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1

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

2

****(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.

3

****(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 Central Contractor Registry (CCR) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at http://www.sam.gov	
11. FOR INFORMATION CALL: _____ PHONE: _____ e-MAIL: _____ COLLECT CALLS WILL NOT BE ACCEPTED.	
	_____ Contracting Officer Office of Acquisitions _____

4

****(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.

7

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

ARTICLE B.3. ESTIMATED COST

The estimated cost of this contract is $ _____ .

8

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

9

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

ARTICLE B.3. 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 NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a

not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

11

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

ARTICLE B.3. 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 $ _____ .

12

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

13

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

ARTICLE B.3. 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 $ _____ .

14

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts

to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

15

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

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- The contract MUST also include ARTICLE B. ESTIMATED COST- INCREMENTALLY FUNDED CONTRACT, HHSAR 352.232-71, which is included as a choice in this SECTION B.)****

ARTICLE B.4. 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.

16

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

17

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

Note: *If this contract will be incrementally funded, the contract MUST also include ARTICLE B. ESTIMATED COST- INCREMENTALLY FUNDED CONTRACT, HHSAR 352.232-71, which is included as a choice in this SECTION B .*

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)]			

18

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

19

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

Note: *If this contract will be incrementally funded, the contract MUST also include ARTICLE B. ESTIMATED COST- INCREMENTALLY FUNDED CONTRACT, HHSAR 352.232-71, which is included as a choice in this SECTION B .*

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)]			

20

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

21

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

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. If this contract will be incrementally funded, the contract MUST also include ARTICLE B.. ESTIMATED COST- INCREMENTALLY FUNDED CONTRACT, HHSAR 352.232-71, which is included as a choice in this SECTION B.
2. 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:

1. **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.a for RFPs.
2. **Subparagraph b (Table):** Include all evaluation periods and associated available award fee for the life of the contract.
3. **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.

22

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

23

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

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. If this contract will be incrementally funded, the contract MUST also include ARTICLE B.. ESTIMATED COST- INCREMENTALLY FUNDED CONTRACT, HHSAR 352.232-71, which is included as a choice in this SECTION B.
2. 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:

1. **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.a for RFPs.
2. **Subparagraph b.1 (CONTRACTS ONLY):** List all evaluation periods separately with applicable Award Fee Amounts for the Base Period Only.
3. **Subparagraph b.2 (CONTRACTS ONLY):** List all options and indicate the evaluation periods and associated available award fee for each option.
4. **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.

24

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

25

****(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, HHSAR 352.232-71 (July 2013)

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.

(End of Clause)

26

**** (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.]

27

****(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:

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

Program Year	Estimated Cost ($)	Fixed Fee ($)	Estimated Cost Plus Fixed Fee ($)
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.

28

****(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.

29

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

30

****(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.

31

****(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.

32

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

33

****(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]*

34

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

35

****(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

36

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR FIXED-PRICE CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor shall be paid by the National Library of Medicine (NLM) in an amount of $ _____ . The Contractor shall be paid by the National Technical Information Service (NTIS) in an amount of $ _____ NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

37

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

38

****(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.

39

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR FIXED-PRICE CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor shall be paid by the National Library of Medicine (NLM) in an amount of $ _____ . The Contractor shall be paid by the National Technical Information Service (NTIS) in an amount of $ _____ NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

40

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

41

****(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.

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**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR FIXED-PRICE CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor shall be paid by the National Library of Medicine (NLM) in an amount of $ _____ . The Contractor shall be paid by the National Technical Information Service (NTIS) in an amount of $ _____ NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

43

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

44

****(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.

45

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR FIXED-PRICE CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor shall be paid by the National Library of Medicine (NLM) in an amount of $ _____ . The Contractor shall be paid by the National Technical Information Service (NTIS) in an amount of $ _____ NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

46

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR COST-REIMBURSEMENT CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor will be reimbursed by the National Library of Medicine (NLM) a not to exceed amount of $ _____ . The Contractor will be reimbursed by the National Technical Information Service (NTIS) a not to exceed amount of $ _____ . NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

47

****(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.

48

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR FIXED-PRICE CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor shall be paid by the National Library of Medicine (NLM) in an amount of $ _____ . The Contractor shall be paid by the National Technical Information Service (NTIS) in an amount of $ _____ NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

49

****(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 ($)

50

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR FIXED-PRICE CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor shall be paid by the National Library of Medicine (NLM) in an amount of $ _____ . The Contractor shall be paid by the National Technical Information Service (NTIS) in an amount of $ _____ NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

51

****(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 ($)

52

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR FIXED-PRICE CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor shall be paid by the National Library of Medicine (NLM) in an amount of $ _____ . The Contractor shall be paid by the National Technical Information Service (NTIS) in an amount of $ _____ NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

53

****(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

54

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR FIXED-PRICE CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor shall be paid by the National Library of Medicine (NLM) in an amount of $ _____ . The Contractor shall be paid by the National Technical Information Service (NTIS) in an amount of $ _____ NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

55

****(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.

56

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR FIXED-PRICE CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor shall be paid by the National Library of Medicine (NLM) in an amount of $ _____ . The Contractor shall be paid by the National Technical Information Service (NTIS) in an amount of $ _____ NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

57

****(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 & 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

58

**** (USE BELOW, FOR NLM: USE THE FOLLOWING PARAGRAPH FOR FIXED-PRICE CONTRACTS, WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

The Contractor shall be paid by the National Library of Medicine (NLM) in an amount of $ _____ . The Contractor shall be paid by the National Technical Information Service (NTIS) in an amount of $ _____ NLM is not responsible for payment to the Contractor of amounts to be paid by NTIS. Under Interagency Agreement No. _____ , NTIS has agreed to make the payments identified in this contract.

59

****(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.

60

****(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.

61

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

62

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

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

63

****(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).

64

****(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's Representative (COR).

65

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

ARTICLE C.2. REPORTING REQUIREMENTS

66

****(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 required herein shall be submitted in electronic format. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

All electronic reports submitted 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: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

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).

67

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

a. **Technical Progress Reports**

68

****(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).)****

1. 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)

69

**** (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.)****

2. **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.

70

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

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

1. **First Paragraph:** For studies funded with **ARRA Funds** , add the following (or similar) language as the second sentence:
   - **"A separate "Inclusion Enrollment Report" shall be completed for each clinical research protocol funded with ARRA funds."**
2. **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.)****

3. **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 for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "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.

[**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:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, 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 and race/ethnicity.

71

**** (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.) ****

4. **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 (http://www.selectagents.gov/Regulations.html) or listed on the U.S. National Select Agents Registry restricted experiments website (http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Restricted%20Experiments.html);
    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.

72

****(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.)****

b. **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.

73

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

c. **Other Reports/Deliverables**

74

****(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: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45 . See Part 94.5, Management and reporting of financial conflicts of interest for complete information on reporting requirements.

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

75

****(USE BELOW WHEN THE CONTRACT WILL BE FUNDED IN WHOLE OR IN PART WITH RECOVERY ACT FUNDS.)****

2. **American Recovery and Reinvestment Act-Reporting Requirements**

This contract requires the Contractor to provide products and/or services that are funded by the American Recovery and Reinvestment Act of 2009 (Recovery Act). Section 1512(c) of the Recovery Act requires the contractor to report on its use of Recovery Act funds under this contract.

The Contractor shall report the information required by FAR 52.204-11(d), which is incorporated into Article I.4. of this contract, using the online reporting tool available at http://www.FederalReporting.gov .

All work funded, in whole or in part, by the Recovery Act, and for which an invoice is submitted prior to September 30, 2009, shall be reported cumulatively and submitted

on October 10, 2009. After September 30, 2009, reports are due no later than the 10th day after the end of each calendar quarter.

These reports will be made available to the public.

76

****(NCI OA: USE ITEM BELOW FOR ALL AWARDS USING ARRA FUNDING. ***Note:*** *For completion contracts, make sure to include this report in the applicable "Deliveries" Article in Section F of the contract* .)****

In addition, the Contractor shall submit a courtesy copy of each report to the Contracting Officer and Contracting Officer's Representative (COR).

77

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

3. **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 http://www.sam.gov , 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** .

78

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

4. **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.

79

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE THE INFORMATION AND PHYSICAL ACCESS SECURITY ARTICLE IN SECTION H OF THE CONTRACT.)****

5. **Information Security and Physical Access Reporting Requirements**

The Contractor shall submit the following reports as required by the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract. Note: Each report listed below includes a reference to the appropriate subparagraph of this article.

80

****(USE IN ALL SOLICITATIONS AND CONTRACTS THAT INCLUDE THE INFORMATION AND PHYSICAL ACCESS SECURITY ARTICLE IN SECTION H OF THE CONTRACT.)****

a. **Roster of Employees Requiring Suitability Investigations**

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. (Reference subparagraph A.e. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

81

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

b. **IT Security Plan (IT-SP)**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the contractor shall submit the IT-SP within thirty (30) days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.

The Contractor shall review and update the IT-SP in accordance with NIST SP 800-53A, Guide for Assessing the Security Controls in Federal Information Systems and Organizations, on an annual basis.

(Reference subparagraph D.c.1. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

82

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

c. **IT Risk Assessment (IT-RA)**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the contractor shall submit the IT-RA within thirty (30) days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or

augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy.

The Contractor shall update the IT-RA on an annual basis.

(Reference subparagraph D.c.2. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

83

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

d. **FIPS 199 Assessment**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the Contractor shall submit a FIPS 199 Assessment within thirty (30) days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard.

(Reference subparagraph D.c.3. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECITON H of this contract.

84

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE CONTRACTOR DEVELOPMENT, MAINTENANCE, AND ACCESS TO FEDERAL INFORMATION SYSTEM(S).)****

e. **IT Security Certification and Accreditation (IT-SC&A)**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, the Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed within three (3) months after contract award.

The Contractor shall perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid.

(Reference subparagraph D.c.4. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

85

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT INCLUDE THE INFORMATION AND PHYSICAL ACCESS SECURITY ARTICLE IN SECTION H OF THE CONTRACT.)****

f. **Reporting of New and Departing Employees**

The Contractor shall notify the Contracting Officer's Representative (COR) and Contracting Officer within five working days of staffing changes for positions that require suitability determinations as follows:

1. **New Employees who have or will have access to HHS Information systems or data:** Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position,

provide a description of the position and the Government will determine the appropriate security level.

2. **Departing Employees:** 1) Provide the name, position title, and security clearance level held by or pending for the individual; and 2) Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the COR and/or Contracting Officer upon request.

(Reference subparagraph E.2.a-c. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

86

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT INCLUDE THE INFORMATION AND PHYSICAL ACCESS SECURITY ARTICLE IN SECTION H OF THE CONTRACT.)****

g. **Contractor - Employee Non-Disclosure Agreement(s)** The contractor shall complete and submit a signed and witnessed "Commitment to Protect Non-Public Information - Contractor Agreement" form for each contractor and subcontractor employee who may have access to non-public Department information under this contract. This form is located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf .

(Reference subparagraph E.3.d. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

87

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN THE CONTRACTOR WILL HOST NIH WEB PAGES OR DATABASES.)****

h. **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 separate cover on a monthly basis.

(Reference subparagraph E.5. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

88

****(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.)****

6. **Section 508 Annual Report**

The contractor shall submit an annual Section 508 report in accordance with the schedule set forth in the ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY Article in SECTION H of this contract. The Section 508 Report Template and Instructions for completing the report are available at: http://www.hhs.gov/web/508/contracting/technology/vendors.html under "Vendor Information and Documents."

89

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

7. **Multiple Principal Investigators Leadership Plan**

The Contractor shall 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.

90

****(NHLBI: USE BELOW FOR CONTRACTS THAT INCLUDE THE NHLBI Data Repository of Epidemiology and Clinical Trials CLAUSE IN SECTION H.)****

8. **NHLBI Data Repository of Epidemiology and Clinical Trials**

The Contractor shall 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://biolincc.nhlbi.nih.gov/home/ .

91

****(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:**
   - 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.
   - 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 encouraged 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.

92

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

SECTION D - PACKAGING, MARKING AND SHIPPING

93

****(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.

94

****(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

_____

95

ARTICLE D.2. MARKING

_____

96

ARTICLE D.3. SHIPPING

_____

97

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

SECTION E - INSPECTION AND ACCEPTANCE

98

****(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 & 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:

_____
_____
_____
_____
_____
_____
_____
_____

99

****(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.

100

****(PROVIDING THE TERMS FOR ACCEPTANCE IS MANDATORY . USE BELOW WHEN A 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).

101

****(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.

102

****(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).

103

****(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).

104

****(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).

105

****(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).

106

****(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).

107

****(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.

108

****(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).

109

****(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.

110

****(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).

111

****(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).

112

****(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).

113

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

SECTION F - DELIVERIES OR PERFORMANCE

114

****(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 _____ .

115

****(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

116

****(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

117

****(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. 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.

118

****(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] .

119

****(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

120

****(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

121

****(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

122

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							

123

****(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.

124

****(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.

125

****(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.9. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 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: http://www.acquisition.gov/far .

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.

126

****(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).

127

****(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]."

128

****(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).

129

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

SECTION G - CONTRACT ADMINISTRATION DATA

130

****(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's 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'S REPRESENTATIVE (COR)

The following Contracting Officer's 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.

131

****(USE BELOW FOR ALL SOLICITATIONS AND CONTRACTS THAT INCLUDE MULTIPLE PRINCIPAL INVESTIGATORS, OR OTHER CONTRACTS AS NECESSARY AND APPROPRIATE.

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 352.242-70 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

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

Name	Title

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****(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's 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.

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****(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 issued over $3,000 unless the following exception(s) apply:
      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 $3,000 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 Million, in accordance with 16.505(b)(1)(iii); and,
   iii. For orders exceeding $5 Million, in accordance with FAR 16.505(b)(1)(iv).

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****(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 over $3,000 unless the following exception(s) apply:
   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 $3,000 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 Million, in accordance with 16.505(b)(1)(iii); and,
   iii. For orders exceeding $5 Million, in accordance with FAR 16.505(b)(1)(iv).

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****(USE BELOW, FOR "PAYBACK" CONTRACTS.) ****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ARTICLE:

- **Subparagraphs a, b, and c:** Insert description of materials, e.g., animals, drugs, tissues, etc., being provided for reimbursement in the appropriate spaces, below.
- **Subparagraphs b and c:** Insert the applicable I/C in the spaces provided.
- **Subparagraphs b & d:** make sure that the Price List AND the 'Monthly Summary Sheet of Sales' are included in SECTION J and attached to the contract.)****

ARTICLE G.6. RECIPIENTS REIMBURSEMENT PROCEDURES

a. During the course of this contract, the Contracting Officer or his duly designated representative will notify the Contractor to make certain shipments of _____ directly to specified U.S. Government Recipients, Contractors, Government Agencies, or other private organizations and the Contractor shall make such shipments as directed.
b. The Contractor shall bill recipients directly for the _____ provided. The charges for these _____ shall be based upon the current _____ price list for the items listed in an Attachment in SECTION J, of this contract. Under no circumstances shall the Contractor bill prices other than those listed in the referenced price list. Prices listed are subject to change. Revised price lists will be issued by the Government when appropriate without the concurrence of the Contractor.
c. The Contractor shall keep an accurate account of all payments received from recipients of _____ separate from other fiscal aspects of the contract. The Contractor shall record as credits on monthly invoices to the Government, all payments received from the Government Grantees, Contractors, Government Agencies, or other private organizations. The income from recipients must be credited to the Government in the billing period actually received. Thus, the Contractor shall bill the Government directly for payment of contract costs and shall subtract as a credit all payments received from recipients. The actual collections from sales shall be offset against the gross billing, leaving a net amount due on the invoice.

   The _____ Contracting Officer's Representative (COR) may direct from time to time that shipments be made entirely at Government expense.

d. The Contractor shall account for the contract related income separately in accordance with its own double entry accounting system. The Contractor shall submit to the Government a Monthly Summary Sheet of Sales, which is listed as an Attachment in SECTION J of this contract. The Contractor shall submit a copy of this Attachment each month with the Monthly Progress Report.

   The administration of the contract related income shall be subject to the terms of this contract, including specifically and without limitation, FAR Clause 52.215-2, Audit and Records--Negotiation, of the General Clauses (including applicable Alternates), and the applicable cost principles of the Federal Acquisition Regulation.

e. The Contractor shall use the following procedures for collection of delinquent accounts:

   Step 1 - Accounts 30 days past due. A copy of the invoice shall be sent to the recipient with a notation that the account is overdue and request payment.

   Step 2 - Accounts 60 days past due. The Contractor shall turn the account over to a collection agency.

f. When the completion (final) invoice is submitted on this contract, a listing of all outstanding recipient invoices shall be provided along with details as to what disposition is expected on each.

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

ARTICLE G.7. 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 15.8. Should a proposal cost exceed $700,000 for a change, certified cost or pricing data should be submitted on SF1411 in a format which satisfies the requirements of FAR 15.804-6. 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.

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****(USE BELOW, FOR COST-REIMBURSEMENT SOLICITATIONS AND CONTRACTS WHICH ARE NOT PAID UNDER LETTER OF CREDIT.

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.8. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

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****(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.

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

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **Subparagraph b:** Complete the address for the invoice approving official.) ****

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**
   a. The original invoice shall be submitted to the following **designated billing office** :
   National Institutes of Health
   Office of Financial Management
   Commercial Accounts
   2115 East Jefferson Street, Room 4B-432, MSC 8500
   Bethesda, MD 20892-8500

b. One copy of the invoice shall be submitted to the following **approving official** :

Contracting Officer
Office of Acquisitions
_____
_____ Room __
_____ MSC __
_____ - __

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****(DESELECT THIS ITEM IF A PAPER COPY OF THE INVOICE IS REQUESTED BY THE APPROVING OFFICIAL. INCLUDE ONE OR BOTH OF THE PARAGRAPHS BELOW:
ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. **First paragraph:** Insert the Contracting Officer's email address (Delete this paragraph if not needed).
2. **Second Paragraph:** Insert the Central Point of Distribution (CPD) email box for receipt of two-way match invoices from the Contractor. (Delete this paragraph if not needed.)****

E-mail:
The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. ***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

Central Point of Distribution:
The Contractor shall submit an electronic copy of the payment request to the Central Point of Distribution mailbox. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. ***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

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

ADDITIONAL INSTRUCTIONS FOR COMPLETING THIS ITEM:

- Select the appropriate Central Point of Distribution.)****

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

   a. The original invoice shall be submitted to the following designated billing office:
   National Institutes of Health
   Office of Financial Management
   Commercial Accounts
   2115 East Jefferson Street, Room 4B-432, MSC 8500
   Bethesda, MD 20892-8500

   b. One courtesy copy of the original invoice shall be submitted electronically as follows:
      1. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.
      2. **Save** the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "Ash Stevens_Invoice 123456") [Note: Please do not use special characters such as (#, $, %,*, &, !) when saving your attachment. Only the underscore symbol (_) is permitted.]
      3. **Transmit** the saved single attachment via e-mail to the appropriate branch's Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is [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] . Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number_ Contract Title_ Contractor's Name_ unique Invoice number

         (e.g, HHSN2612XXXXXC_Clinical Genetics Support_Ash Stevens_Invoice 12345) **[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office listed in subparagraph a, above, to meet the requirements of a "proper invoice." Also, The Contractor must certify on the payment request that the electronic**

courtesy copy is a duplicate of the original invoice mailed to NIH's Office of Financial Management.]

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**
    a. The original invoice shall be submitted to the following designated billing office:
    National Institutes of Health
    Office of Financial Management
    Commercial Accounts
    2115 East Jefferson Street, Room 4B-432, MSC 8500
    Bethesda, MD 20892-8500

    b. One copy shall be sent via e-mail as set forth below:
        i. Please scan your invoice along with the necessary backup documentation (not to exceed 30MB) as one single attachment.
        ii. Save your invoice attachment in the following format: YourVendorName_Invoice number (e.g., if your Vendor name is AE Construction Inc. and you are submitting Invoice 123456, Save your invoice attachment as 'AE Construction, Invoice 123456')
        Note: Please do not use special characters such as (#,$%*&!) when saving your attachment.
        iii. Send an email with your invoice attached (invoice and all supporting backup as one attachment) to our invoice processing email distribution mailbox: ORFOAInvoice3Way@mail.nih.gov . In the subject line of your email, please use the same format 'YourVendorName, Invoice number'. (e.g., AE Construction, Invoice 12345)
        iv. You will receive an automated email reply confirming that our Invoice processing received your invoice 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 . Only resend an invoice if you have not received an email confirmation within 24 hours. If you have any questions or concerns please call the Intake Center at 301-402-0878.

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****(USE BELOW IN ALL SOLICITATIONS & 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, DUNS, or VIN, contact the Contracting Officer.
   c. DUNS or DUNS+4 Number. The DUNS 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 DUNS 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, DUNS, 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

144

****(NCI OA Only: USE BELOW IN ALL SOLICITATIONS & 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 .)****

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, DUNS, or VIN, contact the Contracting Officer.
   c. DUNS or DUNS+4 Number. The DUNS 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 DUNS 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, DUNS, 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

145

****(USE BELOW IN ALL RFPs & 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].

146

**** (FOR NLM USE: INCLUDE THE FOLLOWING SUBPARAGRAPH (3) WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

c. Invoice Payment -- NTIS Processed Invoices

Invoices/Financing Requests shall refer to the Interagency Agreement No. _____ between NLM and NTIS. NLM will verify each invoice/financing request and forward it to NTIS which will be responsible for paying the Contractor based on the verified invoice submitted to NTIS by NLM. Inquiries regarding payment of invoices by NTIS should be directed to the Contracting Officer's Representative.

Payments under this contract will be due on the **twenty-ninth** calendar day (**thirtieth** calendar day for a completion or final invoice) after the Contracting Officer approves the invoice for payment.

For purposes of determining the due date for payment, and for no other purpose, approval by the Contracting Officer will be deemed to occur on the **sixteenth** calendar day (**thirtieth** calendar day for completion or final invoice) after the later of:

a. The date of actual receipt of a proper invoice, or
b. The date the supplies, services, technical or other reports are accepted by the Government.

If the supplies, services, technical or other reports are rejected for failure to conform to the technical requirements of the contract, or for damage in transit or otherwise, the provisions in paragraph (b) above will apply to the new delivery of replacement supplies and resubmission of a proper invoice.

The date of the check issued in payment or the date of payment by wire transfer through the Treasury Financial Communications System will be considered to be the date payment is made.

Invoices shall not be submitted more frequently than once per month.

147

**** (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.) ****

d. 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."

148

****(USE BELOW, WHEN THE CONTRACT WILL BE FUNDED UNDER A LETTER OF CREDIT-See FAR 32.406.)****

ARTICLE G.9. LETTER OF CREDIT PAYMENT INFORMATION

149

a. Advance payments will be provided under Letter of Credit Number _____ in accordance with FAR 32.406 Letters of Credit, Part 6, Chapter 2000 of the Treasury Financial Manual, and Department of Treasury Circular 1075 (31 CFR Part 205, http://www.access.gpo.gov/nara/cfr/waisidx_00/31cfr205_00.html).

The Contractor shall withdraw cash only when needed for disbursements and report cash disbursements and balances in accordance with the CONTRACT FINANCIAL REPORT ARTICLE in SECTION G of this contract. The Contractor shall impose the same standards of timing and amount upon any subcontractors, including the furnishing of reports of cash disbursements and balances. Failure to adhere to these provisions may cause the Government to withhold further withdrawals under Letter of Credit.

150

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS UNDER LETTER OF CREDIT.)****

b. Inquiries regarding advance payments shall be directed to the following office:

Division of Payment Management
11400 Rockville Pike
Rockwall Building #1, Suite 700
Rockville, MD 20852
(http://www.dpm.psc.gov/ under Contacts)

151

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS UNDER LETTER OF CREDIT.)****

c. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract for submission of the completion and/or final invoice(s). 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. Payment requests for the Completion and/or Final Invoice shall be submitted as follows:

152

**** (USE BELOW IN ALL SOLICITATIONS & CONTRACTS. EXCEPT NCI OA AND ORF.
ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **Subparagraph b:** Complete the address for the invoice approving official.) ****

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

   a. The original invoice shall be submitted to the following **designated billing office** :
   National Institutes of Health
   Office of Financial Management
   Commercial Accounts
   2115 East Jefferson Street, Room 4B-432, MSC 8500
   Bethesda, MD 20892-8500

   b. One copy of the invoice shall be submitted to the following **approving official** :
   Contracting Officer
   Office of Acquisitions
   _____
   _____ Room __
   _____ MSC __
   _____ - __

153

****(DESELECT THIS ITEM IF A PAPER COPY OF THE INVOICE IS REQUESTED BY THE APPROVING OFFICIAL. INCLUDE ONE OR BOTH OF THE PARAGRAPHS BELOW:

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. **First paragraph:** Insert the Contracting Officer's email address (Delete this paragraph if not needed).
2. **Second Paragraph:** Insert the Central Point of Distribution (CPD) email box for receipt of two-way match invoices from the Contractor. (Delete this paragraph if not needed.)****

E-mail:

The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. ***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

Central Point of Distribution:

The Contractor shall submit an electronic copy of the payment request to the Central Point of Distribution mailbox. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. ***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

154

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

ADDITIONAL INSTRUCTIONS FOR COMPLETING THIS ITEM:

- Select the appropriate Central Point of Distribution.)****

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

    a. The original invoice shall be submitted to the following designated billing office:
    National Institutes of Health
    Office of Financial Management
    Commercial Accounts
    2115 East Jefferson Street, Room 4B-432, MSC 8500
    Bethesda, MD 20892-8500

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

1. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.
2. **Save** the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "Ash Stevens_Invoice 123456") [Note: Please do not use special characters such as (#, $, %,*, &, !) when saving your attachment. Only the underscore symbol (_) is permitted.]
3. **Transmit** the saved single attachment via e-mail to the appropriate branch's Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is [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] . Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number_ Contract Title_ Contractor's Name_ unique Invoice number

   (e.g, HHSN2612XXXXXC_Clinical Genetics Support_Ash Stevens_Invoice 12345) **[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office listed in subparagraph a, above, to meet the requirements of a "proper invoice." Also, The Contractor must certify on the payment request that the electronic courtesy copy is a duplicate of the original invoice mailed to NIH's Office of Financial Management.]**

155

****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

   a. The original invoice shall be submitted to the following designated billing office:
   National Institutes of Health
   Office of Financial Management
   Commercial Accounts
   2115 East Jefferson Street, Room 4B-432, MSC 8500
   Bethesda, MD 20892-8500

b. One copy shall be sent via e-mail as set forth below:
    i. Please scan your invoice along with the necessary backup documentation (not to exceed 30MB) as one single attachment.
    ii. Save your invoice attachment in the following format: YourVendorName_Invoice number (e.g., if your Vendor name is AE Construction Inc. and you are submitting Invoice 123456, Save your invoice attachment as 'AE Construction, Invoice 123456')
    Note: Please do not use special characters such as (#,$%*&!) when saving your attachment.
    iii. Send an email with your invoice attached (invoice and all supporting backup as one attachment) to our invoice processing email distribution mailbox: ORFOAInvoice3Way@mail.nih.gov . In the subject line of your email, please use the same format 'YourVendorName, Invoice number'. (e.g., AE Construction, Invoice 12345)
    iv. You will receive an automated email reply confirming that our Invoice processing received your invoice 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 . Only resend an invoice if you have not received an email confirmation within 24 hours. If you have any questions or concerns please call the Intake Center at 301-402-0878.

156

****(USE BELOW IN ALL SOLICITATIONS & 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, DUNS, or VIN, contact the Contracting Officer.
   c. DUNS or DUNS+4 Number. The DUNS 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 DUNS 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, DUNS, 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

157

****(NCI OA Only: USE BELOW IN ALL SOLICITATIONS & 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 .)****

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, DUNS, or VIN, contact the Contracting Officer.
   c. DUNS or DUNS+4 Number. The DUNS 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 DUNS 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, DUNS, 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

158

****(USE BELOW IN ALL RFPs & 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.)
****

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

159

**** (FOR NLM USE: INCLUDE THE FOLLOWING SUBPARAGRAPH (3) WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

e. Invoice Payment -- NTIS Processed Invoices

Invoices/Financing Requests shall refer to the Interagency Agreement No. _____ between NLM and NTIS. NLM will verify each invoice/financing request and forward it to NTIS which will be responsible for paying the Contractor based on the verified invoice submitted to NTIS by NLM. Inquiries regarding payment of invoices by NTIS should be directed to the Contracting Officer's Representative.
Payments under this contract will be due on the **twenty-ninth** calendar day (**thirtieth** calendar day for a completion or final invoice) after the Contracting Officer approves the invoice for payment.

For purposes of determining the due date for payment, and for no other purpose, approval by the Contracting Officer will be deemed to occur on the **sixteenth** calendar day (**thirtieth** calendar day for completion or final invoice) after the later of:

a. The date of actual receipt of a proper invoice, or
b. The date the supplies, services, technical or other reports are accepted by the Government.

If the supplies, services, technical or other reports are rejected for failure to conform to the technical requirements of the contract, or for damage in transit or otherwise, the provisions in

paragraph (b) above will apply to the new delivery of replacement supplies and resubmission of a proper invoice.

The date of the check issued in payment or the date of payment by wire transfer through the Treasury Financial Communications System will be considered to be the date payment is made.

Invoices shall not be submitted more frequently than once per month.

160

**** (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.) ****

f. 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."

161

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

ARTICLE G.10. INVOICE SUBMISSION

162

****(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.

163

**** (USE BELOW IN ALL SOLICITATIONS & CONTRACTS. EXCEPT NCI OA AND ORF.
ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **Subparagraph b:** Complete the address for the invoice approving official.) ****

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

    a. The original invoice shall be submitted to the following **designated billing office** :
    National Institutes of Health
    Office of Financial Management
    Commercial Accounts

2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

b. One copy of the invoice shall be submitted to the following **approving official**:
Contracting Officer
Office of Acquisitions
_____
_____ Room __
_____ MSC __
_____ - __

164

****(DESELECT THIS ITEM IF A PAPER COPY OF THE INVOICE IS REQUESTED BY THE APPROVING OFFICIAL. INCLUDE ONE OR BOTH OF THE PARAGRAPHS BELOW:
ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. **First paragraph:** Insert the Contracting Officer's email address (Delete this paragraph if not needed).
2. **Second Paragraph:** Insert the Central Point of Distribution (CPD) email box for receipt of two-way match invoices from the Contractor. (Delete this paragraph if not needed.)****

E-mail:
The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. ***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

Central Point of Distribution:
The Contractor shall submit an electronic copy of the payment request to the Central Point of Distribution mailbox. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. ***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

165

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

ADDITIONAL INSTRUCTIONS FOR COMPLETING THIS ITEM:

- Select the appropriate Central Point of Distribution.)****

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**
    a. The original invoice shall be submitted to the following designated billing office:
    National Institutes of Health
    Office of Financial Management
    Commercial Accounts
    2115 East Jefferson Street, Room 4B-432, MSC 8500
    Bethesda, MD 20892-8500

    b. One courtesy copy of the original invoice shall be submitted electronically as follows:
        1. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.
        2. **Save** the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "Ash Stevens_Invoice 123456") [Note: Please do not use special characters such as (#, $, %,*, &, !) when saving your attachment. Only the underscore symbol (_) is permitted.]
        3. **Transmit** the saved single attachment via e-mail to the appropriate branch's Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is [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] . Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number_ Contract Title_ Contractor's Name_ unique Invoice number

        (e.g, HHSN2612XXXXXC_Clinical Genetics Support_Ash Stevens_Invoice 12345) **[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office listed in subparagraph a, above, to meet the requirements of a "proper invoice." Also, The Contractor must certify on the payment request that the electronic courtesy copy is a duplicate of the original invoice mailed to NIH's Office of Financial Management.]**

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

    a. The original invoice shall be submitted to the following designated billing office:
    National Institutes of Health
    Office of Financial Management
    Commercial Accounts
    2115 East Jefferson Street, Room 4B-432, MSC 8500
    Bethesda, MD 20892-8500

    b. One copy shall be sent via e-mail as set forth below:
        i. Please scan your invoice along with the necessary backup documentation (not to exceed 30MB) as one single attachment.
        ii. Save your invoice attachment in the following format: YourVendorName_Invoice number (e.g., if your Vendor name is AE Construction Inc. and you are submitting Invoice 123456, Save your invoice attachment as 'AE Construction, Invoice 123456')
        Note: Please do not use special characters such as (#,$%*&!) when saving your attachment.
        iii. Send an email with your invoice attached (invoice and all supporting backup as one attachment) to our invoice processing email distribution mailbox: ORFOAInvoice3Way@mail.nih.gov . In the subject line of your email, please use the same format 'YourVendorName, Invoice number'. (e.g., AE Construction, Invoice 12345)
        iv. You will receive an automated email reply confirming that our Invoice processing received your invoice 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 . Only resend an invoice if you have not received an email confirmation within 24 hours. If you have any questions or concerns please call the Intake Center at 301-402-0878.

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****(USE BELOW IN ALL SOLICITATIONS & 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, DUNS, or VIN, contact the Contracting Officer.
   c. DUNS or DUNS+4 Number. The DUNS 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 DUNS 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, DUNS, 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 & 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 .)****

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, DUNS, or VIN, contact the Contracting Officer.
   c. DUNS or DUNS+4 Number. The DUNS 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 DUNS 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, DUNS, 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 & 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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**** (FOR NLM USE: INCLUDE THE FOLLOWING SUBPARAGRAPH (3) WHEN NTIS FUNDING, EITHER PARTIAL OR FULL, IS INVOLVED. NOTE: Call the NLM Budget Office for the current Interagency Agreement Number.) ****

c. Invoice Payment -- NTIS Processed Invoices

Invoices/Financing Requests shall refer to the Interagency Agreement No. _____ between NLM and NTIS. NLM will verify each invoice/financing request and forward it to NTIS which will be responsible for paying the Contractor based on the verified invoice submitted to NTIS by NLM. Inquiries regarding payment of invoices by NTIS should be directed to the Contracting Officer's Representative.
Payments under this contract will be due on the **twenty-ninth** calendar day (thirtieth calendar day for a completion or final invoice) after the Contracting Officer approves the invoice for payment.

For purposes of determining the due date for payment, and for no other purpose, approval by the Contracting Officer will be deemed to occur on the **sixteenth** calendar day (thirtieth calendar day for completion or final invoice) after the later of:

a. The date of actual receipt of a proper invoice, or
b. The date the supplies, services, technical or other reports are accepted by the Government.

If the supplies, services, technical or other reports are rejected for failure to conform to the technical requirements of the contract, or for damage in transit or otherwise, the provisions in paragraph (b) above will apply to the new delivery of replacement supplies and resubmission of a proper invoice.

The date of the check issued in payment or the date of payment by wire transfer through the Treasury Financial Communications System will be considered to be the date payment is made.

Invoices shall not be submitted more frequently than once per month.

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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.) ****

d. 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, FOR COST-REIMBURSEMENT CONTRACTS PAID UNDER LETTER OF CREDIT OR 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.11. 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.12. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

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 & Address of the cognizant audit agency, below, if it is NOT DFAS.)****

ARTICLE G.13. 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.

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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," which can be found at:
http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q_HHS Contracting Guide.pdf .

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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.15. 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 $650,000 OR MORE. USE OF THIS ARTICLE IN CONSTRUCTION SOLICITATIONS AND CONTRACTS BELOW $650,000 IS OPTIONAL.
- **FOR ARCHITECT-ENGINEER SERVICES:** INCLUDE IN SOLICITATIONS AND CONTRACTS OF $30,000 OR MORE. USE OF THIS ARTICLE IN A&E SOLICITATIONS AND CONTRACTS BELOW $30,000 IS OPTIONAL.

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.16. 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:

http://www.cpars.gov

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****(INCLUDEBELOW IN ALL SOLICITATIONS AND CONTRACTS.)****

SECTION H - SPECIAL CONTRACT REQUIREMENTS

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

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (January 2006)

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 Assurance of Compliance 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. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. 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 imputing liability on the part of the Government for the acts of the Contractor or its employees.
c. If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that 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, and the Contractor's name may be removed from the list of those contractors with approved Human Subject Assurances.

(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 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 June 5, 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 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.5. 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)****

ARTICLE H.6. 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 and Observational Study Monitoring Boards, which may be found at:

http://www.nhlbi.nih.gov/funding/ethics.htm

1. Establishing Data and Safety Monitoring Boards and Observational Study Monitoring Boards
2. Data Quality Assurance in Clinical Trials and Observational Studies-Guidelines
3. Responsibilities of DSMBs Appointed by the NHLBI
4. Responsibilities of OSMBs Appointed by the NHLBI

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

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. For information about how to determine "applicable clinical trial,s" 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:

1. CLINICAL TRIALS CONDUCTED UNDER INVESTIGATIONAL NEW DRUG/INVESTIGATIONAL DEVICE EXEMPTION (IND/IDE) REQUIREMENTS:
    - 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.
2. SINGLE CENTER TRIALS (not conducted under IND/IDE requirements):
    - 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.
3. MULTICENTER TRIALS (not conducted under IND/IDE requirements):
    - 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's*

ARTICLE H.7. 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: http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.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 (http://www.ClinicalTrials.gov).

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

186

****(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's Representative (COR) to assist in making this determination* .)****

ARTICLE H.8. 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 http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.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 (http://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: http://prsinfo.clinicaltrials.gov .

187

****(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.9. 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.

188

****(USE BELOW, WHEN HUMAN MATERIALS WILL BE ACQUIRED AND/OR GENERATED UNDER THE CONTRACT.)****

ARTICLE H.10. 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.

189

****(USE BELOW, WHEN THE CONTRACTOR WILL BE RECEIVING HUMAN MATERIALS FROM AN OUTSIDE SOURCE, ANOTHER CONTRACT OR FROM A SUBCONTRACTOR.)****

ARTICLE H.11. 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).

190

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE RESEARCH INVOLVING HUMAN FETAL TISSUE.)****

ARTICLE H.12. RESEARCH INVOLVING HUMAN FETAL TISSUE

All research involving human fetal tissue shall be in conducted in accordance with the Public Health Service Act, 42 U.S.C. 289g-1 and 289g-2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

191

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE RESEARCH INVOLVING RECOMBINANT DNA MOLECULES [INCLUDING HUMAN GENE TRANSFER RESEARCH].)****

ARTICLE H.13. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (Including Human Gene Transfer Research)

All research involving recombinant DNA molecules that is conducted at or sponsored by an entity that receives any support for recombinant DNA research from NIH shall be conducted in accordance with the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* (See http://oba.od.nih.gov/rdna/nih_guidelines_oba.html). The *NIH Guidelines* stipulate biosafety and containment measures for recombinant DNA research and delineate points to consider in the development and conduct of human gene transfer clinical trials, including ethical principles and safety reporting requirements (See Appendix M of the Guidelines). More information about compliance with the *NIH Guidelines* can be found in a set of Frequently Asked Questions at: http://oba.od.nih.gov/rdna_ibc/ibc_faq.html .

The *NIH Guidelines* apply to both basic and clinical research studies. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the NIH OBA and reviewed by the NIH Recombinant DNA Advisory Committee (RAC). If this contract involves

new protocols that contain unique and/or novel issues, the RAC may recommend that the protocol also be discussed by the RAC in a public forum. Approval of the Institutional Biosafety Committee (IBC) and the Institutional Review Board (IRB) are necessary before the Contracting Officer's Representative (COR) and Contracting Officer may approve the protocol prior to the start of the research. The IBC approval may not occur before the NIH RAC has concluded its review of the protocol.
Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of the contract for any work related to recombinant DNA research or a requirement for Contracting Officer prior approval of any or all recombinant DNA projects under this contract. This includes the requirements of the Institutional Biosafety Committee (IBC) (See http://oba.od.nih.gov/rdna_ibc/ibc.html).

As specified in Appendix M-1-C-4 of the *NIH Guidelines*, any serious adverse event that that is both unexpected and associated with the use of the gene transfer product (i.e., there is reasonable possibility that the event may have been caused by the use of the product) must be reported to the NIH OBA and 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 Contracting Officer (See http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc351276411). Such reports must also be submitted within their mandated time frames to the IRB, Food and Drug Administration, and, if applicable, the HHS Office for Human Research Protections.

192

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE RESEARCH INVOLVING HUMAN EMBRYONIC GERM CELLS AND THE RESEARCH/CONTRACT HAS RECEIVED APPROVAL FROM THE HUMAN PLURIPOTENT STEM CELL REVIEW GROUP (HPSCRG) PRIOR TO CONTRACT AWARD.)****

ARTICLE H.14. HUMAN EMBRYONIC GERM CELL (HEGC) RESEARCH

All HPSCRUG (Human Pluripotent Stem Cell Review Group) approved research involving human embryonic germ cells shall be conducted in accordance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://stemcells.nih.gov/policy/guidelines.asp)

193

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE RESEARCH INVOLVING HUMAN EMBRYONIC GERM CELLS WHEN THE CONTRACT IS TO BE AWARDED PRIOR TO RECEIVING APPROVAL FROM THE HUMAN PLURIPOTENT STEM CELL REVIEW GROUP (HPSCRG).

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

- **Second Paragraph:**
  - Include the paragraph, or language substantially the same to reflect the specifics of the contract, when contract award has been made prior to review and approval of the HPSCRG.
  - Choose the applicable language contained within the brackets and delete the language that is not appropriate or tailor specific language that would be more appropriate to your contractual situation.
  - **Note:** *If HPSCRG approval has been received prior to contract award, the entire second paragraph should not be included in the contract* .)****

ARTICLE H.15. HUMAN EMBRYONIC GERM CELL (HEGC) RESEARCH

Federally funded research involving the use of human embryonic germ cells derived from fetal tissue shall not be conducted under this contract until Human Pluripotent Stem Cell Review Group (HPSCRG) review and approval has been obtained. Once approved by the HPSCRG, all research shall be conducted in accordance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://stemcells.nih.gov/policy/guidelines.asp).

Any work under this contract which requires research involving the use of human embryonic germ cells shall not be conducted under this contract until the HPSCRG review and approval have been obtained, and documented by written notice of such approval by the Contracting Officer. If the HPSCRG disapproves the documentation presented by the Contractor, [the contract may be terminated in accordance with the Termination of Convenience Clause referenced in Article I.1. of this contract/ OR the Contracting Officer may elect not to exercise Option(s) _____ of this contract in accordance with the Option Clause referenced in Article I.3. of this contract.] In addition, it may be necessary for the Contracting Officer to invoke FAR Clause 52.242-15, Stop Work Order, referenced in the CLAUSES INCORPORATED BY REFERENCE Article in Section F of this contract if the review and approval process cannot be accomplished in a time frame that allows for continuity of this research effort.

194

****(USE BELOW IN SOLICITATIONS THAT INVOLVE HUMAN EMBRYONIC STEM CELL (hESC) RESEARCH.)****

ARTICLE H.16. HUMAN EMBRYONIC STEM CELL (hESC) RESEARCH

All research conducted under this contract shall be in accordance with NIH Guidelines on Human Stem Cell Research (http://stemcells.nih.gov/policy/pages/2009guidelines.aspx), and shall involve the use of approved human embryonic stem cells (hESCs) that are listed on the NIH Human Embryonic Stem Cell Registry (http://stemcells.nih.gov/research/registry/).

195

****(INCLUDE THE FOLLOWING IN ALL SOLICITATIONS AND CONTRACTS FOR R&D REQUIREMENTS.)****

ARTICLE H.17. 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 research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov .

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-033.html .

196

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

ARTICLE H.18. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

197

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

ARTICLE H.19. 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.

198

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

ARTICLE H.20. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

199

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR R&D.)****

ARTICLE H.21. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

The Contractor shall not use contract funds for (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 or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 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 or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

200

****(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.22. 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.

201

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS THAT REQUIRE THE DISSEMINATION OF INFORMATION.)****

ARTICLE H.23. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

202

****(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.24. 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.]

203

****(USE BELOW, IN SOLICITATIONS AND CONTRACTS THAT INVOLVE PRIVACY ACT REQUIREMENTS.)****

ARTICLE H.25. PRIVACY ACT, HHSAR 352.224-70 (January 2006)

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 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)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at:
http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html .
The Privacy Act System of Records applicable to this project is Number _____ . This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm .

204

****(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.26. 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.

205

****(USE IN ALL SOLICITATIONS AND CONTRACTS INVOLVING LIVE VERTEBRATE ANIMALS.)****

ARTICLE H.27. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (October 2009)

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by 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 sections 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 Sections 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 of 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 approved 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, 4700 River Road, Riverdale, Maryland 20737 (E-mail: ace@aphis.usda.gov ; Web site: (http://www.aphis.usda.gov/animal_welfare).

(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-10-049 available at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html .)****

ARTICLE H.28. 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: http://grants1.nih.gov/grants/olaw/references/phspol.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:

1. **First sentence:** Insert the appropriate I/C and contract number in each text box.
2. **Fifth sentence:** Insert the appropriate I/C in the text box.)****

ARTICLE H.29. 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.)****

ARTICLE H.30. 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 919-541-3239. 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 (http://www.aphis.usda.gov/permits/). A copy of the completed permit form should be submitted to the Comparative Medicine Branch.

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****(USE BELOW, WHEN THE CONTRACT WILL INCLUDE RESEARCH INVOLVING NON HUMAN PRIMATES.)****

ARTICLE H.31. 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:

http://oma.od1.nih.gov/manualchapters/intramural/3044-2/

210

****(USE BELOW, AS NECESSARY.)****

ARTICLE H.32. OMB CLEARANCE

In accordance with HHSAR 352.201-70, 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's Representative (COR) and the Contracting Officer has issued written approval to proceed.

211

****(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.33. 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.

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****(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.34. 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's 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.35. 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)
   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 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.

   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 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.

   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 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's 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 CONTRACT REQUIRES A SUBCONTRACTING PLAN (All Contracts OVER $650,000 - 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.36. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan**

1. The Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract.
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**

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov .

1. 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

2. Summary Subcontract Report (SSR)
   Regardless of the effective date of this contract, the Summary Subcontract Report shall 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] shall 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:

1. **For SBIR Phase I Contracts**: Select "two thirds" from the drop down box.
2. **For SBIR Phase II Contracts**: Select "one half" from the drop down box.)****

ARTICLE H.37. LIMITATIONS ON SUBCONTRACTING - SBIR

The Contractor shall perform a minimum of [two-thirds/one-half] of the research and/or analytical effort (total contract price 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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****(INCLUDE BELOW IN SOLICITATIONS AND CONTRACTS 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.

General Resource Information for this Article:

1. For more information, see HHS OCIO Policies at: http://www.hhs.gov/ocio/policy/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) - currently Thomas Mitchell, as 301-594-2750; nihisaopolicy@mail.nih.gov .)****

ARTICLE H.38. INFORMATION AND PHYSICAL ACCESS SECURITY

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****(INCLUDE BELOW IN SOLICITATIONS AND CONTRACTS 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:** The Contracting Officer (CO) must include the definitive position sensitivity levels in the awarded contract/order. Based on the recommendation of the ISSO and PO, the CO shall check all levels that apply. Delete those that do not apply. List the applicable Contractor Position Titles in the text box under the heading, if considered appropriate.

  Additional guidance is located in Table 2, Position Sensitivity Designations for Individuals Accessing Agency Information at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Pages/table2.aspx .)****

A. **HHS-Controlled Facilities and Information Systems Security**

a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-

controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:
    1. HHS-OCIO Information Systems Security and Privacy Policy (http://www.hhs.gov/ocio/policy/#Security)
    2. HHS HSPD-12 Policy Document, v. 2.0 (http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf)
    3. Information regarding background checks/badges (http://idbadge.nih.gov/background/index.asp)

c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

[ ] **Level 6: Public Trust - High Risk.** Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).
[ ] **Level 5: Public Trust - Moderate Risk.** Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).
[ ] **Level 1: Non-Sensitive.** Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

d. The personnel investigation procedures for Contractor personnel require that the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with fingerprinting. More restricted positions - i.e., those above non-sensitive, require more extensive documentation and investigation.

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring

Suitability Investigations," is available for contractor use at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx .

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.

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.

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.

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 shall 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 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).

h. The Contractor shall 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 shall return all identification badges to the Contracting Officer or designee.

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****(INCLUDE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE THE OPERATION OR ACQUISITION OF AN INFORMATION SYSTEM.

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- An Information Security Policy Waiver available at: http://sps.nihcio.nih.gov/OCIO/NIH/documents/IT-Security-Forms/NIH-Policy-Waiver_Final.doc) must be approved in order to deviate from HHS OCIO STANDARD 2009-0001.001S, HHS STANDARD FOR SECURITY CONFIGURATIONS LANGUAGE IN HHS CONTRACTS, dated January 30, 2009. See HHSAR 330.101(d)(1) for further information.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Subparagraph b:**
  - Insert the IC/ISSO approved contract-specific configuration.
  - If there are no contract-specific configurations, insert: **"FDCC"**

Note: *Applicable security configuration requirements are based on information provided by the Project Officer, who shall consult with the OPDIV/STAFFDIV Chief Information Security Officer* .)****

B. **Standard for Security Configurations, HHSAR 352.239-70,** (January 2010)

a. The Contractor shall configure its computers that contain HHS data with the applicable Federal Desktop Core Configuration (FDCC) (see http://nvd.nist.gov/fdcc/index.cfm) and ensure that its computers have and maintain the latest operating system patch level and anti-virus software level.

Note: FDCC is applicable to all computing systems using Windows XPTM and Windows VistaTM, including desktops and laptops - regardless of function - but not including servers.

b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:

c. 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 FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC 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 FDCC major version and subsequent major versions.

d. The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.

e. The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.

f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (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.

g. The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

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****(INCLUDE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE THE ACQUISITION OR LEASE OF, OR THE REQUIREMENT TO USE, DESKTOP OR LAPTOP COMPUTERS, MOBILE DEVICES, OR PORTABLE MEDIA TO STORE OR PROCESS HHS SENSITIVE INFORMATION THAT THE PROJECT OFFICER CATEGORIZES AS MODERATE OR HIGH UNDER FEDERAL INFORMATION PROCESSING STANDARD (FIPS) 199, STANDARDS FOR SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS, DATED FEBRUARY 2004.

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- An Information Security Policy Waiver (See http://sps.nihcio.nih.gov/OCIO/NIH/Documents/IT-Security-Forms/NIH-Policy-Waiver_FINAL.doc) must be approved in order to deviate from HHS OCIO STANDARD 2009-0001.001S, HHS STANDARD FOR SECURITY CONFIGURATIONS LANGUAGE IN HHS CONTRACTS, dated January 30, 2009. See HHSAR 330.101(d)(1) for further information.)****

C. **Standard for Encryption language, HHSAR 352.239-71,** (January 2010)

a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004).

b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see http://csrc.nist.gov/cryptval/) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.

c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.

d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).

e. The Contractor shall ensure that this standard is incorporated into the Contractor's property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.

f. The Contractor shall ensure that its subcontractors (all tiers) which perform work under this contract comply with the requirements contained in this clause.

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

D. **Security Requirements For Federal Information Technology Resources, HHSAR 352.239-72,** (January 2010)

a. **Applicability**. This clause applies whether the entire contract or order (hereafter "contract"), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS' mission. The term "information technology (IT)", as used in this clause, 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. This clause does not apply to national security systems as defined in FISMA.

b. **Contractor responsibilities**. The Contractor is responsible for the following:

1. Protecting Federal information and Federal information systems in order to ensure their -
    a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;
    b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and
    c. Availability, which means ensuring timely and reliable access to and use of information.
2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.
3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security

Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.

c. **Contractor security deliverables** . In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:

1. **IT Security Plan (IT-SP)** - due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.
    a. The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:
        i. Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automation Information Resources.
        ii. National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of Federal Information Processing Standard (FIPS) 200, Recommend Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.
        iii. HHS-OCIO Information Systems Security and Privacy Policy.
2. **IT Risk Assessment (IT-RA)** - due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor's final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.
3. **FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment)** - due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor's final version into the contract.

4. **IT Security Certification and Accreditation (IT-SC&A)** - due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems - see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security, Certification and Accreditation of Federal Information Systems; and NIST 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provided it to the Contracting Officer for review, comment, and acceptance.
    a. After resolution of any comments provided by the Government on the draft IT SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor's final version into the contract as a compliance requirement.
    b. The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:
        i. Annual testing of the system contingency plan; and
        ii. The performance of security control testing and evaluation.

d. **Personal identity verification.** The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer's Representative (COR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in "HHS-Controlled Facilities and Information Systems Security" requirements specified in the SOW/PWS of this contract.

e. **Contractor and subcontractor employee training.** The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COR evidencing that Contractor employees have completed the required training.

f. **Government access for IT inspection.** The Contractor shall afford the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.

g. **Subcontracts.** The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -
    a. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or
    b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.

h. **Contractor employment notice.** The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.

i. **Document information.** The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.

j. **Contractor responsibilities upon physical completion of the contract.** The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.

k. **Failure to comply.** Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

(End of Clause)

Note: The NIST Special Publication SP-800-26 cited in subparagraph c.1.a.(ii) of this clause has been superseded by NIST SP 800-53A, "Guide for Assessing the Security Controls in Federal Information Systems and Organizations" for use for the assessment of security control effectiveness. See http://csrc.nist.gov/publications/PubsSPs.html to access NIST Special Publications (800 Series).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE THE CLAUSE AT HHSAR 352.239-72, Security Requirements for Federal Information Technology Resources .)****

E. **Additional NIH Requirements**

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****(INCLUDE BELOW WHEN THE CONTRACTOR WILL 1) DEVELOP; 2) HAVE THE ABILITY TO ACCESS; OR 3) HOST AND/OR MAINTAIN A FEDERAL INFORMATION SYSTEM(S).

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Subparagraph a:** Select the appropriate general information type(s), and include a brief description of the specific type of information.
2. **Subparagraph b:** Select the Security Level for each Security category. The Overall Security Level is the highest level of the three factors (Confidentiality, Integrity, and Availability).

For additional information about Information Types and Security Levels, See:

- NIST SP 800-60 Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories, Appendices C and D, at: http://csrc.nist.gov/publications/nistpubs/800-60-rev1/SP800-60_Vol2-Rev1.pdf ; and,
- Table 1: Security Categorization of Federal Information and Information Systems , at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Pages/table1.aspx .)****

1. **SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS (FIPS 199 Assessment)**
   a. Information Type:

[ ] Administrative, Management and Support Information:
[ ] Mission Based Information:

b. Security Categories and Levels:

Confidentiality Level:	[ ] Low	[ ] Moderate	[ ] High
Integrity Level:	[ ] Low	[ ] Moderate	[ ] High
Availability Level:	[ ] Low	[ ] Moderate	[ ] High
Overall Level:	[ ] **Low**	[ ] **Moderate**	[ ] **High**

c. In accordance with HHSAR Clause 352.239-72, the contractor shall submit a FIPS 199 Assessment within 30 days after contract award. Any differences between the contractor's assessment and the information contained herein, will be resolved, and if required, the contract will be modified to incorporate the final FIPS 199 Assessment.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE THE CLAUSE AT HHSAR 352.239-72, Security Requirements for Federal Information Technology Resources.)****

2. **INFORMATION SECURITY TRAINING**

In addition to any training covered under paragraph (e) of HHSAR 352.239-72, the contractor shall comply with the below training:

a. Mandatory Training

1. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information as defined at HHSAR 304.1300(a)(4), shall complete the NIH Computer Security Awareness Training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.

2. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COR and/or Contracting Officer upon request.

b. Role-based Training

HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance about "NIH Information Security Awareness and Training Policy,"

at: https://ocio.nih.gov/InfoSecurity/Policy/Documents/Final-InfoSecAwarenessTrainPol.doc .

The Contractor shall maintain a list of all information security training completed by each contractor/subcontractor employee working under this contract. The list shall be provided to the COR and/or Contracting Officer upon request.

c. Rules of Behavior
The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior (https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx), which are contained in the NIH Information Security Awareness Training Course http://irtsectraining.nih.gov .

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE THE CLAUSE AT HHSAR 352.239-72, Security Requirements for Federal Information Technology Resources.)****

3. **PERSONNEL SECURITY RESPONSIBILITIES**

In addition to any personnel security responsibilities covered under HHSAR 352.239-72, the contractor shall comply with the below personnel security responsibilities:

a. In accordance with Paragraph (h) of HHSAR 352.239-72, the Contractor shall notify the Contracting officer and the COR **within five working days** before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.

b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.

c. **Departing contractor employees:** The Contractor shall provide the COR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-

checklist.pdf) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COR upon request.

d. **Commitment to Protect Non-Public Departmental Information and Data.**
The Contractor, and any subcontractors performing under this contract, shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (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.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN CONTRACTOR/SUBCONTRACTOR PERSONNEL WILL HAVE ACCESS TO, OR USE OF PERSONALLY IDENTIFIABLE INFORMATION (PII), INCLUDING INSTANCES OF REMOTE ACCESS TO OR PHYSICAL REMOVAL OF SUCH INFORMATION BEYOND AGENCY PREMISES OR CONTROL. FOR ADDITIONAL INFORMATION SEE:

- OMB Memorandum M-07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information, May 22, 2007
  at: www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2007/m07-16.pdf
- NIH Incident Response Policy
  at: https://ocio.nih.gov/InfoSecurity/IncidentResponse/Pages/ir_guidelines.aspx .)****

4. **LOSS AND/OR DISCLOSURE OF PERSONALLY IDENTIFIABLE INFORMATION (PII) - NOTIFICATION OF DATA BREACH**

The Contractor shall report all suspected or confirmed incidents involving the loss and/or disclosure of PII in electronic or physical form. Notification shall be made to the NIH Incident Response Team (IRT) via email (IRT@mail.nih.gov) within one hour of discovering the incident. The Contractor shall follow up with IRT by completing and submitting one of the applicable two forms below within three (3) work days of incident discovery:

NIH PII Spillage Report
at: https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_PII_Spillage_Proced.doc

NIH Lost or Stolen Assets Report at:
https://ocio.nih.gov/InfoSecurity/Policy/Documents/ISSO_Stolen_Device-Media_Handling_Procedures.doc

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN THE CONTRACTOR/SUBCONTRACTOR WILL HOST NIH WEB PAGES OR DATABASES.)****

5. **VULNERABILITY SCANNING REQUIREMENTS**

This acquisition requires the Contractor to host an NIH webpage or database. The Contractor shall conduct periodic and special vulnerability scans, and install software/hardware patches and upgrades to protect automated federal information assets. The minimum requirement shall be to protect against vulnerabilities identified on the SANS Top-20 Internet Security Attack Targets list (http://www.sans.org/top20/?ref=3706#w1). The Contractor shall report the results of these scans to the Project Officer/COR on a monthly basis, with reports due 10 calendar days following the end of each reporting period. The Contractor shall ensure that all of its subcontractors (at all tiers), where applicable, comply with the above requirements.

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****(USE BELOW FOR SOLICITATIONS AND CONTRACTS 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. **Note:** *Exceptions to this requirement can be found at FAR 39.204.*

IMPORTANT NOTE Regarding Electronic Report Submission requirements and applicability: When the **ONLY** EIT product required under the contract is the submission of electronic reports/deliverables, the certification required [in HHS Section 508 policy at 4.3.3] is satisfied when the Contracting Officer and Project Officer include the following statements in the appropriate section of the AP:

- The only Electronic and Information Technology (EIT) product or service required under this contract is the submission of electronic deliverables.; and,
- The contract will require that electronically submitted reports be in a 508 compliant format and the appropriate 508 Standards will be identified in the contract. (Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible.")

In this case, the Electronic and Information Technology Accessibility HHSAR Clause is not applicable to the contract. However, if the CS/CO is unsure whether any additional EIT products or services (no matter how small) will be required in performance of the contract, the Statement of Work should reviewed by the designated I/C Section 508 Coordinator for an applicability determination.

ADDITIONAL INFORMATION FOR COMPLETING THIS ARTICLE when it is applicable:

1. **Subparagraph b:** Select the document applicable to your requirement from the Drop Down List.
2. **Subparagraph d:** (This paragraph is actually HHSAR Clause 352.239-73(c) which should be included or removed as follows):
   - **Include this paragraph:**
     When the conditions at 339.201-70 apply, e.g: Multiple Year contracts that exceed $150,000. This includes option contracts: task and delivery orders awarded under IDIQ or FSS contracts and BPA Orders.

     Schedule for Annual 508 Report: This must be completed by the Contracting Officer at the time of contract/order award.
   - **Delete this paragraph** for contracts awarded for less than one year in an amount less than $150,000.

Notes:

1. HHSAR 352.239-73 is divided in three parts; (a), (b) and (c) as follows: 352.239-73(a) is the HHSAR provision which is included in Section L of the solicitation; 352.239-73(b) is the first two paragraphs of the HHSAR Clause set forth below; and 352.239-73(c) is the last paragraph of the HHSAR Clause set forth below.
2. If this Article is not applicable then the requirement for a Section 508 Annual Report and the requirement for a separate Technical Evaluation Criteria are also not applicable.)****

ARTICLE H.39. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-73(b) (January 2010)

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) products and services developed, acquired, maintained, or used under this contract/order must comply 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. Information about Section 508 provisions is available at http://www.section508.gov/ . The complete text of Section 508 Final provisions can be accessed at http://www.access-board.gov/guidelines-and-standards .

b. The Section 508 standards applicable to this contract/order are identified in the [Statement of Work/Specification/Performance Work Statement] . The contractor must provide a written Section 508 conformance certification due at the end of each contract/order exceeding $100,000 when the contract/order duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the Contractor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

c. In the event of a modification(s) to this contract/order, which adds new EIT products or services or revises the type of, or specifications for, products or services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products or services support Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found on the HHS Web site (http://www.hhs.gov/web/508/contracting/technology/vendors.html).
[(End of HHSAR 352.239-73(b)]

d. Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Project Officer. Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available in the Section 508 policy on the HHS Office on Disability Web site under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report:

[End of HHSAR 352.239-73(c)]

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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: (* http://oma.od.nih.gov/public/MS/manualchapters/Pages/default.aspx *)*

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

• **Second paragraph**: Select all that contract requirements that apply.)****

ARTICLE H.40. 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 1183, "NIH Publications & Audiovisuals: Preparation, Review, Approval & Distribution," is applicable to this contract.
http://oma1.od.nih.gov/manualchapters/management/1183/ .

[ ] Use the NIH name and logo.

NIH Policy Manual Chapter 1186, "Use of NIH Names and Logos," is applicable to this contract.
http://oma1.od.nih.gov/manualchapters/management/1186/ .

[ ] Create and/or Manage a Public Website which includes NIH hosted social media site(s), Web application(s) and mobile Web Site(s).

NIH Policy Manual Chapter 2804, "Public-Facing Web Management," is applicable to this contract.
http://oma1.od.nih.gov/manualchapters/management/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.
http://oma1.od.nih.gov/manualchapters/management/2805/ .

[ ] Create and/or Manage an NIH hosted and/or funded social media site(s), Web application(s) and mobile Web site(s).

NIH Policy Manual Chapter 2809, "NIH Social and New Media Policy," is applicable to this contract.
http://oma1.od.nih.gov/manualchapters/management/2809/ .

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 Contractor 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.41. 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 "Facility Standards for Records Storage Facilities Inspection Checklist," self-certifying that the facility being used to store federal records meets established NARA standards. NARA Standards are available at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=b5a00a361423743ff1a062faafcfdd89&rgn=div5&view=text&node=36:3.0.10.2.23&idno=36

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.42. 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.43. FULL EARNED VALUE MANAGEMENT SYSTEM, HHSAR 352.234-3 (October 2008)

a. 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.

b. If, at the time of award, the Contractor's EVM system has not been 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:
    1. Apply the current system to the contract; and
    2. Take necessary and timely actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

c. 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.

d. 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.

e. 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.

f. 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.

g. 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 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.44. FULL EARNED VALUE MANAGEMENT SYSTEM, HHSAR 352.234-3 (October 2008) with ALTERNATE I (October 2008)

a. 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.

b. 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.

c. 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.

d. 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.

e. -Not Applicable-

f. 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.

g. 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 $25 MILLION; AND,
- REQUIRE A CONTRACTOR TO USE PARTIAL EVMS (See HHSAR 334.201.)****

ARTICLE H.45. PARTIAL EARNED VALUE MANAGEMENT SYSTEM, HHSAR 352.234-4 (October 2008)

a. 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.

b. 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.

c. 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.

d. 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.

e. 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.

f. 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.

g. 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.46. PARTIAL EARNED VALUE MANAGEMENT SYSTEM, HHSAR 352.234-4 (October 2008) with ALTERNATE I (October 2008)

a. 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.

b. 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.

c. 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.

d. 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.

e. -Not Applicable-

f. 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.

g. 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.47. 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.48. CONFIDENTIALITY OF INFORMATION

a. 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.

b. 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.

c. 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.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. 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.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) 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.49. INSTITUTIONAL RESPONSIBILITY 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: : http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45

As required by 45 CFR Part 94, the Institution shall, at a minimum:

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

    1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;
    2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or
    3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

    Significant financial interests do not include the following:

    1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
    2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any NIH-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

c. Designate an 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.

d. 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 interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for NIH-funded research. Require that 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 as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated 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, thorough 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. 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.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. 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 Part 94.5(a).

g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Offerors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the NIH-funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests.. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

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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.50. 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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****(NHLBI: USE BELOW IN ALL NHLBI SOLICITATIONS AND CONTRACTS.)****

ARTICLE H.51. 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's 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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****(NHLBI: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHEN THERE IS A REQUIREMENT FOR THE DELIVERY OF A DATA SET.)****

ARTICLE H.52. NHLBI DATA REPOSITORY OF EPIDEMIOLOGY AND CLINICAL TRIALS

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://biolincc.nhlbi.nih.gov/home/ . 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, WHEN THE SOLICITATION WILL RESULT IN A TASK ORDER OR DELIVERY ORDER CONTRACT.)****

ARTICLE H.53. TASK ORDER/DELIVERY ORDER CONTRACT OMBUDSMAN

In accordance with FAR 16.505(b)(5), 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. Walter Schaffer	Dr. Richard G. Wyatt
NIH Competition Advocate	NIH Competition Advocate
6705 Rockledge Drive, Room 3537	1 Center Drive, Room 160, MSC 0151
Bethesda, MD 20817	Bethesda, MD 20892-0151
Phone: (301) 435-2687	Phone: (301) 496-4920
FAX: (301) 480-0146	FAX: (301) 402-4273
e-mail: schaffew@od.nih.gov e-mail:	e-mail: WyattRG@mail.nih.gov

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

ARTICLE H.54. 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: http://oig.hhs.gov/fraud/hotline/ 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, DESIGN-BUILD AND FACILITIES SERVICES OVER $2,000)****

ARTICLE H.55. WAGE RATES

A wage determination of the Secretary of Labor shall be implemented in accordance with the statutes for labor standards requirements for contracts over $2,000 involving construction (FAR SUBPART 22.4). The wage determination for this requirement is set forth in Section J, "List of Attachments".
If a contract has not been awarded as a result of this solicitation within 90 days after receipt of offers, any wage rate modifications published in the Federal Register prior to award shall be effective with respect to that contract unless an extension of the 90 day period has been granted by the Administrator, Wage and Hour Division, Department of Labor.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR A/E, CQM SERVICES, CONSTRUCTION, DESIGN-BUILD AND FACILITIES SERVICES.)****

ARTICLE H.56. 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.

   3. Automobile Liability
      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. The Contractor shall also require all first-tier subcontractors who will perform work on a Government installation to procure and maintain the insurance required by the Schedule during the entire period of their performance. The Contractor shall furnish (or assure that there has been furnished) to the Contracting Officer a current Certificate of Insurance meeting the requirements of 1. above for each such first-tier subcontractors, at least five (5) days prior to entry of each subcontractor's personnel on the Government installation.

d. Current certificates of insurance shall be furnished by the Contractor and first tier subcontractor(s) 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, DESIGN-BUILD AND FACILITIES SERVICES.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **Last (4th) Paragraph:**
  - **For Contracts:** Select the first sentence from the drop-down box.
  - **For Solicitations:** Select the second sentence from the drop-down box.)****

ARTICLE H.57. 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, DESIGN-BUILD AND FACILITIES SERVICES.)****

ARTICLE H.57.1. CONTRACTOR REQUIREMENTS

a. The work to be performed under this contract is subject to the requirements of this Contractor Health and Safety Requirements Section.

b. The contractor shall comply with applicable Occupational Safety and Health Administration (OSHA) Regulations and the US Army Corps of Engineers Safety and Health Manual 385-1-1 (EM 385-1-1).

c. 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.

d. The contractor will not begin work authorized under this contract, except for authorized preliminary activities (i.e. mobilization), without first submitting for review each deliverable specified in this Contractor Health and Safety Requirements Section. Copies of each deliverable must be provided to the NIH Contracting Officer Representative (COR) and ORF Safety Officer (safety@nih.gov).

e. Prior to Notice to Proceed, but no later than 14-working days before the project start date, the contractor's Project Manager and NIH COR shall meet to review and discuss the safety

requirements of this contract. The contractor's Project Manager is responsible for coordinating the meeting arrangement.

f. The contractor and all subcontractors must have a confined space program on file and demonstrate that this program meets OSHA requirements. The contractor and all subcontractors must assure safe access for all employees as well as on-site OSHA confined space audits.

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****(FOR ORF USE ONLY: USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION, CQM SERVICES, DESIGN-BUILD 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 state that a waiver has been granted and the date granted.)****

ARTICLE H.57.2. 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:
   1. The request must state the specific Contractor Health and Safety Requirement to be waived. State the period of time the requested waiver will cover.
   2. Details as to why it is not possible or practical to comply with the requirement.
   3. The request must explain the impact on the contractor operations and services if this waiver is not approved.
   4. 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;
   5. Explanation of the method the Contractor suggests to use 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.
   6. The waiver request must be submitted to the NIH Contracting Officer Representative (COR) and ORF Safety Officer (safety@nih.gov) at least 14-working days prior to commencement of work.

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

ARTICLE H.57.3. NIH REQUIRED SAFETY TRAINING MANDATE

a. 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.

b. 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.

c. Any card with an issuance date more than three (3) years shall not constitute proof of compliance with this requirement.

d. 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, DESIGN-BUILD AND FACILITIES SERVICES.)****

ARTICLE H.57.4. CONTRACTOR SUPERVISOR ORIENTATION

a. 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.

b. It is the responsibility of the contractor and subcontractor to contact the ORF Safety Officer to register each supervisor for orientation. Class registration should be scheduled at least 14-working days prior to the project start date, or the date that the supervisor is assigned to NIH.

   Contact the ORF Safety Officer (safety@nih.gov) or by phone (301) 496-3353 for the orientation schedule.

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

ARTICLE H.57.5. DELIVERABLES

a. All deliverables required under this Contractor Safety and Health Section must be provided to the NIH Contracting Officer Representative (COR) and ORF Safety Officer (safety@nih.gov). All deliverables shall be submitted at least 14-working days prior to the commencement of work activities. The deliverables must be in either MS Word or Adobe Acrobat format.

b. Acceptance of a deliverable 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.

c. 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.

d. SITE SPECIFIC ACCIDENT PREVENTION PLAN

The contractor shall submit for NIH's review and comment, a Site Specific Accident Prevention Plan. Contents of the Contractor's Site Specific Accident Prevention Plan will be in accordance with Appendix A, EM 3985-1-1.

Note: For LIMITED-SCOPE SERVICE, SUPPLY AND R&D CONTRACTS, (e.g. painting, janitorial service), the ORF Safety Officer may allow an Abbreviated Accident Prevention Plan and waive the more stringent elements of the comprehensive plan. The contractor must make a written request to the ORF Safety Officer (safety@nih.gov) and provide copy to the NIH COR.

e. CONTRACTOR EMPLOYEE SAFETY TRAINING DOCUMENTATION
   1. The contractor shall submit a resume identifying the experience and qualifications for the proposed Contractor Safety and Health Officer(s). The NIH COR may reject anyone he/she deems "Not Qualified".
   2. The contractor shall submit copies of each employee's OSHA 10-hour General Industry Outreach class or OSHA 10-hour Construction Industry Outreach class certification.

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

ARTICLE H.57.6. CONTRACTOR FULLY RESPONSIBLE FOR SITE SAFETY

a. The contractor assumes full and sole responsibility for and shall comply with all laws, regulations, ordinances, and governmental orders pertaining to employee worksite safety in the performance of this contract. 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.

b. The contractor shall be solely and completely responsible for the safety of all workers, NIH employees, public and NIH property in performance of the scope of work. This requirement shall apply at all times while work is being performed under this contract, and is not limited to only normal working hours. Nothing the NIH may do, or fail to do, with respect to safety in the performance of the scope of work shall relieve contractor of this responsibility.

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ARTICLE H.57.7. SELECTION OF CONTRACTOR SITE SAFETY AND HEALTH OFFICER

a. When the number of personnel on any shift is under 40 (including subcontractor employees), the contractor's safety representative will meet the definition of "Collateral Duty Safety Officer" as

defined herein for each shift.

b. For contractors with a total of 40 or more personnel (including subcontractor employees) on any shift, a Full-time Safety Professional as defined above shall be required for each shift.

c. At the NIH Contracting Officer Representative's (COR's) discretion, the requirements for the contractor Site Safety and Health Officer can be reviewed and action taken to decrease or increase the number of Officers onsite. However, the need for a Site Safety and Health Officer is required and will not be waived.

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ARTICLE H.57.8. CONTRACTOR SITE SAFETY AND HEALTH OFFICER RESPONSIBILITIES

a. The responsibility for safety lies with the contractor. Each contractor shall appoint an individual(s) responsible for safety on each contract. 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.

b. The Contractor Site Safety and Health Officer shall be primarily responsible for ensuring contractor's compliance with the safety requirements including but not limited to those provided in this Section. Without limiting the generality of the foregoing, the Contractor Site Safety and Health Officer shall:
    1. Review all subcontractor and sub-tier contractor's Site Specific Accident Prevention Plan and Activity Hazard Analysis for compliance with applicable safety standards.
    2. 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 Activity Hazards Analysis reports. This site specific orientation is in addition to the NIH's Contractor Supervisor Orientation course.
    3. Perform and document worksite inspections, assess and immediately correct any substandard safety conditions or practices, 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 Representative (COR) or ORF Safety Officer.
    4. Immediately report all injuries to personnel, vehicle accidents, near miss incidents and property damage. Undertake a complete investigation of all accidents, injuries, illnesses and implement corrective action to prevent a recurrence. Provide written findings within 24-hours to both the NIH COR and ORF Safety Officer (safety@nih.gov).
    5. 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 Analysis, establish safe working procedures for anticipated hazards, and provide pertinent safety and health training and motivation.

i. Meetings shall be conducted at least once a month for all supervisors at the project location and at least once a week for all workers by supervisors or foremen.
ii. 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.

6. Be responsible for the control, availability, and use of necessary safety equipment, including personal protective equipment and apparel for the employees.

c. A Contractor Site Safety and Health Officer not performing his/her duties in accordance with this Section, shall be replaced without the NIH's advanced written approval. The contractor shall notify the NIH COR when this person cannot be on duty while work is being performed and shall submit the name(s) and qualifications of the individual assigned to perform said duties.

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ARTICLE H.57.9. SITE SAFETY AND HEALTH OFFICER DEFINITIONS

a. 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.

b. 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.

c. CONTRACTOR
The General Contractor contracted with NIH.

d. 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. He/She shall have no other duties.
ii. An individual possessing a minimum of five (5) 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 Safety & Health Course. This requirement may be waived in lieu of a 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 report.
viii. Is proficient in the development and presentation of "tool box" meetings and safety training.

2. Collateral Duty Safety Officer qualifications include:
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.

i. Possess a minimum five (5) years progressive experience in their trade.
ii. Be knowledgeable concerning all federal, state, and local regulations applicable to safety.
iii. Have successfully completed the OSHA 30-hour Safety & Health Course.
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. Be trained in, and possess current certification for CPR and First Aid.
vi. Possess verifiable training and be capable of performing accident investigations and developing a concise report.
vii. Possess verifiable training in the development and presentation of "tool box" meetings and safety training.

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ARTICLE H.57.10. 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 employees are adequately trained in occupational safety and health topics relevant to the activities to be performed under this contract. Maintain documentation of the employee training, to include the date and subject taught.
d. Instruct all employees of safe work methods and practices when assigning work.
e. Ensure that employees have and use the proper protective equipment and tools for the job.
f. Ensure that all heavy equipment operators (i.e. cranes, loaders and forklifts) are properly qualified and trained on the specific piece of equipment in use.
g. Cooperate fully with the NIH and its representatives in connection with all matters pertaining to safety.

h. Conduct an orientation training program for new employees that includes at a minimum, a review of:
    1. Potential hazards in the work areas
    2. Required personal protective equipment and apparel
    3. Methods to mitigate hazards as appropriate
    4. Emergency response relevant to the area

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.

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ARTICLE H.57.11. ACCIDENT PREVENTION

a. The contractor shall be responsible for correcting hazardous conditions and practices. When more than one contractor is working within a job site, any project management personnel shall have the authority to prevent physical harm or significant property damage.

b. If it is determined there is "Imminent Danger" the contractor shall:
    1. Take immediate action to remove/safeguard workers 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 Representative (COR) and then the ORF Safety Officer.
    3. Each worker shall immediately report any condition known, or suspected to be unsafe or unhealthy to the Contractor Site Safety Officer. If there is no resolution of the concern at that level, the employee shall report the concern to the NIH COR.

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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.)****

ARTICLE H.57.12. CONTRACTOR INJURIES AND ILLNESSES

a. Ensure prompt medical treatment is administered to any injured or ill employee. At the NIH Bethesda Campus, contractor injuries and illnesses should be treated by the Occupational Medical Service (Building 10, 6th Floor, Room 6C306, phone 301-496-4411). Injuries and illnesses other than first-aid treatment should be administered by third-party provider arranged for by the contractor.

b. In all cases, an injury or illness resulting from work under this contract shall be reported to the NIH Contracting Officer Representative (COR) and ORF Safety Officer (safety@nih.gov) within 24-hours of the incident.

c. For work conducted at remote locations where emergency medical service personnel are not capable of responding within four (4) minutes, at least one person shall be available at the work site at all times to render first aid. This person must have a valid certificate in first-aid training 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.

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ARTICLE H.57.13. NIH RIGHTS

a. INSPECTIONS/INVESTIGATIONS
   1. The NIH Contracting Officer Representative (COR) 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 it not limited to, the right to attend all safety meetings.
   2. Upon request, the NIH COR shall receive copies of any safety inspection reports completed by the contractor or anyone performing work for, on behalf of or under the auspices of the contractor.
   3. The NIH COR 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 auspices of the contractor. The NIH may also, at its sole discretion and in any reasonable manner, undertake its own accident investigation.

b. CORRECTIVE ACTIONS/STOP-WORK
   1. The NIH COR 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.).
   2. The NIH COR shall have the right to require the removal, from the work site, any person, property or equipment that, in the NIH's opinion, is deemed unsafe.
   3. The NIH COR 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.
   4. The NIH COR shall have the right to suspend the work pending the completion of any accident/incident investigation, whether undertaken by contractor, the NIH or others.
   5. 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.

c. 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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ARTICLE H.57.14. 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:

a. Asbestos: Many of NIH's buildings have asbestos-containing materials. It is the contractor's responsibility to coordinate with the NIH Contracting Officer Representative (COR) to ensure that a survey for asbestos is conducted prior to commencing work. The contractor shall ensure that all workers and subcontractors have received and documented initial and annual Asbestos Awareness training prior to the start of work.

b. Entry into Confined Spaces.
    1. The contractor shall provide the NIH COR a copy of its Confined Space Entry Program as part of the Site Specific Accident Prevention Plan submittal.
    2. Should the contractor employ subcontractors to work in confined spaces, it shall be the contractor's responsibility to submit the required documentation for each subcontractor.
    3. Work shall not start in a confined space until the required submittals have been made and appropriate safety precautions taken by the contractor. In the event the contractor does not comply with these regulations, ACCESS WILL BE DENIED.

c. Electrical - Safe Clearance Procedures
    1. Entry into High Voltage Areas: Work under this contract may require entry into High Voltage Areas.
    2. 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 COR.
    3. To prevent employee exposure or damage to electrical systems, the contractor shall exhaust all options and means to de-energize live electrical parts.

d. Fire Prevention: The contractor shall ensure that the fire prevention measures on-site are in accordance with OSHA, NIH Fire Department policies, and National Fire Protection agency (NFPA) 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 where required.
    1. Open Flame Devices: Prohibit the use of unapproved fuel-burning types of lanterns, torches, flares or other open-flame devices on NIH property.
    2. 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.

e. Excavating & Trenching:

1. Before work commences, entry excavations and trenches shall be evaluated for confined spaces.
2. Ensure a competent person inspects all excavations 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.
3. All excavations, regardless of depth, shall be barricaded or covered. If barricades are utilized and are left overnight they shall be equipped with appropriate lights or reflectors.
4. 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.

f. Construction activities that pose a potential risk of exposure to contaminated soil (such as excavations) shall be supervised by personnel who have a current 40-hour Hazardous Waste Supervisor's certification. 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 contaminated soil shall have a current 40-hour Hazardous Waste Certification and medical monitoring, in accordance with OSHA regulations. The contractor is responsible for soil sampling and air monitoring to determine hazards and exposures to their employees.

g. Cranes and Hoisting Operations

A written lift plan shall be submitted for all crane operations. The written lift plan will include as a minimum:

1. Make and model of the crane
2. Name of the crane operator, documentation of training and competent person responsible for the execution of the lift plan.
3. A copy of the crane's most recent certificate of annual inspection.
4. A copy of the cranes maximum loads at various boom angles and radii.
5. Utilizing the crane boom angle and radius information identify all loads that will exceed 75% of the crane capability.
6. Identify if two or more cranes are required.
7. Provide a sketch or drawing of the anticipated boom angle, radius, center of gravity and crane placement.
8. Provide a sketch or drawing of anticipated rigging methods to include:
    i. Number of slings
    ii. Type of configuration
    iii. Size and length of slings
    iv. Rated capacity of slings
    v. Sling angle
    vi. Size, number and rated capacity of shackles
9. Identify number of ground handlers and location of ground handlers
10. Communication method between ground handlers and crane operator
11. Location of material staging area
12. Method of managing vehicle and pedestrian traffic

h. 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. Material Safety Data Sheets for each chemical must be maintained on site.

i. Protection of the Public: The contractor shall submit a plan for the protection of the public on or adjacent to construction and demolition operations.

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ARTICLE H.57.15. 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's (COR's) or Contracting Officer's discretion:
    1. Removal and replacement of management personnel.
    2. 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.
    3. Hiring an independent 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 COR.
    4. Conduct a "Safety Stand Down" (suspend all work or any action thereof). Suspended work shall not be allowed to resume until the contractor has completed the required actions for review and acceptance by the NIH COR.
    5. 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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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.)****

ARTICLE H.58. SECURITY

GENERAL

a. The Contractor and all subcontractor's personnel will observe and adhere to all National Institutes of Health (NIH) security regulations and requirements 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.

b. 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.

c. 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:
    1. Companies: Name of each company performing the work.
    2. Personnel: Name, social security number, date and place of birth, citizenship and, where applicable, visa status of each individual who is to work.
    3. Time: The exact time, date, and hours of work.
    4. Areas: Specific areas of the building in which work is to be performed.

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ARTICLE H.58.1. CONTRACTOR RESPONSIBILITY

a. Contractors shall be responsible for security of their property and material from theft and vandalism.

b. The Government does not accept responsibility for loss or damage to any property or work it has not accepted.

c. Contractors shall be responsible for excluding all but authorized persons from their work sites.

d. 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).

e. 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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ARTICLE H.58.2. CONTRACTOR SECURITY PLAN

a. 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.

b. 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.

c. 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.

d. The Contractor Security Plan shall include provisions to address various Security Alert Levels as determined by the Department of Homeland Security.

e. 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.

   The Contract specific Contractor Security Plan seeks to achieve the following security goals:

   1. Screen contractor workforce consistent with NIH policies and procedures.
   2. Safeguard NIH employees and assets from events or persons who could cause harm.
   3. 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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ARTICLE H.58.3. CONTRACTOR PERSONNEL

a. 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 all 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.
    d. In addition to other disqualifying factors as determined by the NIH, the following shall apply:

        1. Conviction for tax evasion may disqualify contractor personnel being considered for sensitive positions.

2. 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 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, a period 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, but at least 15 minutes should be allowed 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.

b. Security Manager

1. 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.
2. 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.
3. The individual must be fluent in speaking and writing English.
4. The individual must undergo and pass a U.S. Government Background Investigation prior to receiving security sensitive information from the NIH Police.

5. The individual must be capable of understanding potential security problems, exploring issues and developing efficient and effective solutions.
6. 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.
7. 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.
8. The only duties and responsibilities of the construction security manager are to manage and implement the construction security program on this contract.

c. All personnel engaged on the Contract will be required to execute a National Institutes of Health Confidentiality Non-Disclosure Certification. (See Section J - List of Attachments.)

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ARTICLE H.58.4. SECURITY PROCEDURES

Upon commencement of the work under this contract, the following security procedures shall apply to the Contractor and all subcontractors.

a. Contractor personnel shall not enter the NIH campus without appropriate NIH ID Badge.

b. 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.

c. 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.

d. 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.

e. 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.

f. 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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ARTICLE H.59. OTHER ON-SITE

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ARTICLE H.59.1. 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, dropcloths, 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.59.2. 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.59.3. USE OF GOVERNMENT BUILDING FACILITIES

General

Where the term "NIH Reservation" appears herein, it shall be defined as also including all "off reservation" facilities.

a. 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.

b. 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.

c. 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.

d. 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 used 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 used NIH toilet facilities. The Contractor shall make arrangements for portable toilet facilities.

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ARTICLE H.59.4. MATERIAL DELIVERY, STORAGE AREAS AND DEBRIS REMOVAL

a. 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.

b. 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.

c. 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.

d. Combustible debris and trash must be removed from the work site daily.

e. No corridor or stairwell can be locked, blocked, closed or used for storage without the written permission of the COR.

f. 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.59.5. CONSTRUCTION DEBRIS

The ORF Division of Environmental Protection (DEP) 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.59.6. FIRE PREVENTION

a. 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.

b. 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.

c. 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.

d. 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.

e. 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.59.7. 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 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 collects loading dock cardboard at each dock in the mornings and afternoons.

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ARTICLE H.59.8. ENVIRONMENTAL

a. The contractor shall strictly follow all the conditions and requirements in the Maryland Department of the Environment (MDE)-approved drawings.

b. Inspect all the erosion and sediment control measures daily and perform necessary repairs.

c. 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/out side of the site cleaning) performed.

d. Make the above inspection log available upon request by NIH-Division of Environmental Protection (DEP) representative and/or MDE inspector.

e. Completely cover any dirt/stock piles with plastic tarp at the end of every business day regardless of the weather condition.

f. 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.

g. 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.

h. 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.

i. 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.

j. As-built drawings of the stormwater management features shall be provided to DEP upon completion.

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ARTICLE H.59.9. 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".

b. 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 (i.e., 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.59.10. MOTOR VEHICLE AND PARKING REGULATIONS

a. 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.

b. 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.

c. 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.

d. 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.

e. 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.59.11. PARKING REGULATIONS

Parking Policy for Construction Personnel and Miscellaneous Contract Service Vehicles at the National Institutes of Health (NIH) Bethesda, Maryland Campus.

The purpose of this clause is to establish clear directives for parking of Construction/Contract service vehicles and their personnel.
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.59.12. 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…Poolsville, 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 (to be determined)
    1. When revisions are made, distribute updated plans to the same parties.

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.59.13. 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.59.14. GROUNDS, ROADS AND WALKWAYS

a. Contractors shall perform their work in such a manner as to cause minimum damage to roads, walkways, and plantings, including lawns, shrubs, and trees. Any damaged items not specifically designated in the contract specifications for demolition, removal or alteration shall be restored to original condition or replaced, as satisfactory to the Contracting Officer Representative (COR). Ground areas disturbed during construction shall be landscaped and planted to original condition as promptly as possible. During the progress of the contract the Contractor shall, within the construction area, protect and maintain all plant material including lawns and temporary ground cover by mowing, spraying, watering, etc., sufficient to provide a level of maintenance conforming to that of other areas of the Reservation, and at no time shall weeds or undesirable grasses be allowed to seed.

b. Contractors shall not create obstruction to the flow of traffic on NIH roadways, including temporary reductions in horizontal or vertical clearances, except in accordance with schedules and by such means satisfactory to the COR.

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ARTICLE H.59.15. SANITATION AND FOOD SERVICES

a. 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.

b. 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).

c. 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, backcharging the Contractor for this service.

d. No food or drinks are allowed within the building.

e. 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.

f. The government will provide catered food services under a separate contract. General contractor is to coordinate locations and time schedules.

g. 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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ARTICLE H.59.16. 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 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 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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ARTICLE H.59.17. 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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ARTICLE H.59.18. RELEASE OF INFORMATION

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 provided a commercially available encryption software compatible with Microsoft Outlook approved in advance for use by The NIH.

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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ARTICLE H.60. WORK BY THE GOVERNMENT

a. 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 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.

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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ARTICLE H.60.1. 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 Task Order 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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ARTICLE H.60.2. 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 Representative (COR); 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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ARTICLE H.61. 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 Maryland 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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ARTICLE H.61.1. 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 Representative (COR), replacements shall match the existing in dimensions, finish, color, and design.

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ARTICLE H.61.2. 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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ARTICLE H.62. CONTRACTOR FURNISHED ITEMS

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

ARTICLE H.62.1. CONTRACTOR MACHINERY AND STORAGE

a. 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.
b. 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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ARTICLE H.62.2. 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.

a. Motor vehicles and trailers shall have and display valid license plates.
b. There are no fueling facilities on either campus. Bulk gasoline storage containers over five (5) gallons are not permitted.
c. 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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ARTICLE H.62.3. PRODUCT AND SERVICE GUARANTEE

All materials and workmanship shall be guaranteed for a period of one (1) year from date of final Government acceptance of the work.

Manufacturer's descriptive data shall include:

- Name of the product
- Certificates of compliance attesting that material(s)/product meets the requirements specified in the Task Order.
- Model number and any other applicable identifying information,
- Catalog cut,
- Performance data including ratings, curves, mounting/support details, and construction details for all equipment.
- Application/installation instructions that clearly illustrates the proposed item meets the applicable standards specified; and
- Testing, adjusting and balancing (TAB) reports of existing conditions for air and water systems.

Materials with lead, asbestos, or mercury are unacceptable for use for Task Order and shall not be provided.

Product samples shall include a sufficient quantity of material to allow for Government analysis and evaluation.

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ARTICLE H.62.4. 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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ARTICLE H.62.5. 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 that 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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ARTICLE H.63. PARTNERING

a. 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.

b. 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:
   1. A quality project done right the first time.
   2. 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 will 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.)****

ARTICLE H.64. CONTRACTOR QUALITY CONTROL (CQC) PROGRAM

a. 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.

b. 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:

    1. 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.
    2. The name(s) and qualifications of the individual(s) tasked to perform the quality control inspections, and the extent of their authority.
    3. A method for identifying deficiencies in the quality of services performed and taking corrective action before the level of performance becomes mandatory.

c. 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.)****

ARTICLE H.65. DESIGN BUILD CONTRACT - ORDER OF PRECEDENCE

a. 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 of that agreement.

b. 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:
    1. Betterments: Any portions of the Offeror's proposal which both meet and exceed the provisions of the solicitation.
    2. The provisions of the solicitation. (See also FAR Clause 52.236-21, Specifications and Drawings for Construction.)
    3. All other provisions of the accepted proposal.
    4. 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

a. 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.

b. 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.

c. The rights and remedies of the Government provided for under this contract are in addition to any other rights and remedies provided by law.

d. If the Contractor is comprised of more than one legal entity shall be jointly and severally liable there under.

SEQUENCE OF DESIGN-CONSTRUCTION

a. 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.

b. 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.

c. 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)

a. 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.

b. 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.

c. 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.

PRECONSTRUCTION CONFERENCE . (FAR 36.305)

a. A preconstruction conference will be arranged by the contracting officer after award of contract and before commencement of work. The contracting officer or designated representative will notify the Contractor of the time and date set for the meeting. At this conference, the Contractor shall be oriented with respect to Government procedures and line of authority, contractual, administrative, and construction matters.

b. The Contractor shall bring to this conference, in completed form, a Certificate of Insurance, plus the following items in either completed or draft form:

   Accident Prevention Plan (5 copies)
   Quality Control Plan (5 copies)
   Letter Appointing Superintendent
   Transmittal Register
   Power of Attorney and Certified Copy of Resolution
   Network Analysis System, when applicable
   List of Subcontractors

c. A letter of record will be written documenting all items discussed at the conference, and a copy will be furnished by the contracting officer to all in attendance.

PAYMENT FOR DESIGN UNDER FIXED-PRICE DESIGN-BUILD CONTRACTS

a. 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.

b. 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.

UNSCHEDULED JOBSITE SHUTDOWNS

Due to security reasons during the life of this contract the government may on an unscheduled basis ask the contractor to shutdown their jobsite for 2 days per year.

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ARTICLE H.66. EMERGENCY TASK ORDER PROCEDURES

Emergency work is defined as work of such an unusual or compelling nature that the NIH would suffer serious or irreparable damage if the work is not completed immediately. The Government reserves the right to award an emergency Task Order to any IDIQ contract holder related to this IDIQ.

Emergency work is received by the Government Call Center through the MS2000 system. The Contracting Officer Representative (COR) notifies the Contractor telephonically of the nature and the location of the emergency; and, the Contractor, upon receipt of a Contracting Officer's verbal or written Notice to Proceed (NTP) shall mobilize without delay in response to such calls be on-site and ready to commence work at the designated time arranged by the COR.

Where the Contract is specifically directed to perform designated emergency work, the Contractor shall be entitled to add a surcharge to his standard (non-premium time) labor rates when work is performed outside of regular work hours. For emergency work outside normal work hours, the Contractor shall use the fixed labor rates for Evening/Weekend work as identified in the Fixed Labor Rate tables in Section B of the contract.

The COR will accompany the Contractor to inspect finished emergency Task Order work upon notification by the Contractor that work is complete before the Contractor is released.

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****(USE BELOW IN CONTRACTS WHICH IN WHICH INFORMATION TECHNOLOGY SERVICES AND/OR SUPPLIES WILL BE ACQUIRED. **Note:** *This special provision includes three (3) Year 2000 Warranties covering different situations. Review the prescriptions for each. The contract may require use of one or more of these warranties depending on the requirement* .)****

ARTICLE H.67. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

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****(USE WHEN ACQUIRING SERVICES INVOLVING THE USE OF COMPUTER ITEMS IN THE PERFORMANCE OF THE REQUIREMENT.)****

1. **Service Involving the Use of Information Technology**

YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

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****(USE WHEN ACQUIRING CUSTOM COMPUTER ITEMS (E.G., HARDWARE, SOFTWARE AND SYSTEMS). **Note:** *The words "Listed Below" in the clause refer to items that the Offeror has identified as being Year 2000 compliant in response to the procuring agency's specifications* .)****

2. **Noncommercial Supply Items Warranty**

YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS

The Contractor warrants that each noncommercial item of hardware, software, and firmware delivered or developed under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with the item documentation provided by the Contractor, provided that all listed or unlisted items (e.g., hardware, software and firmware) used in combination with such listed item properly exchange date data with it. If the contract requires that specific listed items must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed items as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of any general warranty provisions of this contract provided that notwithstanding any provision to the contrary in such warranty provision(s), or in the absence of any such warranty provision(s), the remedies available to the Government under this warranty shall include repair or replacement of any listed item whose noncompliance is discovered and made known to the Contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

YEAR 2000 COMPLIANT ITEMS

(End of Clause)

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****(USE WHEN ACQUIRING YEAR 2000 COMPLIANT SOFTWARE, HARDWARE AND SYSTEMS COMPRISED OF COMMERCIAL INFORMATION TECHNOLOGY PRODUCTS. THE WORDS "LISTED BELOW" IN THE CLAUSE REFER TO PRODUCTS THAT THE OFFEROR HAS IDENTIFIED AS BEING YEAR 2000 COMPLIANT IN RESPONSE TO THE PROCURING AGENCY'S SPECIFICATIONS.)****

3. **Commercial Supply Products Warranty**

YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS

The Contractor warrants that each hardware, software and firmware product delivered under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in

accordance with the product documentation provided by the Contractor, provided that all listed or unlisted products (e.g., hardware, software, firmware) used in combination with such listed product properly exchange date data with it. If the contract requires that specific listed products must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed products as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of the Contractor's standard commercial warranty or warranties contained in this contract, provided that notwithstanding any provision to the contrary in such commercial warranty or warranties, the remedies available to the Government under this warranty shall include repair or replacement of any listed product whose non-compliance is discovered and made known to the Contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

YEAR 2000 COMPLIANT ITEMS

(End of Clause)

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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*.) ****

ARTICLE H.68. 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's 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.)****

ARTICLE H.69. 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.

307

****(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.)****

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: http://www.ott.nih.gov/mta-policy .

The contractor shall coordinate with the **NCI Technology Transfer Center** (see http://ttc.nci.nih.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.

309

****(USE BELOW FOR CONTRACTS THAT REQUIRE A "DATA SHARING PLAN" FOR SHARING OF FINAL RESEARCH DATA.

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.70. SHARING RESEARCH DATA

[The data sharing plan submitted by the Contractor is acceptable/The Contractor's data sharing plan, 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.

The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

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 the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data

intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

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****(USE BELOW WHEN CONTRACT PERFORMANCE WILL INVOLVE POSSESSION, USE OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS. **Note:** *At t his time, may only be applicable to NIAID projects*.)****

ARTICLE H.71. 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 (http://www.selectagents.gov/Regulations.html) 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 mailto: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 http://funding.niaid.nih.gov/researchfunding/sci/biod/pages/saconproc.aspx . 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 http://www.selectagents.gov/ and http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html .

For foreign institutions, see the NIAID Select Agent Award information:
(http://funding.niaid.nih.gov/researchfunding/sci/biod/pages/default.aspx).

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****(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* .)****

ARTICLE H.72. 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:

1. The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)(http://www.cdc.gov/biosafety/publications/index.htm under "Publications);
2. The Contractor's Institutional Biosafety Committee (IBC) or equivalent body; or
3. 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.

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****(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.73. 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: http://apps.usfa.fema.gov/hotel/ .

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****(USE BELOW, IN ALL SOLICITATIONS AND CONTRACTS FUNDED WITH APPROPRIATED BIO-DEFENSE FUNDS. **Note:** *At t his time, may only be applicable to NIAID projects* .)****

ARTICLE H.74. 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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****(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* .)****

ARTICLE H.75. GOVERNMENT CONTROL OVER UNDELIVERED AND/OR UNPUBLISHED RECORDS AND DATA

a. 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 punchcards, 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.
b. 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.
c. 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.

d. 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.
e. 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.

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**** (USE BELOW IN ALL RFPs & CONTRACTS WITH EDUCATIONAL INSTITUTIONS.) ****

ARTICLE H.76. 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.

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****(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:

- 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 IC EO, NIH Director or HHS Deputy Secretary as applicable in accordance with the NIH Policy Memorandum Implementation Guidance of the HHS Efficient Spending Policy, dated June 15, 2012. See http://oamp.od.nih.gov under Efficient Spending Policy.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- **3rd Paragraph:**
  - Complete the information in the Table for any conferences or meetings that have been approved at the time of award.
  - Remove this paragraph, including the Table, if conferences and/or meetings have not been approved at the time of award.)****

ARTICLE H.77. 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		

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****(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.78. 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's 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.

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****(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.79. 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.

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****(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.80. 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:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHERE THE POSSIBILITY EXISTS THAT THE CONTRACTOR WILL PROVIDE OR PURCHASE PROMOTIONAL ITEMS.)****

ARTICLE H.81. 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.

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****(USE BELOW IF NONE OF THE ABOVE CLAUSES ARE APPLICABLE.)****

THERE ARE NO ARTICLES CONTAINED IN THIS SECTION.

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**** (USE THE FOLLOWING IN ALL RFP's & CONTRACTS.) ****

PART II - CONTRACT CLAUSES

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**** (USE THE FOLLOWING IN ALL RFP's & CONTRACTS.) ****

SECTION I - CONTRACT CLAUSES

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****(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:
http://oamp.od.nih.gov/DGS/generalClauses.aspx

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ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE ARCHITECT-ENGINEER CONTRACT

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ARTICLE I.1. GENERAL CLAUSES FOR A FIXED-PRICE CONSTRUCTION CONTRACT

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ARTICLE I.1. GENERAL CLAUSES FOR A FIXED-PRICE RESEARCH AND DEVELOPMENT SBIR PHASE I CONTRACT

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ARTICLE I.1. GENERAL CLAUSES FOR A FIXED-PRICE RESEARCH AND DEVELOPMENT SBIR PHASE II CONTRACT

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ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SBIR PHASE II CONTRACT

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ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS

331

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT CONTRACT WITH NON-PROFIT ORGANIZATIONS OTHER THAN EDUCATIONAL INSTITUTIONS

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ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT

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ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT

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ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SUPPLY CONTRACT

335

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE RESEARCH AND DEVELOPMENT CONTRACT

336

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE SERVICE CONTRACT

337

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE SUPPLY CONTRACT

338

ARTICLE I.1. GENERAL CLAUSES FOR A SEALED BID CONSTRUCTION CONTRACT

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ARTICLE I.1. GENERAL CLAUSES FOR A SEALED BID SERVICE CONTRACT

340

ARTICLE I.1. GENERAL CLAUSES FOR A SEALED BID SUPPLY CONTRACT

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ARTICLE I.1. GENERAL CLAUSES FOR A TIME AND MATERIAL OR A LABOR HOUR CONTRACT

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

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:

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****(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** (July 2013) is deleted in its entirety and FAR Clause **52.204-12, Data Universal Numbering System Number Maintenance** (December 2012) is substituted therefor.*

   *FAR Clause **52.232-33, Payment By Electronic Funds Transfer--System for Award Management** (July 2013) is deleted in its entirety and FAR Clause **52.232-34, Payment by Electronic Funds Transfer--Other Than System for Award Management** (July 2013) is substituted therefor.*

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****(USE BELOW WHEN CONTRACTING BY SEALED BIDDING, IN ALL SOLICITATIONS AND CONTRACTS, IF THE ACQUISITION WILL USE RECOVERY ACT FUNDS.)****

b. ***Alternate I** (March 2009) of FAR Clause **52.214-26, Audit and Records--Sealed Bidding** (October 2010) is added.*

346

****(USE BELOW WHEN CONTRACTING BY NEGOTIATION, IN ALL SOLICITATIONS AND CONTRACTS, IF THE ACQUISITION WILL USE RECOVERY ACT FUNDS.)****

c. ***Alternate I** (March 2009) of FAR Clause **52.215-2, Audit and Records--Negotiation** (October 2010) is added.*

347

****(USE BELOW FOR COST REIMBURSEMENT CONTRACTS OVER THE SIMPLIFIED ACQUISITION THRESHOLD WHEN THE CONTRACT IS WITH A STATE OR LOCAL GOVERNMENT.)****

d. ***Alternate II** (April 1998) of FAR Clause **52.215-2, Audit and Records--Negotiation** (October 2010) is added.*

348

****(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** (October 1997) of FAR Clause **52.215-14, Integrity of Unit Prices** (October 2010) is added.

349

****(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** (October 2010); **52.215-18, Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, **52.215-19** , **Notification of Ownership Changes** (October 1997), are deleted in their entirety.

350

****(USE BELOW IN SOLICITATIONS AND CONTRACTS OF ANY TYPE **OTHER THAN** COST-REIMBURSEMENT and/or VALUED AT LESS THAN THE SIMPLIFIED ACQUISITION THRESHOLD WHEN THE CONTRACTING OFFICER DETERMINES THAT INCLUSION OF THE CLAUSE IS APPROPRIATE. For further information, see FAR Clause 52.215-23.)****

g. *FAR Clause **52.215-23, Limitations on Pass-Through Charges** (October 2009), is added.*

351

****(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** (October 2010) of FAR Clause **52.215-21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data--Modifications** (October 2010) is added.*

352

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN A COST-PLUS-INCENTIVE-FEE IS CONTEMPLATED.)****

i. FAR Clause **52.216-8, Fixed Fee** (June 2011) is deleted in its entirety and FAR Clause **52.216-10, Incentive Fee** (June 2011) is substituted therefor.

353

****(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 $650,000 [$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** (July 2013), and **52.219-16, Liquidated Damages--Subcontracting Plan** (January 1999) are deleted in their entirety.

354

****(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** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (July 2013) is added.

355

****(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** (July 2010) of FAR Clause **52.219-9** , **Small Business Subcontracting Plan** (July 2013) is added.

356

****(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** (December 2010) is deleted in its entirety.

357

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR:

- Awards NOT expected to exceed the simplified acquisition threshold; **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** (August 2013) is deleted in its entirety.

358

****(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 Act--Supplies** (June 2003) is deleted in its entirety and FAR Clause **52.225-3, Buy American Act--Free Trade Agreements--Israeli Trade Act** (November 2012) is substituted therefor.
Alternate I (March 2012) [is/is not] applicable to this contract.
Alternate II (March 2012) [is/is not] applicable to this contract.
Alternate III (NOV 2012) [is/is not] applicable to this contract.

359

****(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 Act--Supplies** (June 2003) is deleted in its entirety and FAR Clause **52.225-5, Trade Agreements** (November 2013) is substituted therefor.

360

****(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** (April 1984), of FAR Clause **52.227-1, Authorization and Consent** (December 2007) is deleted in its entirety.
FAR Clause **52.227-11, Patent Rights--Ownership by the Contractor** (December 2007) is deleted in its entirety.

Alternate IV (December 2007), of FAR Clause **52.227-14, Rights In Data--General** (December 2007) is deleted in its entirety.

Alternate II (April 2012), of FAR Clause **52.245-1, Government Property** (April 2012) is deleted in its entirety.

361

****(USE BELOW WHEN BOTH COMPLETE CONTRACT PERFORMANCE AND DELIVERY ARE OUTSIDE OF THE UNITED STATES.)****

r. FAR Clause **52.227-1, Authorization and Consent** (December 2007), and
FAR Clause **52.227-2, Notice and Assistance Regarding Patent and Copyright Infringement** (December 2007) are deleted in their entirety.

362

****(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** (December 2007) is deleted in its entirety.

363

****(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** (April 1984)
- FAR Clause **52.203-5, Covenant Against Contingent Fees** (April 1984)
- FAR Clause **52.203-6, Restrictions on Subcontractor Sales to the Government** (September 2006)
- FAR Clause **52.203-7, Anti-Kickback Procedures** (October 2010)
- FAR Clause **52.203-8, Cancellation, Recission, and Recovery of Funds for Illegal or Improper Activity** (January 1997)
- FAR Clause **52.203-10, Price or Fee Adjustment for Illegal or Improper Activity** (January 1997)
- 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** (October 2010)
- FAR Clause **52.215-14, Integrity of Unit Prices** (October 2010)
- FAR Clause **52.219-8, Utilization of Small Business Concerns** (July 2013)
- FAR Clause **52.219-14, Limitations on Subcontracting** (December 1996)
- FAR Clause **52.222-40, Notification of Employee Rights Under the National Labor Relations Act** (December 2010)
- FAR Clause **52.229-3, Federal, State and Local Taxes** (February 2013)
- FAR Clause **52.232-2, Payments under Fixed-Price Research and Development Contracts** (April 1984)
- FAR Clause **52.232-17, Interest** (October 2010)
- FAR Clause **52.242-13, Bankruptcy** (July 1995)
- FAR Clause **52.244-5, Competition in Subcontracting** (December 2010)

The following clause(s) is substituted as follows:

- FAR Clause **52.249-1, Termination for the Convenience of the Government (Fixed-Price)(Short Form)** (April 1984) is deleted in its entirety and **FAR Clause 52.249-2, Termination for the Convenience of the Government (Fixed Price)** (April 2012) is substituted therefor.

364

****(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)** (February 2013) is added in its entirety.

365

****(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** (February 2013) is deleted in its entirety, and FAR Clause **52.229-4, Federal, State and Local Taxes (State and Local Adjustments)** (February 2013) is substituted therefor.

366

****(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** (February 2013), is deleted in its entirety, and FAR Clause **52.229-6, Taxes--Foreign Fixed-Price Contracts** (February 2013) is substituted therefor.

367

****(USE BELOW IN FIXED PRICE SOLICITATIONS AND CONTRACTS WITH FOREIGN GOVERNMENTS.)****

x. FAR Clause **52.229-3, Federal, State and Local Taxes** (February 2013) is deleted in its entirety, and FAR Clause **52.229-7, Taxes--Fixed-Price Contracts with Foreign Governments** (February 2013) is substituted therefor.

368

****(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** (October 2010) is applicable to this contract.

369

****(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** (October 2010) is deleted.

370

****(USE BELOW IN ALL COST REIMBURSEMENT INCREMENTALLY FUNDED SOLICITATIONS AND CONTRACTS)****

aa. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 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.]**

371

****(USE BELOW IN COST-REIMBURSEMENT R&D SOLICITATIONS AND CONTRACTS FOR SUPPLIES.)****

bb. **Alternate I** (February 2002), of FAR Clause **52.232-25, Prompt Payment** (July 2013) is deleted.

372

****(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** (July 2013), is deleted in its entirety and FAR Clause **52.232-36, Payment By Third Party** (July 2013) is substituted therefor.

373

****(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**, (December 1991), of FAR Clause **52.233-1, Disputes** (December 1998) is added.

374

****(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** (November 1991) of FAR Clause **52.236-13, Accident Prevention** (November 1991), is added.

375

****(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** (April 1984) is applicable to this contract.

FAR Clause **52.236-3, Site Investigations and Conditions Affecting the Work** (April 1984) is applicable to this contract.

FAR Clause **52.236-6, Superintendence by the Contractor** (April 1984) is applicable to this contract.

FAR Clause **52.236-8, Other Contracts** (April 1984) is applicable to this contract.

FAR Clause **52.236-9, Protection of Existing Vegetation, Structures, Equipment, Utilities and Improvements** (April 1984) is applicable to this contract.

FAR Clause **52.236-10, Operations and Storage Areas** (April 1984) is applicable to this contract.

FAR Clause **52.236.11, Use and Possession Prior to Completion** (April 1984) is applicable to this contract.

FAR Clause **52.236-12, Cleaning Up** (April 1984) is applicable to this contract.

FAR Clause **52.236-13, Accident Prevention** (November 1991) is applicable to this contract.

FAR Clause **52.236-21, Specifications** (February 1997)

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

376

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR FIXED-PRICE REQUIREMENTS WHEN SERVICES **AND** SUPPLIES ARE TO BE FURNISHED.)****

gg. **Alternate I** (April 1984) of FAR Clause **52.243-1, Changes, Fixed Price** (August 1987), is hereby deleted in its entirety and **Alternate II** (April 1984) of FAR Clause **52.243-1, Changes, Fixed Price** (August 1987), is substituted therefor.

377

****(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** (October 2010) is applicable to this contract.

378

****(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** , (September 1996), of FAR Clause **52.249-2, Termination for Convenience of the Government (Fixed-Price)** (April 2012) is added.

379

****(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,** (September 1996), of FAR Clause **52.249-2, Termination for Convenience of the Government (Fixed-Price)** (April 2012) is added.

380

****(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** , (September 1996) and **Alternate III** , (September 1996), of FAR Clause **52.249-2, Termination for Convenience of the Government (Fixed-Price)** (April 2012) are added.

381

****(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)** (April 2012), **Alternate I** (September 1996), is deleted in its entirety and FAR Clause **52.249-1, Termination for Convenience of the Government (Fixed-Price) (Short Form)** (April 1984) is substituted therefor.

382

****(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)** (April 2012), is deleted in its entirety and FAR Clause **52.249-1, Termination for Convenience of the Government (Fixed-Price) (Short Form)** (April 1984) is substituted therefor.

383

****(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)** (April 1984), is deleted in its entirety and FAR Clause **52.249-2, Termination for Convenience of the Government (Fixed Price)** (April 2012) is substituted therefor.

384

****(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,** (September 1996), of FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (September 1996) is added.

385

****(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** , (September 1996), of FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (September 1996) is added.

386

****(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** , (September 1996) and **Alternate V** , (September 1996), of FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (September 1996) are added.

387

****(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** (April 1984), are deleted in their entirety and FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)** (September 1996), is substituted therefore.

388

****(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)** (April 1984) is applicable to this contract.

389

****(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)** (April 1984) is deleted in its entirety and FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)** (September 1996), is substituted therefore.

390

****(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)** (April 1984) is applicable to this contract.

391

****(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)** (April 1984) is applicable to this contract.

392

****(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** (April 1984) is deleted in its entirety and FAR Clause **52.216-8 Fixed Fee** (June 2011) is substituted therefor.

FAR Clause **52.232-17, Interest** (October 2010) is added.

FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Non-Profit Institutions)** (April 1984) is deleted in its entirety and FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (May 1986) is substituted therefor.

393

****(USE BELOW IN A COST-REIMBURSEMENT CONTRACT WITH A STATE AGENCY THAT IS **PARTIALLY** IMMUNE FROM TORT LIABILITY.)****

xx. **Alternate I** (April 1984) of HHSAR Clause **352.228-7, Insurance--Liability to Third Persons** (December 1991) is added.

394

****(USE BELOW IN A COST-REIMBURSEMENT CONTRACT WITH A STATE AGENCY THAT IS **TOTALLY** IMMUNE FROM TORT LIABILITY.)****

yy. **Alternate II** (April 1984) of HHSAR Clause **352.228-7, Insurance--Liability to Third Persons** (December 1991) is added.

395

****(USE BELOW IN COST-REIMBURSEMENT SOLICITATIONS AND CONTRACTS WITH:

1. A foreign government or agency of the government; or
2. An international organization or a subsidiary body of that organization that the HCA determines would not be appropriate.)****

zz. HHSAR Clause **352.242-74, Final Decisions on Audit Findings** (April 1984) is deleted in its entirety.

396

****(USE BELOW IF NONE OF THE ABOVE CLAUSES ARE APPLICABLE.)****

aaa. THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.

397

****(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.

398

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

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

399

****(USE BELOW IN SOLICITATIONS AND CONTRACTS EXPECTED TO EXCEED $5,000,000 AND THE PERFORMANCE PERIOD IS 120 DAYS OR MORE.)****

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (April 2010).

400

****(USE BELOW FOR ALL SOLICITATIONS AND CONTRACTS EXPECTED TO EXCEED $5,000,000 UNLESS THE CONTRACT IS FOR THE ACQUISITION OF A COMMERCIAL ITEM 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)** (December 2007).
   ".....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf

401

****(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(June 2010).

402

****(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** (December 2011).

403

****(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** (August 1996).
   Alternate I (April 1984) [is/is not] applicable to this contract.
   Alternate II (April 1984) [is/is not] applicable to this contract.

404

****(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** (January 2011).

405

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS FUNDED IN WHOLE OR IN PART WITH RECOVERY ACT FUNDS, EXCEPT CLASSIFIED SOLICITATIONS AND CONTRACTS. THIS INCLUDES, BUT IS NOT LIMITED TO , GOVERNMENTWIDE ACQUISITION CONTRACTS (GWACs), MULTI-AGENCY CONTRACTS (MACs), FEDERAL SUPPLY SCHEDULE (FSS) CONTRACTS, OR AGENCY INDEFININTE-DELIVERY/INDEFINITE QUANTITY (ID/IQ) CONTRACTS THAT WILL BE FUNDED WITH RECOVERY ACT FUNDS.)****

7. Far Clause **52.204-11, American Recovery and Reinvestment Act--Reporting Requirements** (July 2010).

406

****(USE BELOW (or a clause substantially the same) IN SOLICITATIONS AND CONTRACTS THAT INVOLVE A LEASE WITH OPTION TO PURCHASE.)****

8. FAR Clause **52.207-5, Option to Purchase Equipment** (February 1995).

407

****(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 DUNS NUMBER, OR IN CLASSIFIED SOLICITATIONS, CONTRACTS OR ORDERS.)****

9. FAR Clause **52.204-14**, **Service Contract Reporting Requirements** (January 2014).

408

****(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 DUNS NUMBER, OR IN CLASSIFIED SOLICITATIONS, CONTRACTS OR ORDERS.)****

10. FAR Clause **52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts** (January 2014).

409

****(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** (April 2002).

410

****(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** (October 2008).

411

****(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** (September 1989).
    Alternate I (January 1997) [is/is not] applicable to this contract.
    Alternate II (September 1989) [is/is not] applicable to this contract.

412

****(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** (September 1989).
    Alternate I (January 1997) [is/is not] applicable to this contract.
    Alternate II (September 1989) [is/is not] applicable to this contract.

413

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN USING FUNDS APPROPRIATED IN FY 2008 THROUGH FY 2010, UNLESS WAIVED IN ACCORDANCE FAR 9.108-4.

Note: This prohibition does not apply as follows:

1. When using Fiscal Year 2008 funds for any contract entered into before December 26, 2007, or for any order issued pursuant to such contract;
2. When using Fiscal Year 2009 funds for any contract entered into before March 11, 2009, or for any order issued pursuant to such contract;
3. When using Fiscal Year 2010 funds for any contract entered into before December 16, 2009, or for any order issued pursuant to such contract.)****

15. FAR Clause **52.209-10, Prohibition on Contracting With Inverted Domestic Corporations** (May 2012).

414

****(USE BELOW IN SOLICITATIONS AND CONTRACTS OVER $5 MILLION FOR THE PROCUREMENT OF ITEMS OTHER THAN COMMERCIAL ITEMS.)****

16. FAR Clause **52.210-1, Market Research** (April 2011).

415

****(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** (September 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."

416

****(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** (September 2000).

417

****(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** (January 1997).

418

****(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** (June 2011).

419

****(USE BELOW IN COST SHARING RFPs & 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** (April 1984).
    Alternate I (April 1984) [is/is not] applicable to this contract.

420

****(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** (April 1998).

421

****(USE BELOW IN INDEFINITE DELIVERY, DEFINITE-QUANTITY SOLICITATIONS AND CONTRACTS.)****

23. FAR Clause **52.216-20, Definite Quantity** (October 1995).

    "(d) ...the Contractor shall not be required to make any deliveries under this contract after _____ [insert date]..."

422

****(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** (October 1997).

423

****(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** (March 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] ...."

424

****(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** (March 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] ...."

425

****(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** (November 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].

426

****(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** (November 2011).

427

****(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** (November 2011), FAR Clause **52.219-3, Notice of HUBZone Set-Aside or Sole Source Award** (November 2011).

428

****(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** (January 2011).

    "(c) Waiver of evaluation preference.....
    [ ] Offeror elects to waive the evaluation preference."

429

****(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** (January 2011), FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (January 2011).

430

****(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.
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.)****

32. FAR Clause **52.219-6, Notice of Total Small Business Set-Aside** (November 2011).
    Alternate I (November 2011) [is/is not] applicable to this contract.
    Alternate II (November 2011) [is/is not] applicable to this contract.

431

****(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** (June 2003).
    Alternate I (October 1995) [is/is not] applicable to this contract.
    Alternate II (March 2004) [is/is not] applicable to this contract.

432

****(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** (November 2011).

433

****(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** (November 2011).

434

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT CONSIDER THE EXTENT OF PARTICIPATION OF SDB CONCERNS IN PERFORMANCE OF THE CONTRACT.)****

36. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (July 2013).

435

****(THE CONTRACTING OFFICER MAY USE (when contracting by negotiation) THE FOLLOWING OR A CLAUSE SUBSTANTIALLY THE SAME AS THE ONE BELOW WHEN AUTHORIZED AS OUTLINED IN FAR 19.1203.)****

37. FAR Clause **52.219-26, Small Disadvantaged Business Participation Program--Incentive Subcontracting** (October 2000).

    "(b) If the Contractor exceeds its total monetary target for subcontracting to small disadvantaged business concerns in the authorized NAICS Industry Subsectors, it will receive _ percent of the dollars in excess of the monetary target, unless the Contracting Officer determines that the excess was not due to the Contractor's efforts...."

436

****(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).)****

38. FAR Clause **52.219-27, Notice of Service-Disabled Veteran-Owned Small Business Set-Aside** (November 2011).

437

****(USE BELOW FOR ALL SOLICITATIONS AND CONTRACTS WHEN THE CONTRACT WILL BE PERFORMED IN THE UNITED STATES OR ITS OUTLYING AREAS.)****

39. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013).

438

****(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.)****

40. FAR Clause **52.219-29, Notice of Set-Aside for Economically Disadvantaged Women-Owned Small Business Concerns** (July 2013).

439

****(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.)****

41. FAR Clause **52.219-30** , **Notice of Set-Aside for Women-Owned Small Business Concerns Eligible Under the Women-Owned Small Business Program** (July 2013).

440

****(USE BELOW IN RFPs & 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 items.*)****

42. FAR Clause **52.222-4, Contract Work Hours and Safety Standards Act - Overtime Compensation - General** (July 2005).

441

****(USE BELOW IN SOLICITATIONS FOR CONSTRUCTION WITHIN THE U.S. IN EXCESS OF $2,000.)****

43. FAR Clause **52.222-5, Davis-Bacon Act--Secondary Site of the Work** (July 2005).

442

****(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.)****

44. FAR Clause **52.222-29, Notification of Visa Denial** (June 2003).

443

****(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.)****

45. FAR Clause **52.222-34, Project Labor Agreement** (May 2010)
    Alternate I [is/is not] applicable to this contract.

444

****(**USE IN SOLICITATIONS:**

- WHEN THE PROVISION AT 52.222-48, Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Certification 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 ACT DOES NOT APPLY.)****

46. FAR Clause **52.222-51, Exemption from Application of the Service Contract Act to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Requirements** (November 2007).

445

****(**USE IN SOLICITATIONS:**

- WHEN THE PROVISION AT 52.222-52, Exemption from Application of the Service Contract Act to Contracts for Certain Services--Certification 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 ACT DOES NOT APPLY.)****

47. FAR Clause **52.222-53, Exemption from Application of the Service Contract Act to Contracts for Certain Services--Requirements** (February 2009).

446

****(USE BELOW IN SERVICE OR CONSTRUCTION SOLICITATIONS AND CONTRACTS, UNLESS THE CONTRACT WILL NOT INVOLVE THE USE OF USDA-DESIGNATED ITEMS AT http://www.biopreferred.gov/ or 7 CFR Part 2902.)****

48. FAR Clause **52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts** (September 2013).

447

****(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)****

49. FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (January 1997), with **Alternate I** (July 1995).

448

****(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.)****

50. 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.

449

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR CONTRACTOR OPERATION OF GOVERNMENT OWNED OR LEASED FACILITIES AND FOR SUPPORT SERVICES AT SUCH FACILITIES.)****

51. FAR Clause **52.223-10, Waste Reduction Program** (May 2011).

450

****(USE BELOW 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.)****

52. FAR Clause **52.223-12, Refrigeration Equipment and Air Conditioners** (May 1995).

451

****(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.)****

53. FAR Clause **52.223-15, Energy Efficiency in Energy-Consuming Products** (December 2007).

452

****(USE BELOW IN SOLICITATIONS AND CONTRACTS (performed in the United States) FOR:

- PERSONAL COMPUTER PRODUCTS;
- SERVICES THAT REQUIRE FURNISHING OF PERSONAL COMPUTER PRODUCTS FOR USE BY THE GOVERNMENT; OR
- CONTRACTOR OPERATION OF GOVERNMENT-OWNED FACILITIES.

Note: *See FAR 23.705 for additional information in case an exception to the requirement is necessary*.)****

54. FAR Clause **52.223-16, IEEE 1680 Standard for the Environmental Assessment of Personal Computer Products** (December 2007).

453

****(USE BELOW IN ALL SERVICE AND CONSTRUCTION SOLICITATIONS AND CONTRACTS **UNLESS** THE CONTRACT WILL NOT INVOLVE THE USE OF EPA-DESIGNATED ITEMS.)****

55. FAR Clause **52.223-17, Affirmative Procurement of EPA-designated Items in Service and Construction Contracts** (May 2008).

454

****(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.*)****

56. FAR Clause **52.223-19, Compliance with Environmental Management Systems** (May 2011).

455

****(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.)****

57. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).

456

58. FAR Clause **52.224-2, Privacy Act** (April 1984).

457

****(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.)****

59. FAR Clause **52.225-8, Duty-Free Entry** (October 2010).

458

(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.)****

60. FAR Clause **52.225-26, Contractors Performing Private Security Functions Outside the United States** (July 2013).

459

****(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* .)****

61. FAR Clause **52.226-1, Utilization of Indian organizations and Indian-owned Economic Enterprises** (June 2000).

460

****(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.)****

62. FAR Clause **52.226-4, Notice of Disaster or Emergency Area Set-Aside** (November 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 boundries.]....."*

461

****(USE BELOW IN SOLICITATIONS & CONTRACTS THAT INVOLVE LOCAL AREA SET-ASIDES. See FAR Part 26.2.)****

63. FAR Clause **52.226-5, Restrictions on Subcontracting Outside Disaster or Emergency Area** (November 2007).

462

****(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.)****

64. **Alternate II** (December 2007), FAR Clause **52.227-1, Authorization and Consent** (December 2007).

463

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT MAY RESULT IN THE DELIVERY OF COMMERCIAL ITEMS, 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 items, 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 items, 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.) ****

65. FAR Clause **52.227-3, Patent Indemnity** (April 1984).

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

(c) This patent
indemnification shall not apply to the following items:
N/A

Alternate II (April 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.

464

****(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*.)****

66. FAR Clause **52.227-13, Patent Rights--Ownership by the Government** (December 2007).

465

****(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* .) ****

67. FAR Clause **52.227-14, Rights in Data - General** (December 2007).

466

****(USE BELOW WHEN THE ALTERNATE DEFINITION OF LIMITED RIGHTS DATA IS APPROPRIATE. See FAR 27.404-2(b).)****

68. **Alternate I** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

467

****(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.)****

69. **Alternate II** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

Additional purposes for which the limited rights data may be used are:

468

****(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.)****

70. **Alternate III** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

    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:

469

****(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.)****

71. **Alternate IV** (December 2007), FAR Clause **52.227-14, Rights in Data - General** (December 2007).

470

****(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.)****

72. **Alternate V** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

    Specific data items that are not subject to paragraph (j) include:

471

****(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).)* ****

73. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

472

****(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.)****

74. FAR Clause **52.227-17, Rights in Data--Special Works** (December 2007).

473

****(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.)****

75. FAR Clause **52.227-18, Rights in Data--Existing Works** (December 2007).

474

****(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.)****

76. FAR Clause **52.227-19, Commercial Computer Software License** (December 2007).

475

****(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 specifed in the contract. Use the text box below to specify this information or to identify where, in the contract, this information is located.)****

77. FAR Clause **52.227-21, Technical Data Declaration, Revision, and Withholding of Payment--Major Systems** (December 2007).
The following technical information is applicable to this clause:

476

****(USE BELOW WHEN A BID GUARANTEE IS REQUIRED - LANGUAGE MAY BE MODIFIED FOR NEGOTIATED CONTRACTS. See FAR 28.101-2 for additional prescriptive information.)****

78. FAR Clause **52.228-1, Bid Guarantee** (September 1996).

"The amount of the bid guarantee shall be % of the bid price or $ whichever is less."

477

****(USE BELOW WHEN BONDS ARE REQUIRED.)****

79. FAR Clause **52.228-2, Additional Bond Security** (October 1997).

478

**** (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.) ****

80. FAR Clause **52.228-5, Insurance - Work on a Government Installation** (January 1997).

479

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHICH REQUIRE THE SUBMISSION OF BID GUARANTEES, PERFORMANCE OR PAYMENT BONDS.)****

81. FAR Clause **52.228-11, Pledges of Assets** (September 2009).

480

****(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 Items*.)****

82. FAR Clause **52.228-12, Prospective Subcontractor Requests for Bonds** (October 1995).

481

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR SERVICES, SUPPLIES OR CONSTRUCTION, WHEN A BID GUARANTEE, OR PERFORMANCE AND PAYMENT BONDS ARE REQUIRED.)****

83. FAR Clause **52.228-14, Irrevocable Letter of Credit** (December 1999).

482

****(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.)****

84. FAR Clause **52.229-8, Taxes-Foreign Cost-Reimbursement Contracts** (March 1990).

483

****(USE BELOW IN SOLICITATIONS AND CONTRACTS TO BE AWARDED ON A COST-REIMBURSEMENT BASIS WITH A FOREIGN GOVERNMENT.)****

85. FAR Clause **52.229-9, Taxes-Cost-Reimbursement Contracts with Foreign Governments** (March 1990).

484

****(USE BELOW IN NEGOTIATED CONTRACTS OVER $700,000 - 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 .)****

86. FAR Clause **52.230-2, Cost Accounting Standards** (May 2012).

485

****(USE BELOW IN NEGOTIATED CONTRACTS OVER $700,000 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 .)****

87. FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (May 2012).

486

****(USE BELOW IN NEGOTIATED CONTRACTS OVER $700,000 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 .)****

88. FAR Clause **52.230-4, Disclosure and Consistency of Cost Accounting Practices for Contracts Awarded to Foreign Concerns** (May 2012).

487

****(USE BELOW IN NEGOTIATED CONTRACTS AND SUBCONTRACTS AWARDED TO EDUCATIONAL INSTITUTIONS, WHEN THE CONTRACT OR SUBCONTRACT PRICE EXCEEDS $700,000, 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.)****

89. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (May 2012).

488

****(USE BELOW IN NEGOTIATED CONTRACTS THAT CONTAIN EITHER FAR CLAUSES 52.230-2, 52.230-3, or 52.230-5.)****

90. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (June 2010).

489

****(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.)****

91. FAR Clause **52.232-18, Availability of Funds** (April 1984).

490

****(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.)****

92. FAR Clause **52.232-36, Payment by Third Party** (July 2013).

491

****(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.)****

93. FAR Clause **52.232-37, Multiple Payment Arrangements** (May 1999).

492

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR SERVICES TO BE PERFORMED AT GOVERNMENT FACILITIES AND TECHNICAL REPRESENTATIVES ADVISE THAT SPECIAL PRECAUTIONS ARE APPROPRIATE.)****

94. FAR Clause **52.236-13, Accident Prevention** (November 1991), with **Alternate I** (November 1991).

493

****(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.)****

95. FAR Clause **52.236-16, Quantity Surveys** (April 1984).

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

494

****(USE BELOW IN ALL ARCHITECT-ENGINEER SOLICITATIONS AND CONTRACTS EXCEPT AS STATED IN FAR 36.609-1(c).)****

96. 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 $ _____ ."

495

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR SERVICES TO BE PERFORMED ON A GOVERNMENT INSTALLATION. NOT APPLICABLE TO CONSTRUCTION CONTRACTS.)****

97. FAR Clause **52.237-2, Protection of Government Buildings, Equipment and Vegetation** (April 1984).

496

****(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.)****

98. FAR Clause **52.237-3, Continuity of Services** (January 1991).

497

****(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.")****

99. FAR Clause **52.237-7, Indemnification and Medical Liability Insurance** (January 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

498

****(USE BELOW IN SOLICITATIONS AND CONTRACTS FOR SERVICES THAT INVOLVE BUSINESS OPERATIONS CONDUCTED IN U.S. COINS AND CURRENCY, INCLUDING VENDING MACHINES, ON ANY PREMISES OWNED BY THE UNITED STATES OR UNDER THE CONTROL OF ANY AGENCY OR INSTRUMENTALITY OF THE U.S.)****

100. FAR Clause **52.237-11, Accepting and Dispensing of $1 Coin** (September 2008).

499

****(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.)****

101. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

500

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS OVER $700,000 EXCEPT FIXED PRICE CONTRACTS WITHOUT INCENTIVES OR ANY FIRM-FIXED-PRICE CONTRACT FOR COMMERCIAL ITEMS.)****

102. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

501

****(USE BELOW IN FIXED PRICE SOLICITATIONS AND CONTRACTS THAT PROVIDE FOR THE ESTABLISHMENT OF FINAL INDIRECT COST RATES.)****

103. FAR Clause **52.242-4, Certification of Final Indirect Costs** (January 1997).

502

****(THE BELOW SHOULD BE ADDED TO COST-REIMBURSEMENT CONTRACTS WITH EDUCATIONAL INSTITUTIONS WHENEVER POSSIBLE AND/OR APPROPRIATE.)****

104. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).

503

****(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*.)****

105. FAR Clause **52.244-2, Subcontracts** (October 2010).

504

****(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.)****

106. FAR Clause **52.244-5, Competition in Subcontracting** (December 1996).

505

****(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.)****

107. FAR Clause **52.245-1, Government Property** (April 2012).

506

****(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.)****

108. **Alternate I** (April 2012), FAR Clause **52.245-1, Government Property** (April 2012).

507

****(USE BELOW IN FIXED-PRICE SOLICITATIONS & CONTRACTS WITH EDUCATIONAL OR NONPROFIT INSTITUTIONS WHEN THE GOVERNMENT WILL PROVIDE GOVERNMENT PROPERTY.)****

109. **Alternate II** (April 2012), FAR Clause **52.245-1, Government Property** (April 2012).

508

****(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.)****

110. FAR Clause **52.245-2, Government Property (Installation Operation Services)** (April 2012).

509

****(USE IN ALL FIXED PRICE SOLICITATIONS AND CONTRACTS THAT WILL INCLUDE THE CLAUSE AT 52.245-1, Government Property.)****

111. FAR Clause **52.245-9, Use and Charges** (April 2012).

510

****(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.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Use with Alternate I** : If the Government has justified the use of any equipment by "brand name and model.")****

112. FAR Clause **52.246-21, Warranty of Construction** (April 1984).
Alternate I (April 1984) [is/is not] applicable to this contract.

511

****(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 Items* .

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.)****

113. FAR Clause **52.246-23, Limitation of Liability** (February 1997).

512

****(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 Items* .

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.)****

114. FAR Clause **52.246-24, Limitation of Liability - High-Value Items** (February 1997). **Alternate I** (April 1984) [is/is not] applicable to this contract

513

**** (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 items* .)****

115. FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).

514

****(USE BELOW IN SOLICITATIONS AND CONTRACTS, WHEN OCEAN TRANSPORTATION OF SUPPLIES IS ANTICIPATED.)****

116. FAR Clause **52.247-64, Preference for Privately Owned U.S. Flag Commercial Vessels** (February 2006).

515

****(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.)****

117. FAR Clause **52.247-68, Report of Shipment (REPSHIP)** (February 2006).

516

****(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.)****

118. FAR Clause **52.248-1, Value Engineering** (October 2010).

517

****(USE BELOW WHEN THE GOVERNMENT REQUIRES AND PAYS FOR A SPECIFIC VALUE ENGINEERING EFFORT IN ARCHITECT-ENGINEER CONTRACTS.)****

119. FAR Clause **52.248-2, Value Engineering Program - Architect-Engineer** (March 1990).

518

****(USE BELOW WHEN THE CONTRACTING OFFICER MAY AUTHORIZE THE CONTRACTOR TO ACQUIRE SUPPLIES AND SERVICES FROM A GOVERNMENT SUPPLY SOURCE.)****

120. FAR Clause **52.251-1, Government Supply Sources** (April 2012).

519

****(USE BELOW WHEN NONE OF THE ABOVE CLAUSES ARE APPLICABLE TO THE CONTRACT.)****

121. **THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.**

520

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

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

521

****(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.)****

1. HHSAR Clause **352.201-70, Paperwork Reduction Act** (January 2006).

522

****(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.)****

2. HHSAR Clause **352.219-71, Mentor-Protégé Program Reporting Requirements** (January 2010).

523

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INVOLVING HAZARDOUS MATERIALS OR OPERATIONS.)****

3. HHSAR Clause **352.223-70, Safety and Health** (January 2006).

524

****(USE BELOW IN EXTRAMURAL SOLICITATIONS AND CONTRACTS, WHEN A COST-REIMBURSEMENT, FIXED-PRICE LEVEL-OF-EFFORT, TIME-AND-MATERIALS, OR LABOR HOUR CONTRACT IS CONTEMPLATED. **NOTE:** *HHSAR 331.101-70(a), as revised in APM 2012-03, defines "EXTRAMURAL" as "...activities that a contractor undertakes for specified programmatic purposes, other than those of an administrative nature or in support of Federal laboratories, facilities, or information technology systems, through a formal and legally-binding contract.")* ****

4. HHSAR Clause **352.231-70, Salary Rate Limitation** (August 2012).

Note: *P.L. 112-74 sets forth the Salary Rate Limitation at the Executive Level II Rate, effective December 23, 2011.*

See the following Web site for Executive Schedule rates of pay: http://www.opm.gov/oca/ .

(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.)

525

****(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.)****

5. HHSAR Clause **352.233-70, Choice of Law (Overseas)** (October 2009).

526

****(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.)****

6. HHSAR Clause **352.237-70, Pro-Children Act of 1994** (January 2006).

527

****(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, INCLUDING, BUT NOT LIMITED TO, 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.)****

7. HHSAR Clause **352.237-71, Crime Control Act of 1990--Reporting of Child Abuse** (January 2006).

528

****(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.)****

8. HHSAR Clause **352.237-72, Crime Control Act--Requirement for Background Checks** (January 2006).

529

****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS WHEN SOME OR ALL OF THE CONTRACTOR'S PERFORMANCE WILL TAKE PLACE ON HHS PROPERTIES. ***Note:*** *This clause is not required when contractor staff will attend occasional meetings on HHS properties* . See HHSAR 342.302-(c)(3) for additional information on applicability requirements including Construction contracts.)****

9. HHSAR Clause **352.242-71, Tobacco-Free Facilities** (January 2006).

530

****(USE BELOW WHEN MEETINGS ARE REQUIRED BY THE STATEMENT OF WORK.)****

10. HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).

531

****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT PROVIDE FUNDING, IN WHOLE OR IN PART, TO SUPPORT A CONFERENCE.)****

11. HHSAR Clause **352.270-7, Conference Sponsorship Request and Conference Materials Disclaimer** (January 2010).

532

****(USE BELOW IN SOLICITATIONS AND CONTRACTS 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, TUB AND MALARIA ACT OF 2003. See HHSAR 370.701 for more information.)****

12. HHSAR Clause **352.270-8, Prostitution and Related Activities** (January 2010)
    Any enforcement of this clause is subject to Alliance for Open Society International v. USAID, 05 Civ. 8209 (S.D.N.Y., orders filed on June 29, 2006 and August 8, 2008)(orders gaining preliminary injunction) for the terms of the orders.

    The List of the members of the GHC and InterAction is found at: http://www.usaid.gov/business/business_opportunities/cib/pdf/GlobalHealthMemberlist.pdf

533

****(USE BELOW WHEN NONE OF THE ABOVE CLAUSES ARE APPLY TO THE CONTRACT.)****

13. THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.

534

****(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:

535

****(USE BELOW IN ALL CONTRACTS WITH THE WORLD HEALTH ORGANIZATION (WHO) AND ITS AGENCIES, e.g., PAN AMERICAN HEALTH ORGANIZATION (PAHO), INTERNATIONAL AGENCY FOR RESEARCH ON CANCER (IARC), ETC.)****

1. **NIH (RC)-8, Maintenance and Examination of Records** (6/26/89) (Comptroller General Memorandum - 5/16/89).

536

**** (USE BELOW IN ALL CONTRACTS WITH THE WORLD HEALTH ORGANIZATION AND ITS AGENCIES, e.g., PAN AMERICAN HEALTH ORGANIZATION (PAHO), INTERNATIONAL AGENCY FOR RESEARCH ON CANCER (IARC), ETC. INCLUDE D&F IN THE CONTRACT FILE, BUT NOT IN THE CONTRACT.)****

2. **NIH (RC)-9, Disputes** (Assistant Secretary for Health and Surgeon General Determinations and Findings (D&F), 9/28/79, 4/1/84).

537

****(USE BELOW IN SOLICITATIONS AND CONTRACTS INVOLVING PATIENT CARE.)****

3. **NIH(RC)-11, Research Patient Care Costs** (4/1/84).

538

****(FOR NLM USE ONLY . INCLUDE THE FOLLOWING WHEN NLM REQUIRES OWNERSHIP OF THE DATA FIRST PRODUCED UNDER THE CONTRACT.)****

4. **NLM(RC)--Rights in Data--Special Works** (11/30/97).

539

****(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.

540

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

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES

541

****(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.)****

1. *FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (July 2013)*

   As prescribed in 32.706-1(b), 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* http://www.acquisition.gov .
   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)

542

****(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.)****

2. FAR Clause **52.216-2, Economic Price Adjustment--Standard Supplies** (January 1997).

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 item 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)

543

****(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.)****

3. *FAR Clause **52.216-3, Economic Price Adjustment--Semi Standard Supplies** (JANUARY 1997)*
    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 item 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.*
        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)

544

****(USE BELOW IN INDEFINITE DELIVERY, DEFINITE-QUANTITY, REQUIREMENTS, OR INDEFINITE-QUANTITY RFPs & 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.)****

4. FAR Clause **52.216-18, Ordering** (October 1995).
   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)

545

****(USE BELOW [OR WORDS SUBSTANTIALLY THE SAME] IN INDEFINITE DELIVERY, DEFINITE-QUANTITY, REQUIREMENTS, OR INDEFINITE-QUANTITY SOLICITATIONS AND CONTRACTS.)****

5. FAR Clause **52.216-19, Order Limitations** (October 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.

546

****(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.)****

6. FAR Clause **52.216-21, Requirements** (October 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 (April 1984) [is not/is] applicable to this contract.

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

Alternate III (October 1995) [is not/is] applicable to this contract.

Alternate IV (October 1995) [is not/is] applicable to this contract.

547

****(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*.)****

7. FAR Clause **52.216-22, Indefinite Quantity** (October 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)

548

****(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.)****

8. FAR Clause **52.217-9, Option to Extend the Term of the Contract** (March 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].

549

****(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).)****

9. FAR Clause **52.223-7, Notice of Radioactive Materials** (January 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.

550

****(USE BELOW IN SOLICITATIONS AND CONTRACTS EXCEEDING $150,000 THAT ARE FOR, OR SPECIFY THE USE OF EPA DESIGNATED ITEMS CONTAINING RECOVERED MATERIALS.)****

10. 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*].

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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.)****

11. **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 IN SOLICITATIONS AND CONTRACTS FOR SUPPLIES CONTAINING OR MANUFACTURED WITH CLASS I OR CLASS II OZONE-DEPLETING SUBSTANCES OR CONTAINERS OF CLASS I OR CLASS II OZONE-DEPLETING SUBSTANCES.)****

12. FAR Clause **52.223-11, Ozone-Depleting Substances** (May 2001)

a. Definition. Ozone-depleting substance, as used in this clause, 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), and (d) and 40 CRF 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). "

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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 $7,777,000. ***Note:*** *The Contracting Officer must list all foreign construction material excepted from the requirements of the Buy American Act in paragraph (b)(2)* .)****

13. FAR Clause **52.225-9, Buy American Act--Construction Materials** (September 2010)

(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 item (as defined in paragraph (1) of the definition at 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 section 3 of the Shipping Act of 1984 (46 U.S.C. App. 1702), 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 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) An unmanufactured construction material mined or produced in the United States;
(2) A construction material manufactured in the United States, if--

(i) The cost of its components mined, produced, or manufactured in the United States exceeds 50 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; or
(ii) The construction material is a COTS item.

Foreign construction material means a construction material other than a domestic construction material.

United States means the 50 States, the District of Columbia, and outlying areas.

(b) *Domestic preference*.

(1) This clause implements the Buy American Act (41 U.S.C. 10a-10d) by providing a preference for domestic construction material. In accordance with 41 U.S.C. 431, the component test of the Buy American Act is waived for construction material that is a COTS item (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 item or to the construction material 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 Act is unreasonable when the cost of such material exceeds the cost of foreign material by more than 6 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 Act. (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 Act 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 Act applies, use of foreign construction material is noncompliant with the Buy American Act.

(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 and any applicable duty (whether or not a duty free entry certificate is issued).]

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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 $7,777,000 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 Act, other than designated country construction material* .)****

14. FAR Clause **52.225-11, Buy American Act--Construction Materials Under Trade Agreements** (November 2013)

(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 item (as defined in paragraph (1) of the definition at 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 section 3 of the Shipping Act of 1984 (46 U.S.C. App. 1702), such as agricultural products and petroleum products.

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.

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 country (Armenia, Aruba, 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, Netherlands, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, or United Kingdom);
(2) A Free Trade Agreement country (Australia, Bahrain, Canada, 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, East Timor, 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) An unmanufactured construction material mined or produced in the United States;
(2) A construction material manufactured in the United States, if--

(i) The cost of its components mined, produced, or manufactured in the United States exceeds 50 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; or
(ii) The construction material is a COTS item.

Foreign construction material means a construction material other than a domestic construction material.

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.

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 the Buy American Act (41 U.S.C. chapter 83) by providing a preference for domestic construction material. In accordance with 41 U.S.C. 1907, the component test of the Buy American Act is waived for construction material that is a COTS item (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 Act restrictions are waived for designated county 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 item 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 Act is unreasonable when the cost of such material exceeds the cost of foreign material by more than 6 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 Act or Balance of Payments Program. (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 Act 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 Act, use of foreign construction material is noncompliant with the Buy American Act.

(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:

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 and any applicable duty (whether or not a duty-free entry certificate is issued).]

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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 $7,777,000 OR MORE, BUT LESS THAN $10,074,262. ***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 Act, unless the excepted foreign construction material is from a designated country other than Bahrain, Mexico, and Oman* .)****

15. ***Alternate I*** *(March 2012), FAR Clause* ***52.225-11, Buy American Act--Construction Materials Under Trade Agreements*** *(November 2013)*

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) Construction materials. (1) This clause implements the Buy American Act (41 U.S.C. chapter 83) by providing a preference for domestic construction material. In accordance with 41 U.S.C. 1907, the component test of the Buy American Act is waived for construction material that is a COTS item (See FAR 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, NAFTA, and the Oman FTA apply to this acquisition. Therefore, the Buy American Act 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 $7,777,000. ***Note:*** *The Contracting Officer must list all foreign construction material excepted from the requirements of the Buy American Act in paragraph (b)(3).*) ****

16. FAR Clause **52.225-21, Required Use of American Iron, Steel, and Manufactured Goods-Buy American Act--Construction Materials** (October 2010)

(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 Act 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.)

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 .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. 11-5), 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) The Buy American Act (41 U.S.C. 10a-10d) 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 6 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 Act 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 Act.* (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 Act 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 Act applies, use of foreign construction material is noncompliant with section 1605 of the American Recovery and Reinvestment Act or the Buy American Act.

(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 $7,777,000 OR MORE. ***Note:*** *The Contracting Officer must list, in paragraph (b)(3) of the clause, all foreign construction material excepted from the Buy American Act or section 1605 of the Recovery Act, other than Recovery Act designated country construction material.*)****

17. FAR Clause **52.225-23, Required Use of American Iron, Steel, and Manufactured Goods--Buy American Act--Construction Materials Under Trade Agreements** (November 2013)

(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, 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, Netherlands, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, or United Kingdom);

(2) A Free Trade Agreement (FTA) country (Australia, Bahrain, Canada, Chile, Columbia, 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 Act 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, 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, Netherlands, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, Taiwan, or United Kingdom);

(2) A Free Trade Agreement country (FTA)(Australia, Bahrain, Canada, 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 .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 Act 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 Act 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 6 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 Act 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 Act.*

(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 Act 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 Act 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 Act.

(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)

558

****(WHEN USING RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS AND CONTRACTS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES, VALUED AT $7,777,000 OR MORE BUT LESS THAN $10,074,262. ***Note:*** *The Contracting Officer must list, in paragraph (b)(3) of the clause, all foreign construction material excepted from the Buy American Act 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.*)****

18. **Alternate I** (October 2010) FAR Clause **52.225-23, Required Use of American Iron, Steel, and Manufactured Goods-Buy American Act-Construction Materials under Trade Agreements** (November 2013)

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 Act 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 Act 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.

559

****(USE BELOW IN SOLICITATIONS AND CONTRACTS GREATER THAN $25,000 FOR THE PROVISION, SERVICE, OR SALE OF FOOD IN THE UNITED STATES.)****

19. FAR Clause **52.226-6, Promoting Excess Food Donation to Nonprofit Organizations** (March 2009)

(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.

560

****(USE BELOW IN RFPs AND CONTRACTS FOR CONSTRUCTION, WHEN THE ESTIMATED VALUE OF THE ACQUISITION EXCEEDS $30,000 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.)****

20. FAR Clause **52.228-13, Alternative Payment Protections** (July 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.

561

****(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.)****

21. FAR Clause **52.228-16, Performance And Payment Bonds--Other Than Construction** (November 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 .

562

****(USE BELOW WITH THE ABOVE CLAUSE (ALTERNATE I) WHEN ONLY PERFORMANCE BONDS ARE REQUIRED.)****

Alternate I (July 2000) of FAR Clause **52.228-16, Performance And Payment Bonds--Other Than Construction** (November 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.

563

****(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.)****

22. FAR CLAUSE **52.232-19, Availability of Funds for the Next Fiscal Year** (April 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.

564

****(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 & LIQUIDATION MUST BE PROVIDED AS REQUIRED BY FAR 32.1004.)****

23. FAR Clause **52.232-32, Performance-Based Payments** (April 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 inquires 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)

565

****(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.)****

24. FAR Clause **52.236-4, Physical Data** (April 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)

566

****(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)****

25. 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, multitank 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 umber 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.

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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.)****

26. FAR Clause **52.247-67, Submission of Transportation Documents for Audit** (February 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]

568

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

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

569

****(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.")****

a. HHSAR Clause **352.204-16, Prevention and Public Health Fund--Reporting Requirements** (March 2012).

(a) Pursuant to Public Law 112-74, FY2012 Labor, HHS and Education Appropriations Act, Sec. 220, 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 period.

(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)

570

****(USE BELOW SOLICITATIONS, CONTRACTS AND ORDERS TO DELIVER SERVICES UNDER HHS' PROGRAMS DIRECTLY TO THE PUBLIC.)****

b. HHSAR Clause **352.237-73, Non-Discrimination in Service Delivery** (March 2012). 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 sub¬contracts 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.

571

****(USE BELOW WHEN NO FULL TEXT FAR CLAUSES ARE APPLICABLE TO THE CONTRACT.)****

c. **THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.**

572

**** 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.

573

574

****(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) Concerns** (June 2003) **with Alternate For Acquisitions Under FAR 19.800 (Deviation)** (HHS/SBA PA - October 23, 2012 until amended)

(a) Offers are solicited only from (a) 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 and which meet the following criteria at the time of submission of offer--

(1) The Offeror is in conformance with the 8(a) support limitation set forth in its approved business plan; and
(2) The Offeror is in conformance with the Business Activity Targets set forth in its approved business plan or any remedial action directed by the SBA.

(b) By submission of its offer, the Offeror represents that it meets all of the 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) Agreement.

(1) A small business concern submitting an offer in its own name shall furnish, in performing the contract, only end items manufactured or produced by small business concerns in the United States or its outlying areas. If this procurement is processed under simplified acquisition procedures and the total amount of this contract does not exceed $25,000, a

small business concern may furnish the product of any domestic firm. This subparagraph does not apply to construction or service contracts.

(2) The _____ [INSERT THE 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 or other ownership interest to any other party.

575

**** (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** , (April 2005) is added to FAR Clause **52.219-18, Notification Of Competition Limited To Eligible 8(a) Concerns** (June 2003) as follows:

(a) (3) The offeror's approved business plan is on the file and serviced by _____ [CONTRACTING OFFICER INSERTS THE APPROPRIATE SBA DISTRICT AND/OR REGIONAL OFFICE(S) AS IDENTIFIED BY THE SBA].

576

**** (USE BELOW IF THIS CONTRACT IS FOR A PRODUCT IN A CLASS FOR WHICH THE SBA HAS WAIVED THE NONMANUFACTURE RULE.) ****

c. **Alternate II** (December 1996) is added to FAR Clause **52.219-18, Notification Of Competition Limited To Eligible 8(a) Concerns** (June 2003) as follows:
When the acquisition is for a product in a class for which the Small Business Administration has determined that there are no small business manufacturers or processors in the Federal market in accordance with 19.502-2(c), delete paragraph (d)(1).

577

****(USE BELOW FOR SOLICITATIONS SUBJECT TO THE SERVICE CONTRACT ACT.)****

Any contract awarded from this RFP will contain the following article:

ARTICLE I.6. SERVICE CONTRACT ACT

This contact is subject to the Service Contract Act of 1965. 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.

578

579

****(USE BELOW IN 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 OR WAIVED IN ACCORDANCE WITH FAR 22.1203-3).)****

a. FAR Clause **52.222-17 Nondisplacement of Qualified Workers** (January 2013)

580

**** (USE BELOW IN ALL SOLICITATIONS AND CONTRACTS OVER $2,500 SUBJECT TO THE SERVICE CONTRACT ACT) ****

b. FAR Clause **52.222-41, Service Contract Act of 1965** (November 2007).

581

**** (USE BELOW IN ALL SOLICITATIONS AND CONTRACTS SUBJECT TO THE SERVICE CONTRACT ACT.) ****

c. FAR Clause **52.222-42, Statement of Equivalent Rates For Federal Hires** (May 1989)

In compliance with the Service Contract Act of 1965 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)

582

**** (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 ACT, 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.) ****

d. FAR Clause **52.222-43, Fair Labor Standards Act and Service Contract Act--Price Adjustment (Multiple Year And Option Contracts)** (September 2009).

583

**** (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 ACT, 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.) ****

e. FAR Clause **52.222-44, Fair Labor Standards and Service Contract Act--Price Adjustment** (September 2009).

584

**** (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.) ****

f. FAR Clause **52.222-49, Service Contract Act--Place Of Performance Unknown** (May 1989)

> "(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]....."

585

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

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

586

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

SECTION J - LIST OF ATTACHMENTS

587

****(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:

587.1

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

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location

****(USE BELOW IN ALL SOLICITATIONS.

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

1. Fill out the appropriate form (R & D or Non R & D) from the Attachment Files - Section J Page on the NCI OA Internet site: http://oamp.od.nih.gov/DGS/DGS_Attachments.html under RFP Attachments.
2. Save the file.
3. Upload this file using the Attachment Manager.)****

Attachment 1:	Packaging and Delivery of Proposal (R & D)
Attachment 2:	Packaging and Delivery of Proposal (Non R & D)

Attachment No.	Title	Location

****(USE BELOW IN ALL SOLICITATIONS **EXCEPT** NCI OA.

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 NCI OA Internet site: http://oamp.od.nih.gov/DGS/DGS_Attachments.html under RFP Attachments:
   - **RFP No.**
   - **RFP Title**
   - Select either a **Receipt Date** or indicate that intent forms are due at " **earlest 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 3:	Proposal Intent Response Sheet	

****(**NCI OA:** USE BELOW IN ALL SOLICITATIONS.)****

Attachment 4:	Proposal Intent Response Sheet	http://rcb.cancer.gov/rcb-internet/forms/intent.jsp

****(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: http://oamp.od.nih.gov/DGS/DGS_Attachments.html under RFP Attachments.
2. **Annual Representations and Certifications,** FAR Clause 52.209-7): Fill out 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.)****

Attachment 8:	Information Technology Systems Security - Prospective Offeror Non-Disclosure Agreement	http://oamp.od.nih.gov/DGS/FORMS/IT-security-nondisclosure.pdf

****(USE FOR A PERFORMANCE BASED (PBA) REQUIREMENT WHERE INCENTIVE IS TIED TO FEE.

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

****(USE FOR A PERFORMANCE BASED (PBA) REQUIREMENT USING AN "AWARD TERM" INCENTIVE.

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

587.2

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

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	**Title**	**Location**

****(USE BELOW WHEN THE RESULTANT CONTRACT WILL INVOLVE HUMAN SUBJECTS, UNLESS THE GOV'T HAS DETERMINED INCLUSION OF WOMEN AND MINORITY GROUPS IN THE STUDY POPULATION IS NOT APPROPRIATE.)****

Attachment 11:	Targeted/Planned Enrollment Table, PHS-398/2590 (Rev. 6/09)	http://grants.nih.gov/grants/funding/phs398/enrollment.pdf

****(USE ONLY IF WHEN THE RESULTANT CONTRACT IS A FOLLOW ON OR RENEWAL INVOLVING HUMAN SUBJECTS THAT BEGAN COLLECTING DATA PRIOR TO FY-02 AND THE DATA COLLECTED DOES NOT FIT INTO THE 10/2001 STANDARDS SET FORTH IN TARGETED/PLANNED ENROLLMENT TABLE.)****

Attachment 12:	Inclusion Table (Formerly Annual Technical Progress Report Format for Each Study)	http://grants.nih.gov/grants/funding/women_min/InclusionOld_Form.pdf

****(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* .)****

Attachment 13:	Technical Proposal Cost Summary	http://oamp.od.nih.gov/DGS/FORMS/Tech-Prop-Cost-Summ.pdf

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

Attachment 14:	Summary of Related Activities	http://oamp.od.nih.gov/DGS/FORMS/summary-related-activities.pdf

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

Attachment No.	Title	Location
Attachment 15:	Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310)	http://www.hhs.gov/ohrp/assurances/forms/of310.pdf

****(USE BELOW IN R&D SOLICITATIONS INVOLVING LIVE VERTEBRATE ANIMALS (INCLUDING THEIR USE AS A SOURCE OF TISSUES.)****

Attachment 16:	Contract Proposal Vertebrate Animal Section (VAS) Worksheet	http://grants.nih.gov/grants/olaw/VAScontracts.pdf

****(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.)****

Attachment 17:	HHS Section 508 Product Assessment Template	http://www.hhs.gov/web/508/contracting/technology/vendors.html

587.3

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

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
****(USE IN ALL SOLICITATIONS.)****		
Attachment 18:	Proposal Summary and Data Record, NIH-2043	http://oamp.od.nih.gov/DGS/FORMS/NIH2043.pdf
****(USE IN SOLICITATIONS OVER $650,000 (OR $1.5 Million for construction of Public Facilities). ***Note:*** *This item* ***DOES NOT APPLY*** *to Small Businesses.*)****		
Attachment 19:	Small Business Subcontracting Plan	http://www.hhs.gov/about/smallbusiness/subcontractplan.html
****(USE IN ALL SOLICITATIONS UNLESS AWARD IS BASED ON ADEQUATE PRICE COMPETITION. See FAR 15.403-1.)****		
Attachment 20:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
****(USE AS DESIRED. THIS FORM IS OPTIONAL.)****		
Attachment 21:	Offeror's Points of Contact	http://oamp.od.nih.gov/DGS/FORMS/point-of-contact.pdf
****(USE WHEN CERTIFIED COST OR PRICING DATA IS REQUIRED.)****		
Attachment 22:	Certificate of Current Cost or Pricing Data	http://oamp.od.nih.gov/DGS/FORMS/cert-current-cost.pdf

Attachment No.	Title	Location

****(USE WHEN SERVICE CONTRACT ACT 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: http://wdol.gov . Save the file and upload it here.
2. Make sure to indicate the area covered by the Wage Rate Determination attached.)****

Attachment 23:	Wage Rate Determination	

****(USE BELOW IN ALL SOLICITATIONS WITH AN EXPECTED CONTRACT VALUE OVER $100,000)****

Attachment 24:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://www.gsa.gov/portal/forms/download/116430

587.4

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

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location

****(USE WHEN RESULTANT CONTRACT USE WORK ASSIGNMENTS.)****

Attachment 25:	Sample Work Assignment	http://oamp.od.nih.gov/DGS/FORMS/wkassign.pdf

****(USE WHEN RECIPIENT REIMBURSEMENT PROCEDURES WILL BE PART OF THE RESULTANT CONTRACT.)****

Attachment 26:	Monthly Summary Sheet of Sales	http://oamp.od.nih.gov/DGS/FORMS/monsales.pdf

****(USE AS REQUIRED.)****

Attachment No.	Title	Location
Attachment 27:	Invoice/Financing Request Instructions-CR-NIH(RC)-1	http://oamp.od.nih.gov/DGS/FORMS/rc1_508.pdf

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

Attachment 28:	NIDA Supplemental Billing Instructions, Exhibit A to NIH(RC)-1	http://oamp.od.nih.gov/DGS/FORMS/RC-1-NIDA.pdf

****(USE AS REQUIRED.)****

Attachment 29:	Invoice Instructions for NIH Fixed Price Contracts NIH(RC)-2	http://oamp.od.nih.gov/DGS/FORMS/rc2_508.pdf

****(USE AS REQUIRED.)****

Attachment 30:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://oamp.od.nih.gov/DGS/FORMS/rc4_508.pdf

****(USE AS REQUIRED.)****

Attachment 31:	Financial Report of Individual Project/Contract NIH 2706	http://oamp.od.nih.gov/DGS/FORMS/NIH2706.pdf

Attachment No.	Title	Location

****(USE AS REQUIRED.)****

Attachment 32:	Instructions for Completing Form NIH 2706	http://oamp.od.nih.gov/DGS/FORMS/instructions2706.pdf

****(USE AS REQUIRED. MAKE SURE TO INCLUDE THE APPLICABLE SYSTEM OF RECORDS NUMBER IN THE SPACE PROVIDED.)****

Attachment 33:	Privacy Act System of Records	http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm

****(USE WHEN THE RESULTANT CONTRACT WILL INVOLVE HAZARDOUS MATERIALS OR OPERATIONS.)****

Attachment 34:	Safety and Health, HHSAR Clause 352.223-70	http://oamp.od.nih.gov/DGS/FORMS/Safety-Health-hhsar-1-06.pdf

****(USE WHEN THE RESULTANT CONTRACT WILL INVOLVE PATIENT CARE.)****

Attachment 35:	Research Patient Care Costs, NIH(RC)-11	http://oamp.od.nih.gov/DGS/FORMS/rc11.pdf

****(USE WHEN THE RESULTANT CONTRACT WILL INVOLVE HUMAN SUBJECTS, UNLESS THE GOV'T HAS DETERMINED INCLUSION OF WOMEN AND MINORITY GROUPS IN THE STUDY POPULATION IS NOT APPROPRIATE.)****

Attachment 36:	Inclusion Enrollment Report	http://grants.nih.gov/grants/funding/phs398/enrollmentreport.pdf

****(USE AS REQUIRED.)****

Attachment 37:	Government Property Schedule	To be determined during negotiations.

Attachment No.	Title	Location

****(USE BELOW WHEN THE RESULTANT CONTRACT WILL BE OVER $100,000.)****

Attachment 38:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://www.gsa.gov/portal/forms/download/116430

****(USE WHEN THE RESULTANT CONTRACT IS SUBJECT TO IT SECURITY REQUIREMENTS.)****

Attachment 39:	Commitment to Protect Non-Public Information Contractor Agreement	https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf

****(USE WHEN THE RESULTANT CONTRACT IS SUBJECT TO IT SECURITY REQUIREMENTS.)****

Attachment 40:	Roster of Employees Requiring Suitability Investigations	https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx

****(USE WHEN THE RESULTANT CONTRACT IS SUBJECT TO IT SECURITY REQUIREMENTS.)****

Attachment 41:	Employee Separation Checklist	https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf

****(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.)****

Attachment No.	Title	Location
Attachment 42:	Contract Performance Reports (EVM)	Format 1: Work Breakdown Structure http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-1.pdf Format 2: Organizational Categories http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-2.pdf Format 3: Baseline http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-3.pdf Format 4: Staffing http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-4.pdf Format 5: Explanations and Problem Analyses http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-5.pdf

****(USE BELOW IN ALL SOLICITATIONS FOR CONFERENCES WHEN REGISTRATION FEES WILL BE CHARGED AND COLLECTED.)****

Attachment 43:	Conference Expense Offset Worksheets	Contractor Pre-Conference Expense Offset Worksheet, 1 page. Located at: http://oamp.od.nih.gov/DGS/FORMS/Pre-Conf-worksheet.pdf Post Conference Expense Offset Worksheet, 2 pages. Located at: http://oamp.od.nih.gov/DGS/FORMS/Post-Conf-worksheet.pdf

588

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

PART IV - REPRESENTATIONS AND INSTRUCTIONS

589

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

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

590

****(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: http://www.sam.gov ; 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.

591

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

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

592

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

1. **GENERAL INFORMATION**

593

****(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 Provision 52.215-1 (January 2006)]*

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.*

i. *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.*

ii. *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.

(1) The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification)."

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

"Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(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 contract 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 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 items, the make and model of the item 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)

594

****(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 (*October 1997).As prescribed in 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.

595

****(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 *(October 1997). As prescribed in 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.

596

****(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 (October 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)

597

****(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.

598

****(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.

599

****(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.

600

****(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 _____ .

601

****(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.

602

****(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.
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.

603

****(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 $3,000, 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).

a. **Exceptions to Fair Opportunity**

Contractors may not be given an opportunity to be considered for requirements in excess of $3,000 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.

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.
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.

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 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.

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 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.

604

****(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 _____ .

605

****(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. NCI- _____ ." 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.

606

****(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.

607

****(USE BELOW, WHEN A 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

608

****(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 FEDBIZOPPS 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 Provision 52.211-6)

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)

609

****(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.

610

****(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 , 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 3, 2012, 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, 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 January 30, 2012, Memorandum, entitled, "NIH Guidance Related to the HHS Policies on Promoting Efficient Spending: Use of Appropriated Funds for Conferences, Conference Grants and Meetings, Food, Promotional Items, and Printing and Publications." (See http://oamp.od.nih.gov/)

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.

611

****(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.

612

****(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.

613

****(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 __ , Executive Plaza South, 6120 Executive Boulevard, Rockville, Maryland, 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.

614

****(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.

615

****(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.

616

****(USE BELOW, IN ALL SOLICATIONS. Make sure to complete the address below.)****

u. **SERVICE OF PROTEST** (SEPTEMBER 2006) - FAR 52.233-2

(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)

617

****(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 (January 2006)
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 the best 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)

618

****(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.

619

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

2. **INSTRUCTIONS TO OFFERORS**

620

****(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.

621

****(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.

622

****(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, DUNS 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.

623

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

3. **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).

624

****(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.)****

4. **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.

625

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

5. **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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6. **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.)****

7. **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 if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

628

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

8. **Evaluation of Proposals**

The Government will evaluate proposals in accordance with the factors set forth in PART IV, SECTION M of this RFP.

629

****(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.)****

9. **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.

630

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

10. **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.

631

****(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").)****

11. **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 .

632

****(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.)****

12. **Non-discrimination for Conscience, HHSAR 352.270-9 (January 2010)**
    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)

633

****(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.)****

13. **Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)**

Under the provisions of the Rights in Data General clause (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 BELOWIN ALL SOLICITATIONS.)****

14. **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.

635

****(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.)****

15. **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 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 315.370.

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 FedBizOpps.

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****(USE BELOW FOR ALL R&D REQUIREMENTS EXCEPT THOSE EXPECTED TO BE AWARDED TO A FEDERAL AGENCY.)****

16. **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: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45.

637

****(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* .)****

17. **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.

638

****(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. **Note:** *When preparing the information to include in this section, please refer to the instructions provided in Appendix 1 of NIH MANUAL ISSUANCE 6015-2, entitled PAST PERFORMANCE INFORMATION* .

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.)****

18. **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.

639

****(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.)****

19. **Time-and-Material/Labor-Hour Proposal Requirements--Non-Commercial Item Acquisitions without Adequate Price Competition, FAR 52.216-30 (February 2007**)

(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)

640

****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT LESS THAN $7,777,000.)****

20. **Notice of Buy American Act Requirement--Construction Materials , FAR 52.225-10 (February 2009)**

(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 Act--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 Act 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 Act 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 Act 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)

641

****(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 ACT PRIOR TO RECEIPT OF OFFERS.)****

Alternate I (May 2002), FAR 52.225-10, Notice of Buy American Act--Construction Materials (May 2002). 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 Act 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.

642

****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,777,000 OR MORE.)****

21. **Notice of Buy American Act Requirement--Construction Materials Under Trade Agreements, FAR 52.225-12 (February 2009)**

(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 Act--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 Act 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 Act 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 Act 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)

643

****(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 2002), FAR 52.225-12, Notice of Buy American Act Requirement--Construction Materials Under Trade Agreements (January 2005). 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 Act 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.

644

****(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 $7,777,000 OR MORE, BUT LESS THAN $10,074,262.)****

Alternate II (June 2009), FAR Clause **52.225-12, Notice of Buy American Act Requirement-Construction Materials Under Trade Agreements** (January 2005) **.** 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.

645

****(WHEN USING RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT LESS THAN $7,777,000.)****

22. **Notice of Required Use of American Iron, Steel, and Manufactured Goods--Buy American Act--Construction Materials, FAR 52.225-22 (October 2010)**

(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 Act--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 Act 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 1605 of the Recovery Act or the Buy American Act 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 Act 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) 6 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)

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****(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 ACT PRIOR TO RECEIPT OF OFFERS.)****

Alternate I (March 2009), **FAR 52.225-22, Notice of Required Use of American Iron, Steel, and Manufactured Goods--Buy American Act--Construction Materials** (October 2010). 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 Act 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.

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****(WHEN USING RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,777,000 OR MORE.)****

23. **Notice of Required Use Of American Iron, Steel, and Manufactured Goods--Buy American Act--Construction Materials Under Trade Agreements, FAR 52.225-24 (October 2010)**

(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 Act--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 Act 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 Act 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 Act 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) 6 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)

648

****(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.)****

Alternate I (March 2009), FAR 52.225-24, Notice of Required Use of American Iron, Steel, and Manufactured Goods-Buy American Act-Construction Materials under Trade Agreements (October 2010). 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 Act 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.

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****(WHEN USING RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,777,000 OR MORE, BUT LESS THAN $10,074,262.)****

Alternate II (March 2009), FAR 52.225-24, Notice of Required Use of American Iron, Steel, and Manufactured Goods-Buy American Act-Construction Materials under Trade Agreements (October 2010). 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.

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****(USE BELOW IN NEGOTIATED FIXED-PRICE REQUIREMENTS(excluding A & E and Construction contracts) WHERE PERFORMANCE-BASED CONTRACT FINANCING WILL BE PROVIDED.)****

24. **Invitation to Propose Performance-Based Payments, FAR 52.232-28 (March 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)

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****(USE BELOW, WITH 52.232-28 (above) IN COMPETITIVE NEGOTIATED SOLICITATIONS (excluding A & E and Construction contracts) IF THE GOVERNMENT INTENDS TO ADJUST PROPOSED PRICES FOR PROPOSAL EVALUATION PURPOSES (See FAR 32.1004(e).)****

Alternate I (March 2000), FAR 52.232-28, Invitation to Propose Performance-Based Payments (March 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).

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****(USE BELOW, IN ALL SOLICITATIONS FUNDED WITH APPROPRIATED BIO-DEFENSE FUNDS.
Note: *At this time, may only be applicable to NIAID projects* .)****

25. **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: http://www.hhs.gov/ocio/policy/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) - currently Thomas Mitchell, as 301-594-2750; nihisaopolicy@mail.nih.gov).

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Second paragraph:** Select "Technical" or "Business" as appropriate from the drop-down box.)****

26. **Information and Physical Access Security** 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.

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****(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 in Table 2, Position Sensitivity Designations for Individuals Accessing Agency Information at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Pages/table2.aspx .)****

A. **HHS-Controlled Facilities and Information Systems Security**

a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:

   1. HHS-OCIO Information Systems Security and Privacy Policy (http://www.hhs.gov/ocio/policy/#Security)
   2. HHS HSPD-12 Policy Document, v. 2.0 (http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf)

3. Information regarding background checks/badges
   (http://idbadge.nih.gov/background/index.asp)

c. Position Sensitivity Levels:
   This contract will entail the following position sensitivity levels:
   [ ] **Level 6: Public Trust - High Risk.** Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).
   [ ] **Level 5: Public Trust - Moderate Risk.** Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).
   [ ] **Level 1: Non-Sensitive.** Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

d. The personnel investigation procedures for Contractor personnel require that (upon award) the Contractor prepare and submit background check/investigation forms based on the type of investigation required. The minimum Government investigation for a non-sensitive position is a National Agency Check and Inquiries (NACI) with fingerprinting. More restricted positions - i.e., those above non-sensitive, require more extensive documentation and investigation.

   As part of its proposal, and if the anticipated position sensitivity levels are specified in paragraph (d) above, the Offeror shall notify the Contracting Officer of (1) its proposed personnel who will be subject to a background check/investigation and (2) whether any of its proposed personnel who will work under the contract have previously been the subject of national agency checks or background investigations.

   Upon award, the Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx .

   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.

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.

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.

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 shall 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 than the cost of the additional investigation(s). Accordingly, if position sensitivity levels are specified in paragraph (d) above, the Offeror shall ensure that the employees it proposes for work under this contract/order have a reasonable chance for approval.

g. 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).

h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer.

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 shall return all identification badges to the Contracting Officer or designee.

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****(INCLUDE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE THE OPERATION OR ACQUISITION OF AN INFORMATION SYSTEM.

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- An Information Security Policy Waiver available at: http://sps.nihcio.nih.gov/OCIO/NIH/documents/IT-Security-Forms/NIH-Policy-Waiver_Final.doc) must be approved in order to deviate from HHS OCIO STANDARD 2009-0001.001S, HHS STANDARD FOR SECURITY CONFIGURATIONS LANGUAGE IN HHS CONTRACTS, dated January 30, 2009. See HHSAR 330.101(d)(1) for further information.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Subparagraph b:**
  - Insert the IC/ISSO approved contract-specific configuration.
  - If there are no contract-specific configurations, insert: **"FDCC"**

Note: *Applicable security configuration requirements are based on information provided by the Project Officer, who shall consult with the OPDIV/STAFFDIV Chief Information Security Officer* .)****

B. **Standard for Security Configurations, HHSAR 352.239-70,** (January 2010)

a. The Contractor shall configure its computers that contain HHS data with the applicable Federal Desktop Core Configuration (FDCC) (see http://nvd.nist.gov/fdcc/index.cfm) and ensure that its computers have and maintain the latest operating system patch level and anti-virus software level.

Note: FDCC is applicable to all computing systems using Windows XPTM and Windows VistaTM, including desktops and laptops - regardless of function - but not including servers.

b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:

c. 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 FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC 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 FDCC major version and subsequent major versions.

d. The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.

e. The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.

f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (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.

g. The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

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****(INCLUDE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE THE ACQUISITION OR LEASE OF, OR THE REQUIREMENT TO USE, DESKTOP OR LAPTOP COMPUTERS, MOBILE DEVICES, OR PORTABLE MEDIA TO STORE OR PROCESS HHS SENSITIVE INFORMATION THAT THE PROJECT OFFICER CATEGORIZES AS MODERATE OR HIGH UNDER FEDERAL INFORMATION PROCESSING STANDARD (FIPS) 199, STANDARDS FOR SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS, DATED FEBRUARY 2004.

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- An Information Security Policy Waiver (See http://sps.nihcio.nih.gov/OCIO/NIH/Documents/IT-Security-Forms/NIH-Policy-Waiver_FINAL.doc) must be approved in order to deviate from HHS OCIO STANDARD 2009-0001.001S, HHS STANDARD FOR SECURITY CONFIGURATIONS LANGUAGE IN HHS CONTRACTS, dated January 30, 2009. See HHSAR 330.101(d)(1) for further information.)****

C. **Standard for Encryption language, HHSAR 352.239-71,** (January 2010)

a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004).

b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see http://csrc.nist.gov/cryptval/) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.

c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or

alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.

d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).

e. The Contractor shall ensure that this standard is incorporated into the Contractor's property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.

f. The Contractor shall ensure that its subcontractors (all tiers) which perform work under this contract comply with the requirements contained in this clause.

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

D. **Security Requirements For Federal Information Technology Resources, HHSAR 352.239-72,** (January 2010)

a. **Applicability** . This clause applies whether the entire contract or order (hereafter "contract"), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS' mission. The term "information technology (IT)", as used in this clause, 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. This clause does not apply to national security systems as defined in FISMA.

b. **Contractor responsibilities** . The Contractor is responsible for the following:

1. Protecting Federal information and Federal information systems in order to ensure their -

a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;

b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and
c. Availability, which means ensuring timely and reliable access to and use of information.

2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.
3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.

c. **Contractor security deliverables**. In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:

1. **IT Security Plan (IT-SP)** - due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.
    a. The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:
        i. Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automation Information Resources.
        ii. National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of

Federal Information Processing Standard (FIPS) 200, Recommend Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.

iii. HHS-OCIO Information Systems Security and Privacy Policy.

2. **IT Risk Assessment (IT-RA)** - due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor's final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.
3. **FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment)** - due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor's final version into the contract.
4. **IT Security Certification and Accreditation (IT-SC&A)** - due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems - see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security, Certification and Accreditation of Federal Information Systems; and NIST 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provided it to the Contracting Officer for review, comment, and acceptance.
    a. After resolution of any comments provided by the Government on the draft IT SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor's final version into the contract as a compliance requirement.
    b. The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:

i. Annual testing of the system contingency plan; and
ii. The performance of security control testing and evaluation.

d. **Personal identity verification.** The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer's Representative (COR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in "HHS-Controlled Facilities and Information Systems Security" requirements specified in the SOW/PWS of this contract.

e. **Contractor and subcontractor employee training.** The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COR evidencing that Contractor employees have completed the required training.

f. **Government access for IT inspection.** The Contractor shall afford the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.

g. **Subcontracts.** The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -

a. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or
b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.

h. **Contractor employment notice.** The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.

i. **Document information.** The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.

j. **Contractor responsibilities upon physical completion of the contract.** The Contractor shall return all HHS information and IT resources provided to the

Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.

k. **Failure to comply.** Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

(End of Clause)

Note: The NIST Special Publication SP-800-26 cited in subparagraph c.1.a.(ii) of this clause has been superseded by NIST SP 800-53A, "Guide for Assessing the Security Controls in Federal Information Systems and Organizations" for use for the assessment of security control effectiveness. See http://csrc.nist.gov/publications/PubsSPs.html to access NIST Special Publications (800 Series).

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE THE CLAUSE AT HHSAR 352.239-72, Security Requirements for Federal Information Technology Resources .)****

E. **Additional NIH Requirements**

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****(INCLUDE BELOW WHEN THE CONTRACTOR WILL 1) DEVELOP; 2) HAVE THE ABILITY TO ACCESS; OR 3) HOST AND/OR MAINTAIN A FEDERAL INFORMATION SYSTEM(S).

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Subparagraph a:** Select the appropriate general information type(s), and include a brief description of the specific type of information.
2. **Subparagraph b:** Select the Security Level for each Security category. The Overall Security Level is the highest level of the three factors (Confidentiality, Integrity, and Availability).

For additional information about Information Types and Security Levels, See:

- NIST SP 800-60 Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories, Appendices C and D, at: http://csrc.nist.gov/publications/nistpubs/800-60-rev1/SP800-60_Vol2-Rev1.pdf ; and,
- Table 1: Security Categorization of Federal Information and Information Systems , at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Pages/table1.aspx .)****

1. **SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS (FIPS 199 Assessment)**

a. Information Type:

[ ] Administrative, Management and Support Information:

[ ] Mission Based Information:

b. Security Categories and Levels:

Confidentiality Level:	[ ] Low	[ ] Moderate	[ ] High
Integrity Level:	[ ] Low	[ ] Moderate	[ ] High
Availability Level:	[ ] Low	[ ] Moderate	[ ] High

Overall Level: [ ] **Low** [ ] **Moderate** [ ] **High**

c. In accordance with HHSAR Clause 352.239-72, the contractor shall submit a FIPS 199 Assessment within 30 days after contract award. Any differences between the contractor's assessment and the information contained herein, will be resolved, and if required, the contract will be modified to incorporate the final FIPS 199 Assessment.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE THE CLAUSE AT HHSAR 352.239-72, Security Requirements for Federal Information Technology Resources.)****

2. **INFORMATION SECURITY TRAINING**

In addition to any training covered under paragraph (e) of HHSAR 352.239-72, the contractor shall comply with the below training:

a. Mandatory Training

i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information as defined at HHSAR 304.1300(a)(4), shall complete the NIH Computer Security Awareness Training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.

ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COR and/or Contracting Officer upon request.

b. Role-based Training

HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance about "NIH Information Security Awareness and Training Policy," at: https://ocio.nih.gov/InfoSecurity/Policy/Documents/Final-InfoSecAwarenessTrainPol.doc .

The Contractor shall maintain a list of all information security training completed by each contractor/subcontractor employee working under this contract. The list shall be provided to the COR and/or Contracting Officer upon request.

c. Rules of Behavior
The Contractor shall ensure that all employees, including subcontractor employees, comply with the NIH Information Technology General Rules of Behavior (https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx), which are contained in the NIH Information Security Awareness Training Course http://irtsectraining.nih.gov .

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INCLUDE THE CLAUSE AT HHSAR 352.239-72, Security Requirements for Federal Information Technology Resources.)****

3. **PERSONNEL SECURITY RESPONSIBILITIES**
In addition to any personnel security responsibilities covered under HHSAR 352.239-72, the contractor shall comply with the below personnel security responsibilities:

a. In accordance with Paragraph (h) of HHSAR 352.239-72, the Contractor shall notify the Contracting officer and the COR **within five working days** before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.

b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.

c. **Departing contractor employees:** The Contractor shall provide the COR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Docume

nts/Emp-sep-checklist.pdf) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COR upon request.

d. **Commitment to Protect Non-Public Departmental Information and Data.**
The Contractor, and any subcontractors performing under this contract, shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (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.

662

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN CONTRACTOR/SUBCONTRACTOR PERSONNEL WILL HAVE ACCESS TO, OR USE OF PERSONALLY IDENTIFIABLE INFORMATION (PII), INCLUDING INSTANCES OF REMOTE ACCESS TO OR PHYSICAL REMOVAL OF SUCH INFORMATION BEYOND AGENCY PREMISES OR CONTROL. FOR ADDITIONAL INFORMATION SEE:

- OMB Memorandum M-07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information, May 22, 2007 at: www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2007/m07-16.pdf
- NIH Incident Response Policy at: https://ocio.nih.gov/InfoSecurity/IncidentResponse/Pages/ir_guidelines.aspx .)****

4. **LOSS AND/OR DISCLOSURE OF PERSONALLY IDENTIFIABLE INFORMATION (PII) - NOTIFICATION OF DATA BREACH**

The Contractor shall report all suspected or confirmed incidents involving the loss and/or disclosure of PII in electronic or physical form. Notification shall be made to the NIH Incident Response Team (IRT) via email (IRT@mail.nih.gov) within one hour of discovering the incident. The

Contractor shall follow up with IRT by completing and submitting one of the applicable two forms below within three (3) work days of incident discovery:
NIH PII Spillage Report
at: https://ocio.nih.gov/InfoSecurity/Policy/Documents/NIH_PII_Spillage_Proced.doc
NIH Lost or Stolen Assets Report at:
https://ocio.nih.gov/InfoSecurity/Policy/Documents/ISSO_Stolen_Device-Media_Handling_Procedures.doc

663

****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHEN THE CONTRACTOR/SUBCONTRACTOR WILL HOST NIH WEB PAGES OR DATABASES.)****

5. **VULNERABILITY SCANNING REQUIREMENTS**

This acquisition requires the Contractor to host an NIH webpage or database. The Contractor shall conduct periodic and special vulnerability scans, and install software/hardware patches and upgrades to protect automated federal information assets. The minimum requirement shall be to protect against vulnerabilities identified on the SANS Top-20 Internet Security Attack Targets list (http://www.sans.org/top20/?ref=3706#w1). The Contractor shall report the results of these scans to the Project Officer/COR on a monthly basis, with reports due 10 calendar days following the end of each reporting period. The Contractor shall ensure that all of its subcontractors (at all tiers), where applicable, comply with the above requirements.

664

****(USEBELOW IN ALL SOLICITATIONS.)****

27. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 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):

665

****(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. Central Contractor Registration, FAR Provision 52.204-7 (December 2012).
Alternate I (December 2012) [is/is not] applicable to this solicitation.

666

****(USEBELOW IN ALL SOLICITATIONS THAT DO NOT CONTAIN THE PROVISION AT FAR 52.204-7, Central Contractor Registration (See FAR 4.1102(a) for additional information.) OR MEET A CONDITION AT FAR 4.605(c)(2).)****

b. Data Universal Numbering System Number, FAR Provision 52.204-6 (December 2012).

667

****(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, (April 1991).

668

****(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, (April 1991).

669

****(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, (October 1997).

670

****(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).

671

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

g. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

672

****(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, (October 2009).

673

****(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, (October 1995).

674

****(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, (February 2007).

675

****(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, (February 2007).

676

****(USE BELOW IN ALL SOLICITATIONS EXPECTED TO RESULT IN A CONTRACT OVER $10,000,000.)****

l. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

677

****(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, (February 1999).

678

****(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.

679

****(USE BELOW IN SOLICITATIONS FOR NEGOTIATED CONSTRUCTION CONTRACTS.)****

o. Preparation of Proposals--Construction, FAR Clause 52.236-28, (October 1997).

680

****(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.)****

p. Identification of Uncompensated Overtime, FAR Clause 52.237-10, (October 1997).

681

****(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.)****

q. SAFETY Act Coverage Not Applicable, FAR Clause 52.250-2, (February 2009)

682

****(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.)****

r. SAFETY Act Block Designation/Certification, FAR Clause 52.250-3, (February 2009).

Alternate I (February 2009) [is/is not] applicable to this solicitation.

Alternate II (February 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).]

683

****(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.)****

s. SAFETY Act Pre-qualification Designation Notice, FAR Clause 52.250-4, (February 2009)

Alternate I (February 2009) [is/is not] applicable to this solicitation.

Alternate II (February 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).]

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**** (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.) ****

t. SAFETY Act--Equitable Adjustment, FAR Clause 52.250-5, (February 2009).

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****(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.

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

1. **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

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****(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.

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****(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.

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****(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.

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****(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.

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****(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.

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****(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:
   - The specific items or expertise they will provide.
   - Their availability to the project and the amount of time anticipated.
   - Willingness to act as a consultant.

- How rights to publications and patents will be handled.

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****(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.

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****(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.

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****(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.

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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. **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 SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

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****(INCLUDE IN ALL SOLICITATIONS THAT INVOLVE HUMAN SUBJECTS.)****

a. **Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects, HHSAR 352.270-4(a) (January 2006)**

   a. Copies of the Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the HHS.

   b. The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. 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. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

   c. Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

   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. The Government's Project Officer will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, the Project Officer will consult with OHRP.

   e. In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that: the rights and welfare of the human subjects involved are adequately protected; the risks to the subjects are reasonable in relation to both the potential benefits, if any, to the subjects and the importance of the knowledge to be gained; and informed consent will be obtained by methods that are adequate and appropriate. HHS regulations for the protection of human subjects (45 CFR Part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information can be accessed at the OHRP Web site (at http://www.hhs.gov/ohrp/)

f. Offerors may consult with OHRP for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(End of provision)

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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. **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
   - Human Subjects Involvement and Characteristics:
     - Describe the proposed involvement of human subjects in response to the solicitation.
     - Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
     - Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.
   - Sources of Materials:
     - Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
   - Potential Risks:
     - Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
     - Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

b. Adequacy of Protection Against Risks

- Recruitment and Informed Consent:
  - 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. 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.
- Protection Against Risk:
  - Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
  - Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
  - In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

c. Potential Benefits of the Proposed Research to the Subjects and Others
- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

d. Importance of the Knowledge to be Gained
- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- 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 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: http://phrp.nihtraining.com . This course is also available in Spanish under the title "Protección de los participantes humanos de la investigación" at: http://pphi.nihtraining.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:
http://store.centerwatch.com/c-29-training-guides.aspx .

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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****(USE BELOW, WHEN HUMAN SUBJECTS WILL BE INVOLVED IN THE PROJECT. BY DEFINITION THIS INCLUDES INTERVIEWS AS WELL AS STUDIES AND TRIALS.)****

d. **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center 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 Institute/Center 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. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), **and applies to research subjects of all ages.**

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 October 2001," 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 "Targeted/Planned Enrollment Table"(see Section J, Attachments)

NOTE 1 : *For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at* : http://www.whitehouse.gov/omb/fedreg_notice_15 .

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 OMB Directive No. 15. 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:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm , 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, "Targeted/Planned Enrollment Table," <u>when preparing your response</u> 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, "Inclusion Enrollment Report," for <u>reporting in the resultant contract</u> .

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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.)****

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 21 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.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:

- The objective of the solicitation is not relevant to children.
    - There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
    - 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.
    - A separate, age-specific study in children is warranted and preferable. Examples include:
        - The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
        - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
        - 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

- 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
- 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);
- 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 21 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 21) 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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****(USE BELOW, WHEN HUMAN SUBJECTS WILL BE INVOLVED IN THE PROJECT. BY DEFINITION THIS INCLUDES INTERVIEWS AS WELL AS STUDIES AND TRIALS.)****

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 SUBJECTS WILL BE INVOLVED IN THE PROJECT. BY DEFINITION THIS INCLUDES INTERVIEWS AS WELL AS STUDIES AND TRIALS.)****

f. **Research Involving Human Fetal Tissue**

Human Fetal Tissue means tissue or cells obtained from a dead human fetus, including human embryonic stem cells, human pluripotent stem cells and human embryonic germ cells.

The governing federal statute is the Public Health Service Act, 42 U.S.C. 289g 1 and 289g 2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and

http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

By signing the face page of the proposal, the offeror (authorized institutional official) certifies that researchers using human fetal tissue are in compliance with 42 USC 289g 2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to profit, and does not include reasonable payment for costs associated with the collection processing, preservation, storage, quality control or transportation of these tissues.

Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local law.

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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.)****

g. **Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)**

Recombinant DNA Molecules are either 1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or 2) DNA molecules that result from the replication of those described in 1). All research involving recombinant DNA molecules that is conducted at or sponsored by an entity that receives any support for recombinant DNA research from NIH shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines) (See http://oba.od.nih.gov/rdna/nih_guidelines_oba.html). The NIH Guidelines stipulate biosafety and containment measures for recombinant DNA research and delineate points to consider in the development and conduct of human gene transfer clinical trials, including ethical principles and safety reporting requirements (See Appendix M of the Guidelines). More information about compliance with the NIH Guidelines can be found in a set of Frequently Asked Questions at: http://oba.od.nih.gov/rdna_ibc/ibc_faq.html .

The NIH Guidelines apply to both basic and clinical research studies. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the NIH OBA and reviewed by the NIH Recombinant DNA Advisory Committee (RAC). If this contract involves new protocols that contain unique and/or novel issues, the RAC may recommend that the protocol also be discussed by the RAC in a public forum. Approval of the Institutional Biosafety Committee (IBC) and the Institutional Review Board (IRB) are necessary before the Contracting Officer's Representative (COR) and Contracting Officer may approve the

protocol prior to the start of the research. The IBC approval may not occur before the NIH RAC has concluded its review of the protocol.

Failure to comply with the NIH Guidelines may result in suspension, limitation, or termination of the contract for any work related to recombinant DNA research or a requirement for Contracting Officer prior approval of any or all recombinant DNA projects under this contract. This includes the requirements of the Institutional Biosafety Committee (IBC) (See http://oba.od.nih.gov/rdna_ibc/ibc.html).

As specified in Appendix M-1-C-4 of the NIH Guidelines, any serious adverse event that that is both unexpected and associated with the use of the gene transfer product (i.e., there is reasonable possibility that the event may have been caused by the use of the product) must be reported to the NIH OBA and 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 Contracting Officer (See http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc351276411). Such reports must also be submitted within their mandated time frames to the IRB, Food and Drug Administration, and, if applicable, the HHS Office for Human Research Protections.

705****(USE BELOW, WHEN HUMAN SUBJECTS WILL BE INVOLVED IN THE PROJECT. BY DEFINITION THIS INCLUDES INTERVIEWS AS WELL AS STUDIES AND TRIALS.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Subparagraph 2:** There are Four (4) subparagraphs labeled as 2. from which to choose. One of these subparagraphs must be included as follows:
  - **First Paragraph 2:**

    Use the 1st paragraph 2. if the solicitation is being conducted as a SBIR Phase II, a BAA, or a sole source acquisition AND the Government specifies in the SOW that human embryonic germ cells shall be used to conduct the required research.

    Insert name of IC in the space provided in the first paragraph of this item.
  - **Second Paragraph 2:**

    Use the second paragraph 2. if the solicitation is being conducted as a SBIR Phase II, a BAA, or a sole source acquisition AND the Government DOES NOT specify in the SOW that human embryonic germ cells shall be used to conduct the required research.
  - **Third Paragraph 2:**

    Use the third paragraph 2. if the solicitation is a competitive solicitation, IS NOT an SBIR Phase II, a BAA, or a sole source acquisition AND it requires the use of human embryonic germ cells in the conduct of the research.

    Insert name of IC in the space provided in the first paragraph of this item.

    3rd paragraph of this Paragraph 2 : The number of Phases/Option Periods that may be completed by the Contractor before approval must be obtained for research using human embryonic germ cells is dependent on the Statement of Work. The Contracting Officer should insert in the spaces provided the Phase(s)/Option Period(s) that the Contractor may complete while awaiting approval of its proposal to use human embryonic germ cells under the contract.
  - **Fourth Paragraph 2:**

    Use the fourth paragraph 2. if the solicitation is a competitive solicitation, IS NOT a SBIR Phase II, a BAA, or a sole source acquisition; it DOES NOT REQUIRE the use of human embryonic germ cells; HOWEVER, in response to the Statement of Work Requirements, the offeror may propose to use such human embryonic germ cells, or to conduct the research by using a protocol that derives human embryonic germ cells from fetal tissue.

    3rd paragraph of this Paragraph 2 : The number of Phases/Option Periods that may be completed by the Contractor before approval must be obtained for research using human embryonic germ cells is dependent on the Statement of Work. The Contracting Officer should insert in the spaces provided the Phase(s)/Option Period(s), above, that the Contractor may complete while awaiting approval of its proposal to use human emb
    contract.)****

h. **Human Embryonic Germ Cell (HEGC) Research**

1. Guidelines .

Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://stemcells.nih.gov/policy/guidelines.asp) (only the information regarding human embryonic germ cells is relevant). Embryonic germ cells are pluripotent stem cells derived from human embryos. See NIH Guide for Grants and Contracts Notice NOT OD 02 049, requiring that offerors/contractors submit certain documents to the Human Pluripotent Stem Cell Review Group (HPSCRG), which will be reviewed in a public meeting. Research using human embryonic germ cells may not be performed prior to approval by the HPSCRG.

All offerors should read the "NIH Guidelines" (http://stemcells.nih.gov/policy/guidelines.asp) if they either: (1) propose to respond to the Statement of Work requirements by conducting research that uses human embryonic germ cells or, (2) are responding to a Statement of Work that requires the use of human embryonic germ cells.

Offerors may obtain copies of these Guidelines from the website above or from the contact person listed in this solicitation.

2. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

The _____ has determined that human embryonic germ cells are required to be used for the conduct of this research. The offeror must submit an original and two copies of the documentation and assurances that address the areas covered the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," at:
(http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html)

as a separate attachment in its proposal. Prior to any award made under this solicitation, the documentation and assurances will be subject to review by the HPSCRG, which meets in a public meeting. No research involving the use of human embryonic germ cells may begin prior to HPSCRG approval.

Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.b of the NIH Guidelines, at:
(http://stemcells.nih.gov/staticresources/news/newsArchives/fr25au00-136.asp).
Offerors should also review the March 19, 2002, DHHS Office of Human Research Protection's document titled, "Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic

Stem Cells, Germ Cells, and Stem Cell Derived Test Articles," (http://stemcells.nih.gov/StaticResources/news/newsArchives/stemcell.pdf)

OR

2. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

If, in response to the solicitation, the offeror proposes to use human embryonic germ cells, it must submit, as a separate attachment to its proposal, an original and two copies of the documentation and assurances that address the areas covered in the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" at: (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html). Prior to any award made under this solicitation, the documentation and assurances will be subject to review by the HPSCRG, which meets in a public meeting. No research involving the use of human embryonic germ cells may begin prior to HPSCRG approval.

Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.b of the NIH Guidelines. Offerors should also review the March 19, 2002, DHHS Office of Human Research Protection's document titled "Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell Derived Test Articles," at (http://stemcells.nih.gov/StaticResources/news/newsArchives/stemcell.pdf)

OR

2. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

The _____ has determined that human embryonic germ cells are required to be used for the conduct of this research. The offeror must confirm in its proposal that it plans to use human embryonic germ cells as a part of its research. If the offeror receives a contract award, the Contractor may not perform any research using human embryonic germ cells until the Human Pluripotent Stem Cell Review Group (HPSCRG) has reviewed and approved the documentation furnished as prescribed in the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-

049.html) and the Contracting Officer has notified the Contractor of the approval in writing.

Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.b of the NIH Guidelines at: (http://stemcells.nih.gov/staticresources/news/newsArchives/fr25au00-136.asp).
Offerors should also review the March 19, 2002, DHHS Office of Human Research Protection's document titled "Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell Derived Test Articles," at: (http://stemcells.nih.gov/StaticResources/news/newsArchives/stemcell.pdf)

The resultant contract will be divided into discrete phases or option periods. During Option Period(s)/Phase(s) _____ * of the contract, the Contractor shall submit the original and two copies of the required documentation and assurances that address the areas covered in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," at: (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) to the Contracting Officer. This documentation will be forwarded for review and approval to the HPSCRG.

If the HPSCRG disapproves the documentation presented by the Contractor, the Contracting Officer may elect to either terminate the contract in accordance with the Termination for Convenience clause of the contract OR determine not to exercise subsequent option(s) as appropriate based the terms of the specific contract. Otherwise, when the HPSCRG approves the documentation, the Contracting Officer will notify the Contractor in writing that research using the human embryonic germ cells may commence.

Research involving the use of human embryonic germ cells shall not be conducted under the contract until the HPSCRG review and approval have been obtained, and the Contracting Officer has provided written notice of such approval to the Contractor.

OR

2. Procedure for Required Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

If the offeror intends to fulfill the requirements of the Statement of Work by performing research using human embryonic germ cells, it must so state in its proposal.

If the offeror's proposal includes research using human embryonic germ cells and it receives a contract award, the Contractor may not perform any research using these human embryonic germ cells until the Human Pluripotent Stem Cell Review Group (HPSCRG) has reviewed and approved the documentation furnished as prescribed in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) and the Contracting Officer has notified the Contractor of the approval in writing.

The resultant contract will be divided into discrete phases or option period(s). During Option Period(s)/Phase(s) _____ * of the contract, the Contractor shall submit the original and two copies of the required documentation and assurances that address the areas covered in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," at: (http://grants2.nih.gov/grants/guide/notice files/NOT OD 02 049.html) to the Contracting Officer. This documentation will be forwarded for review and approval to the HPSCRG.

If the HPSCRG disapproves the documentation presented by the Contractor, the Contracting Officer may elect to either terminate the contract in accordance with the Termination for Convenience clause of the contract OR determine not to exercise subsequent option(s) as appropriate based the terms of the specific contract. Otherwise, when the HPSCRG approves the documentation, the Contracting Officer will notify the Contractor in writing that research using the human embryonic germ cells may commence.

Research involving the use of human embryonic germ cells shall not be conducted under the contract until the HPSCRG review and approval have been obtained, and the Contracting Officer has provided written notice of such approval to the Contractor.

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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.)****

i. **Human Embryonic Stem Cell (hESC) 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: http://stemcells.nih.gov/policy/pages/2009guidelines.aspx . The Guidelines implement EO 13505 with regard to extramural NIH-funded 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. Specific eligibility requirements for NIH funding of hESCs are included in Section II, *Eligibility of Human Embryonic Stem Cells for Research with NIH Funding* . Ineligible sources and uses of hESCs are addressed in Section IV, *Research Using hESCs and/or Human Induced Pluripotent Stem Cells That, Although the Cells May Come from Eligible Sources, is Nevertheless Ineligible for NIH Funding* , and Section V, *Other Research Not Eligible for NIH Funding* .

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: http://stemcells.nih.gov/research/registry/ . 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: http://hescregapp.od.nih.gov/NIH_Form_2890_Login.htm .

Research involving the derivation of new stem cells from human embryos or the use of human embryonic stem cells that are not listed on the NIH Registry may not be conducted with Federal funding.

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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.)****

j. **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's 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.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan you should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. 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.

The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual /Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multisite trials)
- Institutional Review Board (IRB - required)

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should 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.)****

k. **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;
- 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;
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's 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's Representative (COR) to assist in making this determination* .)****

l. **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 (http://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.

- Where the Contractor is the IND/IDE holder, the Contractor will be considered the Sponsor, therefore the "Responsible Party."
- 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."

- 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 http://prsinfo.clinicaltrials.gov

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****(USEBELOW, IN SOLICITATIONS THAT INVOLVE LIVE VERTEBRATE ANIMALS.)****

5. **Care of Live Vertebrate Animals**

The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

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) (January 2006)

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 award may be made to an applicant organization, 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, applicant organizations must establish an Institutional Animal Care & Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. Applicant organizations are required to provide verification of IACUC approval prior to release of 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 that involve live vertebrate animals that an Assurance and verification of IACUC approval are required. 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, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (E-mail: olaw@od.nih.gov ; Phone: 301-496-7163).

(End of Provision)

The PHS Policy is available on the internet at:
http://www.grants.nih.gov/grants/olaw/olaw.htm .

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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 five points must be addressed in a separate section of the Technical Proposal titled "Vertebrate Animal Section" (VAS):

i. Detailed description of the proposed use of the animals, including species, strains, ages, sex and number to be used.
ii. Justification for the use of animals, choice of species, and numbers to be used.
iii. Information on the veterinary care of the animals.
iv. Description of procedures for minimizing discomfort, distress, pain and injury.
v. Method of euthanasia and the reasons for the selection.

A concise (no more than 1-2 pages), complete description addressing these five points 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 five points in the VAS, see NIH Guide Notice NOT-OD-10-049 at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.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: http://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.)****

7. **Possession, Use and Transfer of Select Biological Agents or Toxins**

Notice to Offerors of Requirements of Select Agents Regulations - October 16, 2008 (http://www.selectagents.gov/Regulations.html): 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 http://www.selectagents.gov/ and http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html
For foreign institutions, see the NIAID Select Agent Award information (http://funding.niaid.nih.gov/researchfunding/sci/biod/pages/default.aspx).

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:

- Include details about the Select Agent in their technical proposal, including the quantity proposed to be used during contract performance.
- Describe the proposed use of the Select Agent or Toxin, including any restricted experiments.
- Comply with 42 CFR part 73, 7 CFR part 331 and/or 9 CFR part 121 at: http://www.selectagents.gov/Regulations.html , 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:

- Include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.
- Describe the proposed use of the Select Agent or Toxin, including any restricted experiments.
- 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: http://www.selectagents.gov/Regulations.html 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: http://www.selectagents.gov/Regulations.html . 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.

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****(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.)****

8. **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

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****(USE BELOW IN SOLICITATIONS WHERE RESEARCH DATA WILL BE GENERATED.
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. **Sharing Research Data**

[Note: This policy applies to **all** NIH contracts, regardless of dollar value, that are expected to generate research data.]

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

[If the resultant contract is part of a collaborative program involving multiple sites,

the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.]

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****(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 (http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf) 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:

- Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) at: http://www.ott.nih.gov/mta-policy ; for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (http://www.autm.net/UBMTA/8847.htm)
- How will inappropriate "reach-through" requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?
- 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 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* .

IMPORTANT NOTE Regarding Electronic Report Submission requirements and applicability:

When the ONLY EIT product required under the contract is the submission of electronic reports/deliverables, the certification required [in HHS Section 508 policy at 4.3.3] is satisfied when the Contracting Officer and Project Officer include the following statements in the appropriate section of the AP:

- The only Electronic and Information Technology (EIT) product or service required under this contract is the submission of electronic deliverables.; and,
- The contract will require that electronically submitted reports be in a 508 compliant format and the appropriate 508 Standards will be identified in the contract.

In this case, the Electronic and Information Technology Accessibility HHSAR Provision, below, is not applicable to the contract. However, if the CS/CO is unsure whether any additional EIT products or services (no matter how small) will be required in performance of the contract, the Statement of Work should reviewed by the designated I/C Section 508 Coordinator for an applicability determination.

Note: *If this item is not applicable, then the requirement for a separate Technical Evaluation Criteria are also not applicable* .)****

9. **Electronic and Information Technology Accessibility, Section 508 Compliance** 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 Proposal, entitled, "Section 508 Compliance."

Electronic and Information Technology Accessibility , **HHSAR 352.239-73(a)** (January 2010)

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, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit--

    1. Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and
    2. Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.

b. Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility standards. Information about Section 508 visions is available at http://www.section508.gov/ . The complete text of Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and-standards .

c. The Section 508 accessibility standards applicable to this solicitation are identified in the Statement of Work/Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Evaluation Template may be found on the HHS Web site (http://www.hhs.gov/web/508/contracting/technology/vendors.html).

d. Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 accessibility standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government -- i.e., after award of a contract/order, that products or services delivered do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level

of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor and at its expense.

(End of provision)

The "HHS Section 508 Product Assessment Template" is included in SECTION J - List of Attachments, of this solicitation.

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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.
4. 36 CFR 1194.41(c) specifies that support services for products shall accommodate the communication needs of end-users with disabilities.)****

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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****(USEBELOW 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.

720

****(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.

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****(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 $700,000 AND Adequate Price Competition IS NOT expected;
2. Proposals will be BELOW $700,000 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 $700,000 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.)****

3. **Data Other than Certified Cost or Pricing Data**

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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.]

723

****(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 $650,000, 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**
   1. **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.

2. **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).

3. **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.

4. **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** (October 2010)

(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 subparagraphs. 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 item exception. For a commercial item 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** (October 2010). 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:

The format specified in paragraph L.2.c.4. Certified Cost or Pricing Data, subparagraph 3. formats for Submission of Line Item Summaries shall be used for the submission of cost data. Submission of all other certified cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

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****(USE BELOW, IN ALL EXTRAMURAL SOLICITATIONS WHEN A COST-REIMBURSEMENT, FIXED-PRICE LEVEL OF EFFORT, TIME-AND-MATERIALS, OR LABOR HOUR CONTRACT IS CONTEMPLATED.)****

6. **Salary Rate Limitation in Fiscal Year 2013**

Offerors are advised that pursuant to P.L. **** , no NIH Fiscal Year 2013 (October 1, 2012 - September 30, 2013) 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 salary rate limitation set by P.L ****** applies only to Fiscal Year 2013 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level II* annual salary rate limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L **.**** states:

"None of the funds appropriated in this title shall be used to pay the salary of an individual through a grant or other extramural mechanism, at a rate in excess of Executive Level II."

LINK TO EXECUTIVE SCHEDULE RATES OF PAY: http://www.opm.gov/oca/
(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.

**** Pending passage of legislation.**

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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 mutli-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:

i. **Adjust accordingly for the number of years proposed.**
ii. **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, AS REQUIRED.

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. The current Subcontracting Goals for HHS can be found at the HHS OSDBU website (http://www.hhs.gov/about/smallbusiness/sb2012goals.html) under **Reporting/HHS Small Business Goals** .)****

9. **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $650,000 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, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

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:

1. 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.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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:
    1. 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.
    2. 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.
    3. 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.
    4. A description of the method used to develop the subcontracting goals.

5. A description of the method used to identify potential sources for solicitation purposes.
6. 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.
7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
8. 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.
9. 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 $650,000 adopt a plan similar to the plan agreed upon by the offeror.
10. 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.
11. 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, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

33% 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 (January 2010)**

    a. Large business prime contractors serving as mentors in the HHS Mentor-Protégé 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 protégé agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protégé 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 http://www.esrs.gov . The mentor firm and protégé 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 protégé firm and provision of $5,000 of developmental assistance as $15,000 of developmental assistance.) 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-Protégé agreement approved by HHS' OSDBU;

        2. Protégé 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 businesses; and (iii) have a Mentor-Protégé agreement approved by HHS' OSDBU; and

        3. Mentor-Protégé 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 IN ALL COMPETITIVE NEGOTIATED ACQUISITIONS EXPECTED TO EXCEED $650,000 ($1.5 million FOR CONSTRUCTION), WITH THE EXCEPTION OF THOSE ACQUISITIONS SPECIFIED IN FAR 19.1202-2(b), i.e. Small Business Set-Asides, 8(a) acquisitions, Foreign contracts, and Negotiated Acquisitions where the lowest price technically acceptable source selection process is used (see FAR 15.101-2.)****

12. **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $650,000 ($1.5 million for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth in Section M - Evaluation Factors for Award shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

The Department of Commerce website for the annual determination for NAICS codes* is: http://www.acquisition.gov/References/sdbadjustments.htm .

* *Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the Prime Contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is

required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	**SDB Dollars**
Total Contract Value- $1,000,000	25%	$250,000
SDB Participation by Prime	10%	$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	$150,000

*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential Prime Contractor, or a potential Prime Contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors

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****(USE BELOW, FOR SOLICITATIONS WHICH WILL RESULT IN A CONTRACT FOR SERVICES WHICH WILL EXCEED $650,000 AND THE SERVICE TO BE PROVIDED WILL REQUIRE MEANINGFUL NUMBERS OF PROFESSIONAL EMPLOYEES.)****

13. **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.)****

14. **Notice of Earned Value Management System - Pre-Award IBR, HHSAR 352.234-1 (October 2008)**

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;
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.

(End of provision)

Offerors **[ ] Will, [ ] Will Not** be directly compensated for the costs of participating in a pre-award IBR.

736

****(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* .)****

15. **Notice of Earned Value Management System - Post-Award IBR, HHSAR 352.234-2 (October 2008)**

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;
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.

(End of provision)

737

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

16. **Other Administrative Data**

738

a. **Property**

739

****(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.

740

****(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.

741

****(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]

742

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

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at: http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q_HHS Contracting Guide.pdf

743

****(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.

744

****(USEBELOW IN ALL SOLICITATIONS.)****

c. **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (JULY 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)

745

****(USEBELOW 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.

746

****(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:

- Complies with generally accepted accounting principles (GAAP).
- Provides for:
  - Proper segregation of direct costs from indirect costs.
  - Identification and accumulation of direct costs by contract.
  - A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
  - Accumulation of costs under general ledger control.
  - A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
  - A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
  - Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.

    - 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.
    - 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.
    - Segregation of preproduction costs from production costs, if applicable.
- Accounting system provides financial information:
    - Required by contract clauses concerning limitation of cost (FAR 52.232-20 and 21) or limitation on payments (FAR 52.216-16).
    - Required to support requests for progress payments.
- 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.
- 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.

747

****(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.

748

****(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 (July 2013)

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," and 352.232-71, "Estimated Cost - Incrementally Funded Contract." 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)

749

****(USE BELOW, IF COMMERCIAL ORGANIZATIONS MIGHT RESPOND TO THE SOLICITATION.)****

g. **Facilities Capital Cost of Money** , FAR 52.215-16, (June 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.

750

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

17. **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.

751

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

18. **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.

   Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:
   http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm

752

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

19. **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

753

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

20. **Travel Costs/Travel Policy**

754

****(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.

755

****(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.

756

****(USE BELOW IN ALL SOLICITATIONS FUNDED WITH APPROPRIATED BIO-DEFENSE FUNDS. **Note:** *At this time, may only be applicable to NIAID projects* .)****

21. **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.

757

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

SECTION M - EVALUATION FACTORS FOR AWARD

758

****(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.

759

****(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:** *This item includes the evaluation of SDB participation which must be considered in all requirements over $650,000 UNLESS any of the exemptions stated in FAR 19.1202(b) apply. If the requirement is exempt from the evaluation of SDB participation, remove the reference to this factor and revise the text below. Additionally, 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 four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation 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.

760

****(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:** *This item includes the evaluation of SDB participation which must be considered in all requirements over $650,000 UNLESS any of the exemptions stated in FAR 19.1202(b) apply. If the requirement is exempt from the evaluation of SDB participation, remove the reference to this factor and revise 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* .)****

3. **GENERAL**

The major evaluation factors for this solicitation include technical (which encompasses experience and past performance factors), cost/price factors and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, cost/price and SDB participation 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.

761

****(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.

762

****(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.]

763

****(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.

764

****(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.

765

****(USE BELOW, IN STUDIES THAT WILL INVOLVE HUMAN SUBJECTS.)****

6. **HUMAN SUBJECT EVALUATION**

This research project involves human subjects. NIH Policy requires:

766

****(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.

767

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 http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.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 21) 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 wit h 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.

769

****(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.

770

****(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.

771

****(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 five points. (See NIH Guide Notice NOT-OD-10-049 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html):

a. Detailed description of the proposed use of the animals, including species, strains, ages, sex and number to be used.
b. Justification for the use of animals, choice of species, and numbers to be used.
c. Information on the veterinary care of the animals.
d. Description of procedures for minimizing discomfort, distress, pain and injury.
e. Method of euthanasia and the reasons for the selection.

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 five points 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 five points, 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.

772

****(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 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 the OCIO Section 508 Sharepoint site at: http://sps.nihcio.nih.gov/OCIO/NIH/508/default.aspx under "Documents," then "508 Contacts."

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.

773

****(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).

774

****(USE BELOW, WHEN THE RESULTANT CONTRACT WILL GENERATE RESEARCH DATA AND SHARING OF THAT DATA MUST BE ADDRESSED BY EITHER PROPOSING A DATA SHARING PLAN OR PROVIDING A JUSTIFICATION FOR NOT SHARING. **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* .)****

10. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data, or, if data sharing is not possible, the offeror's documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

775

****(INCLUDE BELOW, WHEN THE CONTRACT WILL GENERATE RESEARCH DATA AND SHARING OF THAT DATA IS REQUIRED. **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 should be resolved before award* .)****

11. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

If your proposal does not include a plan 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 data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing

plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

776

****(USE BELOW FOR SOLICITATIONS THAT INVOLVE BIOMEDICAL RESEARCH OF MODEL ORGANISMS.)****

12. **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.

777

****(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.)****

13. **EVALUATION OF FOREIGN CURRENCY OFFERS** , FAR 52.225-17, (FEBRUARY 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.

778

****(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 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 the OCIO Section 508 Sharepoint site at: http://sps.nihcio.nih.gov/OCIO/NIH/508/default.aspx under "Documents," then "508 Contacts."

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.)****

14. **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] .

779

****(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.*)****

15. **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.

780

****(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.)****

16. **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.

781

****(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.)****

17. **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.

782

****(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.)****

18. **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.	

783

****(USE BELOW WHEN EVALUATION OF SDB PARTICIPATION WILL BE SCORED.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. The Contracting Officer may select from any of the evaluation factors cited at FAR 19.1202-3 (listed in the Table, below), or may develop other factors unique to the specific acquisition.
2. The Contracting Officer may choose not to give a weight to SDB participation but simply list factors in order of importance. If this second option is used, the word "Weight" shown below should be deleted and a statement indicating that the factor is listed in relative order of importance should be added to the column heading as follows: "FACTORS (Listed in Relative Order of Importance).")****

19. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

FACTORS	WEIGHT
(a) Extent to which SDB concerns are specifically identified	
(b) Extent of commitment to use SDB concerns	
(c) Complexity and variety of the work SDB concerns are to perform	
(d) Realism of the proposal	
(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation	
(f) Extent of participation of SDB concerns in terms of the value of the total acquisition.	

784

****(USE BELOW WHEN EVALUATION OF SDB PARTICIPATION WILL NOT BE SCORED.

ADDITIONAL INFORMATION FOR COMPLETING THIS ITEM:

- The Contracting Officer may select from any of the evaluation factors cited at FAR 19.1202-3 (listed below), or may develop other factors unique to the specific acquisition.)****

20. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

SDB participation will not be scored , but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

a. Extent to which SDB concerns are specifically identified
b. Extent of commitment to use SDB concerns
c. Complexity and variety of the work SDB concerns are to perform
d. Realism of the proposal
e. Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
f. Extent of participation of SDB concerns in terms of the value of the total acquisition.

785

****(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.