508**

The offeror's proposal must demonstrate compliance with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194 for all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order, including EIT deliverables such as electronic documents and reports.

If your proposal does not include a completed HHS "Section 508 Product Assessment Template" (hereafter referred to as the "Template") which demonstrates that EIT products and services proposed support applicable Section 508 accessibility standards, or, if the completed "Template" included in your proposal is considered "noncompliant," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify the "Template" during discussions and in your Final

Proposal Revision (FPR). If your "Template" is still considered "noncompliant" by the Government after discussions, your proposal may not be considered further for award.

785

****(USE BELOW WHEN PAST PERFORMANCE WILL BE TREATED AS A STAND ALONE FACTOR AND THE EVALUATION OF PAST PERFORMANCE INFORMATION WILL BE CONDUCTED INDEPENDENT OF THE TECHNICAL EVALUATION. THE RATING METHOD PRESENTED HERE IS A POSITIVE-NEGATIVE NUMERICAL SCHEME.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. Make sure that this item is consistent with the first paragraph of this Section M., entitled, GENERAL.
2. **First Paragraph:** Select the appropriate paragraph from the first two, below, when the past performance evaluation will be conducted after the initial technical evaluation. The first should be used when award with discussions is contemplated, the second if award without discussions is expected.

18. **PAST PERFORMANCE FACTOR**

Offerors' past performance information will be evaluated prior to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

OR

Offeror's past performance information will be evaluated subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be the product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers all available and relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the

administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

The following rating method shall be used in the evaluation of past performance information:

+2 **Excellent** - Based on the offeror's performance record, no doubt exists that the offeror will successfully perform the required effort. Sources of information are consistently firm in stating that the offeror's performance was superior and that they would unhesitatingly do business with the offeror again.

+1 **Good** - Based on the offeror's performance record, little doubt exists that the offeror will successfully perform the required effort. Sources of information state that the offeror's performance was good, better than average, etc., and that they would do business with the offeror again.

0 **None** - No past performance history identifiable.

-1 **Marginal** - Based on the offeror's performance record, some doubt exists that the offeror will successfully perform the required effort. Sources of information make unfavorable reports about the offeror's performance and express concern about doing business with the offeror again.

-2 **Poor** - Based on the offeror's performance record, serious doubt exists that the offeror will successfully perform the required effort. Sources of information consistently stated that the offeror's performance was entirely unsatisfactory and that they would not do business with the offeror again.

786

****(USE BELOW WHEN PAST PERFORMANCE IS TREATED AS A STAND ALONE FACTOR AND THE EVALUATION OF PAST PERFORMANCE INFORMATION WILL BE CONDUCTED INDEPENDENT OF THE TECHNICAL EVALUATION. THE GENERAL APPROACH FOR THE EVALUATION IS DESCRIBED, HOWEVER, THE RATING METHOD IS NOT DISCLOSED.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. Make sure that this item is consistent with the first paragraph of this Section M., entitled, GENERAL.
2. **First Paragraph:** Select the appropriate paragraph from the first two, below, when the past performance evaluation will be conducted after the initial technical evaluation. The first should be used when award with discussions is contemplated, the second if award without discussions is expected.

19. **PAST PERFORMANCE FACTOR**

Offerors' past performance information will be evaluated prior to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

OR

Offeror's past performance information will be evaluated subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

787

****(USE BELOW WHEN PAST PERFORMANCE IS TREATED AS A STAND ALONE FACTOR AND PAST PERFORMANCE WILL BE EVALUATED BY GOVERNMENT REVIEWERS AT THE TIME OF PROPOSAL EVALUATION. IN THIS EXAMPLE, PAST PERFORMANCE SUBFACTORS ARE USED.)****

Note: *Use of this example would require that reference checks be completed prior to the technical evaluation.*

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. Make sure that this item is consistent with the first paragraph of this Section M., entitled, GENERAL.
2. Past Performance Subfactors (4th Paragraph). The Contracting Officer/Contract Specialist may choose the "GENERIC" list provided below or may tailor the subfactors to the specific requirement.

20. **PAST PERFORMANCE FACTOR**

The Government will evaluate the offeror's past performance based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.
The Government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of relevant a performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

Listed below are past performance subfactors and the weights to be used for evaluation purposes. If no weights are given, each subfactor shall be given equal weight.

Past Performance Subfactors	Weight
Record of conforming to specifications and to standards of good workmanship.	
Record of forecasting and controlling costs under cost-reimbursement contracts.	
Adherence to contract schedules, including the administrative aspects of performance.	
Reputation for reasonable and cooperative behavior and commitment to customer satisfaction.	
Business-like concern for the interest of the customer.	

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****(USE BELOW WHEN THE CONTRACTING OFFICER ELECTS TO INCLUDE THE SUBCONTRACTING PLAN AS A SCORED EVALUATION FACTOR.)****

Note: *The following paragraph advises offerors about what the Government will be looking for in each subcontracting plan. You will need to provide additional information which advises the offeror about the scoring method that will be utilized for the evaluation.*

21. **SUBCONTRACTING PROGRAM EVALUATION FACTORS**

The offeror's proposed Small Business Subcontracting Plan will be evaluated to determine whether it represents the maximum practicable opportunity for subcontracting. Because the offeror's record of previous performance in carrying out the intent of the subcontracting program will be considered as a significant sub-factor, each offeror is encouraged to submit subcontracting plans and documentation that demonstrates their prior corporate support for small, small disadvantaged, women-owned small, HUBZone small, veteran-owned small, and service-disabled veteran-owned small business suppliers.

If offers are received from both large and small businesses, the small business offerors shall receive the maximum possible number of points for this factor.