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

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

585

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

1. **GENERAL INFORMATION**

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

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. This basic provision states that the Government intends to make award WITHOUT discussions. If the CO intends to establish a competitive range and hold discussions with offerors in that range, use this provision with its Alternate I.
2. In accordance with HHSAR 352.215-1, the subparagraph (e) contained in this item has been substituted for the subparagraph (e) of the provision at FAR 52.215-1.

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** FAR 52.215-1 (Nov 2021).

(a) *Definitions* . As used in this provision-

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

In writing , "writing," or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

Proposal modification is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

Proposal revision is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

Time , if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last

day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals.*

(1) Unless other methods (e.g., electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show-

(i) The solicitation number;

(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) Submission, modification, revision, and withdrawal of proposals.

(i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and-

(1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5 , Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17 , Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) Restriction on disclosure and use of data. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall-

(1) Mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed-in whole or in part-for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of-or in connection with-the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]; and

(2) Mark each sheet of data it wishes to restrict with the following legend:

Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

(f) Contract award.

(1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306 (a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection.

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial products, the make and model of the product to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of provision).

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****(USE BELOW WITH THE BASIC PROVISION, ABOVE, IF THE CONTRACTING OFFICER INTENDS TO MAKE AWARD AFTER DISCUSSIONS WITH OFFERORS WITHIN THE COMPETITIVE RANGE.)****

Alternate I (*Oct 1997*). As prescribed in FAR 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

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****(USE BELOW WITH THE BASIC PROVISION IF THE CONTRACTING OFFICER DETERMINES THAT THE SUBMISSION OF ALTERNATE PROPOSALS AND DEVIATIONS FROM THE TERMS AND CONDITIONS OF THE SOLICITATION ARE ACCEPTABLE.)****
Note: This Alternate allows offerors to propose changes in the terms and conditions as well as the technical requirement. Any proposed alternate to the terms and conditions set forth in SECTIONS A-K of the solicitation could have direct impact on the resultant contract. If it is your intent to allow offerors to submit alternate technical proposals ONLY, note that this is authorized in SECTION L.2.a(5), entitled, "Alternate Proposals," in this workform. Please read both paragraphs carefully to determine exactly which situation you wish to authorize.

Alternate II *(Oct 1997).* As prescribed in FAR 15.209(a)(2), add a paragraph (c)(9) substantially the same as the following to the basic clause:

(9) Offerors may submit proposals that depart from stated requirements. Such proposals shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the terms and conditions of the solicitation, as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the solicitation to allow all offerors an opportunity to submit revised proposals based on the revised requirements.

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****(USE BELOW WHEN ISSUING A SOLICITATION FOR INFORMATION OR PLANNING PURPOSES.)****
NOTE: The cover page of the solicitation must be clearly marked indicating that the solicitation is for information or planning purposes.

b. **REQUEST FOR INFORMATION OR SOLICITATION FOR PLANNING PURPOSES FAR 52.215-3** (Oct 1997).

(a) The Government does not intend to award a contract on the basis of this solicitation or to otherwise pay for the information solicited except as an allowable cost under other contracts as provided in subsection 31.205-18, Bid and proposal costs, of the Federal Acquisition Regulation.

(b) Although "proposal" and "offeror" are used in this Request for Information, your response will be treated as information only. It shall not be used as a proposal.

(c) This solicitation is issued for the purpose of: _____ [State Purpose]

(End of provision).

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****(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.

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****(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.

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****(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.

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****(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 _____ .

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****(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.

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****(INCLUDE BELOW IN ALL SOLICITATIONS. MAKE SURE TO INCLUDE SPECIFIC AWARD INFORMATION IN THE APPROPRIATE PARAGRAPHS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Paragraph 1** : Select the appropriate anticipated number of awards within the brackets. Modify this information if needed.
2. **Paragraph 2** : Select the appropriate information for your solicitation from within the bracketed section. *If incremental funding is NOT being contemplated, adjust the paragraph accordingly.*
3. **Paragraph 3** : Include this paragraph for all solicitations EXCEPT Firm-Fixed Price contracts. Delete this paragraph 3 when the resultant contract will be FFP.

g. **TYPE OF CONTRACT AND NUMBER OF AWARDS**

1. It is anticipated that [one/multiple award(s)] will be made from this solicitation and that the award(s) will be made on/about _____ .
2. It is anticipated that the award(s) from this solicitation will be a multiple-year [Cost-Reimbursement/Fixed-Price] type [Completion/Level of Effort] contract with a [Term of _ Years/Period of Performance of _____], and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).
3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a Contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

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****(INCLUDE BELOW IN ALL SOLICITATIONS THAT WILL RESULT IN THE AWARD OF MULTIPLE AWARD INDEFINITE DELIVERY CONTRACTS.)****

h. **TASK ORDERS UNDER MULTIPLE AWARD INDEFINITE DELIVERY CONTRACTS**

a. **General**

The Contractor will be required provide services under the resultant contract only in performance of task orders and modifications to task orders signed by the Contracting Officer. Costs not attributed to the performance of a specific task order shall not be allowed without the prior written consent of the Contracting Officer. The Contractor will commence performance upon the receipt of a Task Order signed by the Contracting Officer. Costs for the

preparation of Task Order proposals shall not be reimbursed as a direct cost under the resultant contract.

One or more task orders may be issued during the performance period of the resultant contract. If a Contractor responds to a Task Order Request for Proposal (TORFP) and is the successful offeror, that Contractor will be required to accept and perform the task order issued by the Contracting Officer within the scope of the resultant contract. The government has no obligation to issue any task orders, beyond the minimum identified in SECTION B of the contract. In the event of any inconsistency between any task order and the contract, the contract shall control.

In accordance with the Federal Acquisition Streamlining Act, the Contracting Officer will provide each Contractor a "Fair Opportunity" to be considered for each Task Order awarded in excess of $3,500, unless one of the conditions in FAR 16.505(b)(2) applies.

The competition requirements in FAR Part 6, and the policies in FAR Subpart 15.3, **DO NOT APPLY** to the task ordering process. For each requirement under the resultant contract, the government intends to provide each Contractor a fair opportunity for consideration of a task order. The Contracting Officer shall:

1. Issue a notice of intent to award a task order for services to all resultant Contractors within a technical area covered by the task order requirement. To satisfy this requirement, the Contracting Officer will provide an e-mail notifying all qualified Contractors of the requirement. The e-mail will identify how the details concerning the requirement, including a description of the work and selection criteria, will be provided, i.e. attached to the e-mail, posted on a website. Contractors will be asked to submit a response to the notice of intent, advising the government of their intent to submit a proposal or quote;

2. Afford all Contractors, within the technical area covered by the task order requirement, who are responding to the notice, a fair opportunity to submit an offer and have that offer fairly considered;

3. Consider price and cost under each order as one of the factors in the selection decision;

4. Keep submission requirements to a minimum;

5. Consider past performance on earlier task orders under this contract to the maximum extent possible. Past performance considerations shall include, but not be limited to, the Contractor's performance regarding

completeness, accuracy, clarity, timeliness and cost control. If a Contractor has no past performance on any earlier task order, past performance will be considered through other sources, such as the Contractor's original proposal.

In addition to the above, for all orders exceeding $5 million, the Contracting Officer will consider all requirements set forth in FAR 16.505(b)(1)(iv).

b. **Exceptions to Fair Opportunity**

Contractors may not be given an opportunity to be considered for requirements in excess of $3,500 if one of the following conditions applies:

1. The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.
2. Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.
3. The order must be issued on a sole-source basis in the interest of economy and efficiency because it is a logical follow-on to an order already issued under the contract, provided that all awardees were given a fair opportunity to be considered for the original order.
4. It is necessary to place an order to satisfy a minimum guarantee.

c. **Requesting Task Order Proposals**

The Contracting Officer or a designated individual may solicit responses to requirements from Contractors within a technical area covered by a task order requirement in writing.

A Task Order Request for Proposals (TORFP) will be prepared and issued for each task order requirement.
All contract clauses contained the resultant contract shall be incorporated in the TORFP and the resultant task order. If conflicts exist between the contract clauses and the information outlined in the task order, the resultant contract language takes precedence over the information in the task order.

d. **Competitive Ordering Process**

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

unless otherwise specified in the proposed task order.

2. Contractors will be provided an adequate time to prepare and submit responses based on the Contracting Officer's consideration of the estimated dollar value and complexity of proposed task order. Responses will not be considered a proposal as defined in FAR Part 15. However, the Contractor shall provide information sufficient for consideration in accordance with FAR Part 16. Each TORFP will indicate the criteria for the evaluation of proposals. The responses shall demonstrate capability for each criterion to be evaluated. Generally, the Contractor will be asked to demonstrate the following as appropriate:
    - Understanding of the requirements;
    - Experience and capability on similar tasks;
    - Technical approach, methods and procedures for satisfying the requirements with a discussion of potential problems to be encountered and proposed solutions and/or risk mitigation strategies.
    - Procedures for assuring quality of work, products, and deliverables;
    - Plan for managing the task order, including meeting requirements and schedules, and performance measures (if applicable);
    - Staffing plan with skill levels and level of effort for each individual proposed. Generally, resumes will be required for proposed personnel (if not previously submitted);
    - References to evaluate past performance; and
    - Cost/Price to perform the task order.

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

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

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

The Contracting Officer will notify the IDIQ Contractors of the selection decision in writing.

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****(INCLUDE BELOW WHEN THE GOVERNMENT INTENDS TO USE A PERFORMANCE BASED ACQUISITION METHOD IN THE AWARD OF THE CONTRACT.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Third Paragraph(s):** Select the one of the three paragraphs below, that is applicable to your SOLICITATION. If you will be using a different incentive than that defined below, you will need to develop language appropriate to your requirement.

i. **PERFORMANCE BASED ACQUISITION**

The Government intends to use a Performance Based Acquisition method in the evaluation and award of any contract resulting from this SOLICITATION.

The Performance Based contract is designed to motivate the Contractor to perform at a higher standard. Outstanding performance is rewarded through an incentive defined in the contract. The following performance incentive will be used in any contract awarded from this SOLICITATION:

Cost-Plus-Award-Fee (CPAF): The CPAF contract includes an estimated cost and an award fee amount that is paid based upon periodic evaluations of Contractor performance. The Quality Assurance Surveillance Plan (QASP), which is included as an attachment to this SOLICITATION sets forth all the elements required for evaluation and determination of the award fee amount. The award fee determination is made unilaterally by the Government and is not subject to Disputes clause procedures. The QASP is included in this SOLICITATION and located _____ .

OR

Award Term: The Award Term contract includes one or more extensions of the contract period for which the Contractor is entitled based upon periodic evaluations of Contractor performance. This is not a Government option to extend the contract. Under the Award Term incentive, if the Contractor's evaluated performance meets the Award Term criteria set forth in the Quality Assurance Surveillance Plan (QASP) and funds are available and there is a continuing need for the items or services set forth in the Statement of Work, the Award Term will be issued. The QASP is included in this SOLICITATION and located _____ .

OR

Award Option: The Award Option contract includes one or more options to extend the contract period based upon periodic evaluations of Contractor performance. Under the Award Option incentive, the Contractor's evaluated performance against the criteria set forth in the Quality Assurance Surveillance Plan (QASP) serves as the precursor to the Government exercising its unilateral rights in accordance with FAR Part 17.2. A successful Award Option evaluation precedes the Government's review and determination to exercise or not to exercise the Award Option. The QASP is included in this RFP and located _____ .

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****(INCLUDE BELOW WHEN A PRE-PROPOSAL CONFERENCE IS SCHEDULED. MAKE SURE TO INCLUDE SPECIFIC CONFERENCE INFORMATION IN THE APPROPRIATE PARAGRAPHS.)****

j. **PRE-PROPOSAL CONFERENCE**

A pre-proposal conference will be held with prospective offerors at _____ on _____ . The pre-proposal conference will be held for the purpose of providing information concerning the Government's requirements which may be helpful in the preparation of proposals and for answering any questions which you have regarding this solicitation.

The success of this type of conference depends largely on the lead-time available to the Government for research in connection with questions submitted by offerors. Therefore, you are requested to mail written questions concerning any areas of uncertainty which, in your opinion, require clarification or correction, in sufficient time to be received on or before _____ at the address specified in Block 7 of SECTION A - Solicitation/Contract Form of this solicitation.

Your questions should be submitted to the Contract Specialist, _____ and the envelope should be marked, "Pre-proposal conference, RFP No. _____ ." A set of all questions and answers will be furnished simultaneously to all prospective offerors whether or not they are in attendance.

Because of space limitations, each prospective offeror shall be limited to a total of _ representatives.

Attendance at the pre-proposal conference is recommended; however, attendance is not a prerequisite for proposal submission and will not be considered a factor in proposal evaluation.

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****(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.

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****(USE BELOW WHEN A COST-REIMBURSEMENT TERM (I.e. LEVEL OF EFFORT) TYPE CONTRACT WILL BE AWARDED FROM THIS SOLICITATION. MAKE SURE TO COMPLETE INFORMATION IN THE PARAGRAPH.)****

l. **LEVEL OF EFFORT**

The Government's requirement for the work set forth in the Statement of Work of this solicitation is _____ direct labor hours. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

Labor Hours

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7

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****(INCLUDE BELOW WHEN BRAND NAME OR EQUAL PURCHASE DESCRIPTIONS ARE INCLUDED IN THE SOLICITATION.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- This item is for use with Brand Name or EQUAL.
- If your solicitation includes the requirement for acquiring a "Brand Name" item ONLY, you must include a written justification as required by FAR 11.105 with your solicitation. Additionally, in accordance with OFPP Memorandum dated, April 11, 2005, entitled "Use of Brand Name Specifications," this justification must be posted in Contract Opportunities at https://sam.gov/content/home with the SOLICITATION. Therefore, if you require a "Brand Name Specification," do not use this item. However, you should tailor a paragraph to be included with your RFP which either includes the justification for Brand Name Specification or references where the justification is published. If providing the justification is inappropriate because of National Security, Trade Secrets, or similar concerns, a copy of the justification to the file must be provided to the Office of Federal Procurement Policy (OFPP) through the Director, DAPE, OAMP, NIH.

m. **BRAND NAME OR EQUAL,** FAR 52.211-6 (Aug 1999).

a. If an item in this solicitation is identified as "brand name or equal,'' the purchase description reflects the characteristics and level of quality that will satisfy the Government's needs. The salient physical, functional, or performance characteristics that "equal'' products must meet are specified in the solicitation.
b. To be considered for award, offers of "equal'' products, including "equal'' products of the brand name manufacturer, must-
    1. Meet the salient physical, functional, or performance characteristic specified in this solicitation;
    2. Clearly identify the item by-
        i. Brand name, if any; and
        ii. Make or model number;
    3. Include descriptive literature such as illustrations, drawings, or a clear reference to previously furnished descriptive data or information available to the Contracting Officer; and
    4. Clearly describe any modifications the offeror plans to make in a product to make it conform to the solicitation requirements. Mark any descriptive material to clearly show the modifications.
c. The Contracting Officer will evaluate "equal'' products on the basis of information furnished by the offeror or identified in the offer and reasonably available to the Contracting Officer. The Contracting Officer is not responsible for locating or obtaining any information not identified in the offer.

d. Unless the offeror clearly indicates in its offer that the product being offered is an "equal'' product, the offeror shall provide the brand name product referenced in the solicitation.

(End of provision).

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

n. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

603

****(INCLUDE BELOW IN ALL SOLICITATIONS THAT INVOLVE LOGISTICAL SUPPORT SERVICES; INCLUDES THE CONDUCT OF A CONFERENCE OR MEETING, EVEN IF INCIDENTAL TO THE PERFORMANCE OF THE CONTRACT; INVOLVES THE PROCUREMENT OF PROMOTIONAL ITEMS; AND PRINTING AND/OR PUBLICATION SERVICES.)****

o. **PROMOTING EFFICIENT SPENDING**

On September 21, 2011, the Office of Management and Budget issued Memorandum M-11-35 , https://obamawhitehouse.archives.gov/sites/default/files/omb/memoranda/2011/m11-35.pdf entitled, "Eliminating Conference Spending and Promoting Efficiency in Government," emphasizing the President's priority to ensure that the Government operates with the utmost efficiency and eliminates unnecessary or wasteful spending. This was followed by the Executive Order on Delivering an Efficient, Effective, and Accountable Government (EO 13576) and the Executive Order on Promoting Efficient Spending (EO 13589). On January 23, 2015, the Department of Health and Human Services (DHHS) issued the memorandum "HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings Spaces, Food, Promotional Items, and Printing, and Publications" (See http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html).

In support of these directives, the NIH issued a November 1, 2015, Memorandum, entitled, "NIH Guidance Related to the HHS Policies on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meeting Space, Food, Promotional Items, and Printing and Publications." (See https://oamp.od.nih.gov/news/NIH-efficient-spending-policy)

Any contract awarded as a result of this solicitation will:

- Specifically prohibit the use of contract funds for the provision of food for meals, light refreshments and beverages for any NIH funded meeting or conference; and
- Limit the procurement of meeting space, promotional items, printing and publications.

604

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

p. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this SOLICITATIONS. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

605

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

q. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

606

****(USE BELOW WHEN REFERENCE MATERIALS WILL BE MADE AVAILABLE FOR PROSPECTIVE OFFERORS. INCLUDE SPECIFIC INFORMATION IN THE APPROPRIATE PARAGRAPHS.)****

r. **REFERENCE MATERIALS**

A "reading room" containing reference materials pertinent to this acquisition is available in Room __ , Address- _____ , from ___ Monday through Friday (except Government holidays) through the closing date of the RFP. Use of the reading room is by appointment only; contact _____ , phone _____ , e-mail _____ for arrangements. Failure of offerors to examine the reference materials prior to proposal preparation and submission will be at the offeror's risk.

607

****(INCLUDE BELOW WHEN THE PROJECT HAS NOT UNDERGONE CONCEPT REVIEW AT THE TIME OF SOLICITATION ISSUANCE.)****

s. **CONCEPT REVIEW**

This project has not been reviewed by the Board of Scientific Counselors as required. Such review will occur prior to technical evaluation. Thus potential offerors are cautioned that cancellation of this RFP due to disapproval by the Board of Scientific Counselors is a possibility.

608

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

t. **PREPARATION COSTS**

This RFP does not commit the Government to pay for the preparation and submission of a proposal.

609

****(USE BELOW IN ALL SOLICITATIONS.)****
Make sure to complete the address below.

u. **SERVICE OF PROTEST** FAR 52.233-2 (Sep 2006).

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

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

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of provision).

610

****(USE BELOW FOR RESEARCH AND DEVELOPMENT PROJECTS WHEN THE HCA DETERMINES THAT USE OF THIS PROVISION IS APPROPRIATE.)****
See HHSAR 315.208.
Note: *IF the project will not require Peer Review, DO NOT use this clause* .

v. **LATE PROPOSALS AND REVISIONS** , HHSAR 352.215-70 (December 2015).

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, the Government may consider a proposal received after the date specified for receipt if it appears to offer significant cost or technical value to the Government and it was received before proposals were distributed for evaluation, or within 5 calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision).

611

****(USE BELOW WHEN ACQUIRING FIP RESOURCES, IF ANY OF THE TERMINOLOGY TO INCORPORATE STANDARDS IN THIS SOLICITATION ARE INCORPORATED BY REFERENCE.)****

w. **AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."**

Copies of the "Federal ADP and Telecommunications Standards Index" can be purchased from the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402.

612

****(NCI Users: USE BELOW WHEN NON-GOVERNMENT PERSONNEL WILL BE UTILIZED IN THE EVALUATION OF TECHNICAL PROPOSALS.
NCI Processes/Procedures - Regulation listed below - Reviewed 9/22)****

x. **USE OF NON-GOVERNMENT PERSONNEL FOR TECHNICAL PROPOSAL EVALUATION**

In accordance with 42 C.F.R. 52h, Non-Government personnel will be utilized as reviewers in the evaluation of Technical Proposals submitted in response to this solicitation. While NIH requires competent, objective, and expeditious evaluation of proposals submitted in response to R&D solicitations, the use of Non-Government reviewers will be strictly controlled. Non-Government reviewers will be utilized in the

evaluation of Technical Proposals only and will not have access to Business proposals submitted in response to this solicitation. All proposed Non-Government reviewers will be required to identify any conflicts of interest held with relation to offeror's organizations and/or investigators submitting proposals in response to this solicitation and will be required to ensure the confidentiality of review documents and proceedings.

613

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

2. **INSTRUCTIONS TO OFFERORS**

614

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

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

615

****(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.

616

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

2. **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this

RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper, printed/copied double-sided, on at least 30 percent post-consumer fiber paper, as required by FAR 4.302(b), and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the SOLICITATION should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, UEI No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

617

****(USE BELOW FOR NHLBI ONLY
NHLBI Processes/Procedures Reviewed 9/22)****

3. **FEDCONNECT SOLICITATION INSTRUCTIONS**

Interested parties are hereby notified that communications and submissions (e.g., proposals, solicitation questions, amendments, negotiation questions and responses, etc.) will be conducted via the FedConnect web portal (www.fedconnect.net). Vendors can register with FedConnect at https://www.fedconnect.net/FedConnect/default.htm . Offerors are advised that proposal/file submissions must not exceed 25 MB and the total size for all attachments must be less than 100 MB. In accordance with FAR 52.215-1, offerors should plan on submitting proposals no later than 5:00 p.m. one working day prior to the date specified for receipt of proposals.

Please note that FedConnect is used by multiple federal agencies and, therefore, FedConnect assistance will be provided by Compusearch Software Systems, not the NHLBI OA. More information about registration requirements can be found by downloading the FedConnect Ready, Set, Go! Guide at https://www.fedconnect.net/fedconnect/Marketing/Documents/ FedConnect_Ready_Set_Go.pdf . For assistance in registering or for other FedConnect technical questions, please call the FedConnect Help Desk at (800) 899-6665 or email at support@fedconnect.net .

618

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

4. **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See SECTION J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

619

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

ADDITIONAL INFORMATION ABOUT THIS ITEM:

This item is written for proposals which will be peer reviewed. These review panels are not given pricing data relating to individual salary information, indirect costs, fee amounts and total costs. If the proposals submitted under your SOLICITATIONS will not undergo peer review, you may want to consider changing the paragraph below to fit your review situation. e.g. you may wish to substitute the Attachment entitled, "Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet," and remove some of the language restricting submission of certain pricing data.

5. **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail

as possible, including, but not limited to, the requirements of the technical proposal instructions.

620

****(NHLBI: USE BELOW IN ALL NHLBI SOLICITATIONS.
NHLBI Processes/Procedures Reviewed 9/22)****

6. **Uniform Resource Locators (URLs) in Contract Proposals**

All proposals must be self-contained within the specific page limitations cited elsewhere in this solicitation. Unless otherwise specified, URLs/Internet addresses shall not be used to provide information necessary to the review because reviewers are under no obligation to review the Internet sites.

621

7. **Page and Formatting Limitations**

The Technical Plan (objectives, approach, methods and procedures, and substudy proposal) of the technical proposal shall not exceed 30 single-sided pages or 15 double-sided pages. This page limitation does not include the cover sheet, abstract, table of contents, personnel, facilities, equipment and resources, other considerations, schedule, other support, cost information, and literature cited. The substudy proposal section of the Technical Plan (included within the 30 page limit) shall not exceed 8 single-sided or 4 double-sided pages. Appendices shall not exceed a total of 50 single-sided pages or 25 double-sided pages. Pages in excess of the limitation will be deleted and will be neither read nor evaluated. Each page of the technical proposal must be numbered sequentially. Offerors are encouraged to limit the overall size of the technical proposal, inclusive of appendices, attachments, etc. Although no page limit has been placed on the business proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

Type density and size must be 10 to 12 points. If constant spacing is used, 15 cpi (characters per inch) or fewer shall be used, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be no less than ½ inch around, exclusive of headers and footers.

622

****(USE BELOW IN ALL SOLICITATIONS IF THE GOVERNMENT WOULD BE WILLING TO ACCEPT ALTERNATE PROPOSALS.)****

8. **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the terms and conditions of the solicitation, as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the solicitation to allow all offerors an opportunity to submit revised proposals based on the revised requirements.

623

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

9. **Evaluation of Proposals**

The Government will evaluate proposals in accordance with the factors set forth in PART IV, SECTION M of this RFP.

624

****(USE BELOW WHEN THE PROVISION AT FAR 52.215-1, Instructions to Offerors - Competitive Acquisition, IS USED WITH ITS ALTERNATE I. THIS PROVISION ADVISES OFFERORS THAT THE GOVERNMENT INTENDS TO MAKE AWARD AFTER CONDUCTING DISCUSSIONS WITH OFFERORS WHOSE PROPOSALS ARE WITHIN THE COMPETITIVE RANGE. THE FOLLOWING MUST BE INCLUDED IN THE SOLICITATION IF THE CONTRACTING OFFICER WISHES TO RESERVE THE RIGHT TO MAKE AWARD WITHOUT DISCUSSIONS NOTWITHSTANDING THE LANGUAGE IN ALTERNATE I.)****

10. **Potential Award Without Discussions**

The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

625

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

11. **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of

measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

Hard Metric - - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

626

****(USE BELOW WHERE THERE MAY BE OFFERS FROM INSTITUTIONS THAT ARE CONSIDERED UNDER THE PRIVACY RULE TO BE "COVERED ENTITIES" (AS DEFINED IN THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 ("HIPAA").)****

12. **Standards for Privacy of Individually Identifiable Health Information**

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply.

Decisions about the applicability and implementation of the Privacy Rule reside with the Contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving

the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html .

627

****(USE BELOW IN SOLICITATIONS FOR PERSONAL PROTECTIVE EQUIPMENT (PPE) WHEN THE ACQUISITION IS ABOVE THE MICRO PURCHASE THRESHOLD.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Applicability of Commercial Clauses:**

When the clause at FAR 52.212-5, Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Products and Commercial Services is included in a solicitation and contract for PPE above the micro purchase threshold, Contracting Officers shall also include the full text of HHSAR 352-225-70 Made in America – Personal Protective Equipment. (***Contracting Officers do not check off paragraphs (b)(48) thru (50) of FAR clause 52.212-5 if HHSAR clause 352.225-70 will apply to the procurement.)*** and HHSAR 352.225-71 Made in America Certificate – Personal Protective Equipment.

When the provision at FAR 52.212-3, Offeror Representations and Certifications—Commercial Products and Commercial Services is included in a solicitation for PPE Contracting Officers shall also include the full text of HHSAR 352-225-70 Made in America – Personal Protective Equipment and HHSAR 352.225-71 Made in America Certificate – Personal Protective Equipment.

- **PPE should be obtained through the NIH Supply Center, the VA, and the GSA.**

13. HHSAR **352.225-70, Made in America – Personal Protective Equipment** (February 2023)**.**

(a) *Definitions*. As used in this clause—

Component, as applied to an item described in subsection (b) of this clause, means an article, material, or supply incorporated directly into personal protective equipment.

Domestic personal protective equipment, as applied to an item described in subsection (b) of this clause, means personal protective equipment, including the materials and components thereof, that is grown, reprocessed, reused, or produced in the United States.

Foreign-made domestic personal protective equipment, as applied to an item described in subsection (b) of this clause, means personal protective equipment that is assembled outside the United States containing only materials and components that are grown, reprocessed, reused, or produced in the United States.

Foreign personal protective equipment means personal protective equipment other than domestic personal protective equipment or foreign-made domestic personal protective equipment.

Personal protective equipment, as applied to an item described in subsection (b) of this clause, means surgical masks, respirator masks and powered air purifying respirators and required filters, face shields and protective eyewear, gloves, disposable and reusable surgical and isolation gowns, head and foot coverings, and other gear or clothing used to protect an individual from the transmission of disease.

United States, as applied to an item described in subsection (b) of this clause, means the 50 States, the District of Columbia, and the possessions of the United States.

(b) The Contractor shall deliver only domestic personal protective equipment, unless it specified delivery of foreign-made domestic personal protective equipment in the provision of the solicitation entitled “Made in America Certificate – Personal Protective Equipment."

(End of clause).

628

****(USE BELOW IN SOLICITATIONS FOR PERSONAL PROTECTIVE EQUIPMENT (PPE) WHEN THE ACQUISITION IS ABOVE THE MICRO PURCHASE THRESHOLD.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Applicability of Commercial Clauses:**

When the clause at FAR 52.212-5, Contract Terms and Conditions Required To Implement Statutes or Executive Orders—Commercial Products and Commercial Services is included in a solicitation and contract for PPE above the micro purchase threshold, Contracting Officers shall also include the full text of HHSAR 352-225-70 Made in America – Personal Protective Equipment. (***Contracting Officers do not check off paragraphs (b)(48) thru (50) of FAR clause 52.212-5 if HHSAR clause 352.225-70 will apply to the procurement.)*** and HHSAR 352.225-71 Made in America Certificate – Personal Protective Equipment.

When the provision at FAR 52.212-3, Offeror Representations and Certifications—Commercial Products and Commercial Services is included in a solicitation for PPE Contracting Officers shall also include the full text of HHSAR 352-225-70 Made in America – Personal Protective Equipment and HHSAR 352.225-71 Made in America Certificate – Personal Protective Equipment.

- **PPE should be obtained through the NIH Supply Center, the VA, and the GSA.**

14. HHSAR **352.225-71, Made in America Certificate – Personal Protective Equipment** (February 2023)**.**

(a)(1) The Offeror certifies that each item of personal protective equipment, except those listed in paragraph (b) of this provision, is domestic personal protective equipment.

(2) The Offeror shall list offered foreign-made domestic personal protective equipment items in paragraph (b).

(3) The terms "domestic personal protective equipment," "foreign-made domestic personal protective equipment," foreign personal protective equipment," and "personal protective equipment," are defined in the clause of this solicitation entitled "Made in America—Personal Protective Equipment."

(b) Foreign-made Domestic Personal Protective Equipment:

Line-Item No.	Country of Origin
_____	_____
_____	_____
_____	_____

[List as necessary.]

(End of provision).

629

****(USE BELOW IN SOLICITATIONS OVER THE MICROPURCHASE THRESHOLD, IN CONNECTION WITH THE IMPLEMENTATION OF HIV/AIDS PROGRAMS UNDER THE PRESIDENT'S EMERGENCY PLAN FOR AIDS RELIEF; OR WHERE THE CONTRACTOR WILL RECEIVE FUNDING UNDER THE UNITED STATES LEADERSHIP AGAINST HIV/AIDS, TUBERCULOSIS AND MALARIA ACT OF 2003. SEE HHSAR 370.701.)****

15. **Non-discrimination for Conscience, HHSAR 352.270-9** (December 2015).

a. Section 301(d) of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act, as amended, provides that an organization, including a faith-based organization, that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961, under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, under the Tom Lantos

and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, or under any amendment to the foregoing Acts for HIV/AIDS prevention, treatment, or care-

1. Shall not be required, as a condition of receiving such assistance, to-
    i. Endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or
    ii. Endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.

2. Shall not be discriminated against under the provisions of law in subparagraph (a) for refusing to meet any requirement described in paragraph (a)(1) in this solicitation.

b. Accordingly, an offeror who believes this solicitation contains work requirements that would require it to endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS, or to endorse, utilize, make referral to, become integrated with, or otherwise participate in a program or activity to which it has a religious or moral objection, shall identify those work requirements it has excluded in its technical proposal.

c. The Government acknowledges that an offeror has specific rights, as cited in paragraph (b) of this provision, to exclude certain work requirements in this solicitation from its proposal. However, the Government reserves the right to not make an award to an offeror whose proposal does not comply with the salient work requirements of the solicitation. Any exercise of that Government right will be made by the Head of the Contracting Activity.

(End of provision).

630

****(USE BELOW IF THE GOVERNMENT MAY REQUIRE A DIFFERENT SCOPE OR SPECIAL REQUIREMENTS IN LIEU OF OR IN ADDITION TO THAT DEFINED IN THE GENERAL RIGHTS IN DATA CLAUSE.)****

Note: *This should be handled on a case-by-case basis. For additional guidance, contact the NIH Office of Technology Transfer (OTT) at (301-496-7057).*

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- The Contracting Officer with the assistance of the Project Officer and/or Contracting Officer's Representative (COR) shall select the appropriate sentence within the [brackets] below. If the special requirements are known at the time of the solicitation, they should be stated in the SOLICITATION.

16. **Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)**

Under the provisions of the Rights in Data General clause (FAR 52.227-14), contractors must seek permission to establish a copyright for software and associated data generated under a contract. As a general rule, permission is normally granted provided, a paid-up, world-wide, irrevocable, nonexclusive license to the Government is provided. This is to advise offerors that for this project, the Government intends to assert additional copyright permissions under this contract. [The scope of the Government's interest in the copyright will be determined during negotiations. - **OR** - The Government will require: *State specific requirements*].

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

17. **Privacy Act - Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this SOLICITATION pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this

information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the Government Accountability Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

632

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

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Subparagraph a:** For R&D SOLICITATIONS include the language within the brackets. For Non R&D SOLICITATIONS remove the bracketed information in its entirety.
2. **Subparagraphs d and f:** Insert the applicable I/C name in the text box.

18. **Selection of Offerors**

a. The acceptability of the [scientific and] technical portion of each [research] contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b. The business portion of each contract proposal found to be technical acceptable will be subjected to a cost and price analysis, management analysis, etc.
c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
d. If the Government intends to conduct discussions prior to awarding a contract -
    1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

       Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.
    2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

       While it is ___ 's policy to conduct discussions with all offerors in the competitive range, ___ reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR Part 315.
e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost

factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.

f. The ___ reserves the right to make a single award, multiple awards, or no award at all to the SOLICITATION. In addition, the SOLICITATION may be amended or canceled as necessary to meet ___ requirements. Synopses of awards exceeding $25,000 will be published in Contract Opportunities at: https://sam.gov/content/home .

633

****(USE BELOW FOR ALL R&D REQUIREMENTS EXCEPT THOSE EXPECTED TO BE AWARDED TO A FEDERAL AGENCY.)****

19. **Institutional Responsibility Regarding Investigator Conflicts of Interest**

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any Investigator financial conflicts of interest. The Institution shall comply with all requirements of 45 CFR Part 94 at: https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94 .

634

****(USE BELOW IN SOLICITATIONS WHERE THERE IS A CHANCE THAT AN EDUCATIONAL INSTITUTION WILL SUBMIT A PROPOSAL.)****

Note: *The prohibition contained in the FY-97 Appropriations Act is intended to be continuous until it is expressly rescinded.*

20. **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of

Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

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****(USE BELOW IN ALL SOLICITATIONS THAT WILL EXCEED $5.5 M)****

21. **Certification Regarding Tax Matters, FAR 52.209-12 (**Oct 2020**)**.

(a) This implements section 523 of Division B of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113- 235), and similar provisions, if contained in subsequent appropriations acts.

(b) If the Offeror is proposing a total contract price that will exceed $5.5 million (including options), the Offeror shall certify that, to the best of its knowledge and belief, it

(1) Has [ ] filed all Federal tax returns required during the three years preceding the certification;

(2) Has [ ] been convicted of a criminal offense under the Internal Revenue Code of 1986; and

(3) Has not [ ] , more than 90 days prior to certification, been notified of any unpaid Federal tax assessment for which the liability remains unsatisfied, unless the assessment is the subject of an installment agreement or offer in compromise that has been approved by the Internal Revenue Service and is not in default, or the assessment is the subject of a non- frivolous administrative or judicial proceeding.

(End of provision).

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****(USE BELOW IN ALL SOLICITATIONS INCLUDING COMMERCIAL ITEMS UNDER FAR PART 12.)****

22. **Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation, FAR 52.203-18** (Jan 2017).

a. *Definition* . As used in this provision-
Internal confidentiality agreement or statement, subcontract, and

subcontractor, are defined in the clause at 52.203-19 , Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements.

b. In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use funds appropriated (or otherwise made available) for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

c. The prohibition in paragraph (b) of this provision does not contravene requirements applicable to Standard Form 312, (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

d. Representation. By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(End of provision).

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****(USE BELOW IN COMPETITIVE SOLICITATIONS THAT ARE EXPECTED TO EXCEED THE SIMPLIFIED ACQUISITION THRESHOLD UNLESS THE CONTRACTING OFFICER HAS DETERMINED IN WRITING THAT EVALUATION OF PAST PERFORMANCE IS NOT ESSENTIAL TO ENSURING AWARD TO THE OFFEROR MOST CAPABLE OF PERFORMING. NOTE: FOR OPTION CONTRACTS THE ESTIMATED BASE AMOUNT PLUS THE OPTION AMOUNTS ARE TO BE CONSIDERED IN DETERMINING THE TOTAL VALUE OF THE RESULTANT CONTRACT.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Paragraph a:**
  - First sentence:
    - Select BUSINESS proposal from the Drop Down List, if proposals are to be reviewed by non-Government employees. Otherwise, the information may be submitted with either the BUSINESS or TECHNICAL proposal based on the Contracting Officer's discretion.
  - Second paragraph:
    - Indicate the number of past contracts for which you would like to see past performance information. Select the appropriate information for your solicitation from within each of the 2 bracketed sections and complete fill in information as required.
    - The Contracting Officer will define "major subcontract" for individual acquisitions. A major subcontract could be defined, for example, as a subcontract that exceeds a certain dollar threshold.

23. **Past Performance Information**
    a. Offerors shall submit the following information as part of their [Business/Technical] proposal.

    A list of the last _ contracts completed during the past [One/Two/Three/Four/Five] years and [ALL CONTRACTS/THE LAST _ CONTRACTS AWARDED] currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as _____ .

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System (NAICS) Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

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****(USE BELOW IN TIME-AND-MATERIAL/LABOR-HOUR SOLICITATIONS FOR NONCOMMERCIAL ITEMS IF THE PRICE IS NOT EXPECTED TO BE BASED ON ADEQUATE PRICE COMPETITION.)****

24. **Time-and-Material/Labor-Hour Proposal Requirements--Non-Commercial Item Acquisitions without Adequate Price Competition, FAR 52.216-30** (Nov 2021).

(a) The Government contemplates award of a Time-and-Materials or Labor-Hour type of contract resulting from this solicitation.

(b) The offeror must specify separate fixed hourly rates in its offer that include wages, overhead, general and administrative expenses, and profit for each category of labor to be performed by—

(1) The offeror;
(2) Each subcontractor; and
(3) Each division, subsidiary, or affiliate of the offeror under a common control.

(c) Unless exempt under paragraph (d) of this provision, the fixed hourly rates for services transferred between divisions, subsidiaries, or affiliates of the offeror under a common control—

(1) Shall not include profit for the transferring organization; but
(2) May include profit for the prime Contractor.

(d) The fixed hourly rates for services that meet the definition of commercial item at 2.101 that are transferred between divisions, subsidiaries, or affiliates of the offeror under a common control may be the established catalog or market rate when it is the established practice of the transferring organization to price interorganizational transfers at other than cost for commercial work of the offeror or any division, subsidiary or affiliate of the offeror under a common control.

(End of provision).

639

****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT LESS THAN $7,008,000.)****

25. **Notice of Buy American Requirement--Construction Materials, FAR 52.225-10** (May 2014).

(a) *Definitions.* "Commercially available off-the-shelf (COTS) item," "construction material," "domestic construction material," and "foreign construction material," as used in this provision, are defined in the clause of this solicitation entitled "Buy American--Construction Materials" (Federal Acquisition Regulation (FAR) clause 52.225-9).

(b) *Requests for determinations of inapplicability.* An offeror requesting a determination regarding the inapplicability of the Buy American statute should submit the request to the Contracting Officer in time to allow a determination before submission of offers. The offeror shall include the information and applicable supporting data required by paragraphs (c) and (d) of the clause at FAR 52.225-9 in the request. If an offeror has not requested a determination regarding the inapplicability of the Buy American statute before submitting its offer, or has not received a response to a previous request, the offeror shall include the information and supporting data in the offer.

(c) *Evaluation of offers.*

(1) The Government will evaluate an offer requesting exception to the requirements of the Buy American statute based on claimed unreasonable cost of domestic construction material, by adding to the offered price the appropriate percentage of the cost of such foreign construction material, as

specified in paragraph (b)(3)(i) of the clause at FAR 52.225-9.
(2) If evaluation results in a tie between an offeror that requested the substitution of foreign construction material based on unreasonable cost and an offeror that did not request an exception, the Contracting Officer will award to the offeror that did not request an exception based on unreasonable cost.

(d) Alternate offers.

(1) When an offer includes foreign construction material not listed by the Government in this solicitation in paragraph (b)(2) of the clause at FAR 52.225-9, the offeror also may submit an alternate offer based on use of equivalent domestic construction material.
(2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer, and a separate price comparison table prepared in accordance with paragraphs (c) and (d) of the clause at FAR 52.225-9 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.
(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of the clause at FAR 52.225-9 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic construction material, and the offeror shall be required to furnish such domestic construction material. An offer based on use of the foreign construction material for which an exception was requested-

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or
(ii) May be accepted if revised during negotiations.

(End of provision).

640

****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW WITH FAR 52.225-10 IF INSUFFICIENT TIME IS AVAILABLE TO PROCESS A DETERMINATION REGARDING THE INAPPLICABILITY OF THE BUY AMERICAN STATUTE PRIOR TO RECEIPT OF OFFERS.)****

Alternate I (May 2014), **FAR 52.225-10, Notice of Buy American Requirement--Construction Materials** (May 2014). As prescribed in 25.1102(b)(2), substitute the following paragraph (b) for paragraph (b) of the basic provision:

(b) Requests for determinations of inapplicability. An offeror requesting a determination regarding the inapplicability of the Buy American statute shall submit the request with its offer, including the information and applicable supporting data required by paragraphs (c) and (d) of the clause at FAR 52.225-9.

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****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,032,000 OR MORE.)****

26. **Notice of Buy American Requirement--Construction Materials Under Trade Agreements, FAR 52.225-12** (May 2014).

(a) *Definitions* . "Commercially available off-the-shelf (COTS) item," "construction material," "designated country construction material," "domestic construction material," and "foreign construction material," as used in this provision, are defined in the clause of this solicitation entitled "Buy American--Construction Materials Under Trade Agreements" (Federal Acquisition Regulation (FAR) clause 52.225-11).

(b) *Requests for determination of inapplicability.* An offeror requesting a determination regarding the inapplicability of the Buy American statute should submit the request to the Contracting Officer in time to allow a determination before submission of offers. The offeror shall include the information and applicable supporting data required by paragraphs (c) and (d) of FAR clause 52.225-11 in the request. If an offeror has not requested a determination regarding the inapplicability of the Buy American statute before submitting its offer, or has not received a response to a previous request, the offeror shall include the information and supporting data in the offer.

(c) *Evaluation of offers.*

(1) The Government will evaluate an offer requesting exception to the requirements of the Buy American statute based on claimed unreasonable cost of domestic construction materials, by adding to the offered price the appropriate percentage of the cost of such foreign construction material, as specified in paragraph (b)(4)(i) of FAR clause 52.225-11.

(2) If evaluation results in a tie between an offeror that requested the substitution of foreign construction material based on unreasonable cost and an offeror that did not request an exception, the Contracting Officer will award to the offeror that did not request an exception based on unreasonable cost.

(d) *Alternate offers.*

(1) When an offer includes foreign construction material, other than

designated country construction material, that is not listed by the Government in this solicitation in paragraph (b)(3) of FAR clause 52.225-11, the offeror also may submit an alternate offer based on use of equivalent domestic or designated country construction material.

(2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer, and a separate price comparison table prepared in accordance with paragraphs (c) and (d) of FAR clause 52.225-11 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.

(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of FAR clause 52.225-11 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic or designated country construction material, and the offeror shall be required to furnish such domestic or designated country construction material. An offer based on use of the foreign construction material for which an exception was requested--

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or

(ii) May be accepted if revised during negotiations.

(End of provision).

642

****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW WITH FAR 52.225-12, IF INSUFFICIENT TIME IS AVAILABLE TO PROCESS A DETERMINATION REGARDING THE INAPPLICABILITY OF THE BUY AMERICAN ACT PRIOR TO RECEIPT OF OFFERS.)****

Alternate I (May 2014), **FAR 52.225-12, Notice of Buy American Requirement--Construction Materials Under Trade Agreements** (May 2014).

As prescribed in 25.1102(d)(2), substitute the following paragraph (b) for paragraph (b) of the basic provision:

(b) Requests for determination of inapplicability. An offeror requesting a determination regarding the inapplicability of the Buy American statute shall submit the request with its offer, including the information and applicable supporting data required by paragraphs (c) and (d) of FAR clause 52.225-11.

643

****(WHEN USING FUNDS **OTHER THAN** RECOVERY ACT FUNDS, USE BELOW WITH FAR 52.225-12, IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,032,000 OR MORE, BUT LESS THAN $12,001,460.)****

Alternate II (June 2009), FAR Clause **52.225-12, Notice of Buy American Requirement-Construction Materials Under Trade Agreements** (May 2014)**.**

As prescribed in 25.1102(d)(3), add the definition of "Bahrainian, Mexican, or Omani construction material" to paragraph (a) and substitute the following paragraph (d) for paragraph (d) of the basic provision:

(d) *Alternate offers.*

(1) When an offer includes foreign construction material, except foreign construction material from a designated country other than Bahrain, Mexico, or Oman that is not listed by the Government in this solicitation in paragraph (b)(3) of FAR clause 52.225-11, the offeror also may submit an alternate offer based on use of equivalent domestic or designated country construction material other than Bahrainian, Mexican, or Omani construction material.

(2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer, and a separate price comparison table prepared in accordance with paragraphs (c) and (d) of FAR clause 52.225-11 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.

(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of FAR clause 52.225-11 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic or designated country construction material other than Bahrainian, Mexican, or Omani construction material. An offer based on use of the foreign construction material for which an exception was requested—

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or
(ii) May be accepted if revised during negotiations.

644

****(WHEN USING RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT LESS THAN $7,032,000.)****

27. **Notice of Required Use of American Iron, Steel, and Manufactured Goods--Buy American Statute--Construction Materials, FAR 52.225-22** (Jan 2021).

(a) *Definitions.* "Construction material," "domestic construction material," "foreign construction material," "manufactured construction material," "steel," and "unmanufactured construction material," as used in this provision, are defined in the clause of this solicitation entitled "Required Use of Iron, Steel, and Manufactured Goods--Buy American Statute--Construction Materials" (Federal Acquisition Regulation (FAR) clause 52.225-21).

(b) *Requests for determinations of inapplicability.* An offeror requesting a determination regarding the inapplicability of section 1605 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act) or the Buy American statute should submit the request to the Contracting Officer in time to allow a determination before submission of offers. The offeror shall include the information and applicable supporting data required by paragraphs (c) and (d) of the clause at FAR 52.225-21 in the request. If an offeror has not requested a determination regarding the inapplicability of section 1605 of the Recovery Act or the Buy American statute before submitting its offer, or has not received a response to a previous request, the offeror shall include the information and supporting data in the offer.

(c) *Evaluation of offers.* (1) If the Government determines that an exception based on unreasonable cost of domestic construction material applies in accordance with FAR 25.604, the Government will evaluate an offer requesting exception to the requirements of section 1605 of the Recovery Act or the Buy American statute by adding to the offered price of the contract--

(i) 25 percent of the offered price of the contract, if foreign manufactured construction material is incorporated in the offer based on an exception for unreasonable cost of comparable manufactured domestic construction material; and

(ii) 20 percent of the cost of foreign unmanufactured construction material included in the offer based on an exception for the unreasonable cost of comparable domestic unmanufactured construction material.

(2) If the solicitation specifies award on the basis of factors in addition to cost or price, the Contracting Officer will apply the evaluation factors as specified in paragraph (c)(1) of this provision and use the evaluated price in determining the offer that represents the best value to the Government.

(3) Unless paragraph (c)(2) of this provision applies, if two or more offers are equal in price, the Contracting Officer will give preference to an offer that does

not include foreign construction material excepted at the request of the offeror on the basis of unreasonable cost of comparable domestic construction material.

(d) *Alternate offers.* (1) When an offer includes foreign construction material not listed by the Government in this solicitation in paragraph (b)(3) of the clause at FAR 52.225-21, the offeror also may submit an alternate offer based on use of equivalent domestic construction material.

(2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer and a separate cost comparison table prepared in accordance with paragraphs (c) and (d) of the clause at FAR 52.225-21 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.

(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of the clause at FAR 52.225-21 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic construction material, and the offeror shall be required to furnish such domestic construction material. An offer based on use of the foreign construction material for which an exception was requested—

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or
(ii) May be accepted if revised during negotiations.

(End of provision).

645

****(WHEN USING RECOVERY ACT FUNDS, USE BELOW WITH FAR 52.225-22 IF INSUFFICIENT TIME IS AVAILABLE TO PROCESS A DETERMINATION REGARDING THE INAPPLICABILITY OF THE BUY AMERICAN STATUTE PRIOR TO RECEIPT OF OFFERS.)****

Alternate I (May 2014), **FAR 52.225-22, Notice of Required Use of American Iron, Steel, and Manufactured Goods--Buy American Statute--Construction Materials** (Jan 2021).

As prescribed in 25.1102(e), substitute the following paragraph (b) for paragraph (b) of the basic provision:

(b) *Requests for determinations of inapplicability* . An offeror requesting a determination regarding the inapplicability of section 1605 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act) or the Buy American statute shall submit the request with its offer, including the information and applicable supporting data required by paragraphs (c) and (d) of

the clause at FAR 52.225-21.

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****(WHEN USING RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,032,000 OR MORE.)****

28. **Notice of Required Use Of American Iron, Steel, and Manufactured Goods--Buy American Statute--Construction Materials Under Trade Agreements, FAR 52.225-24** (Jan 2021).

(a) *Definitions* . "Construction material," "domestic construction material," "foreign construction material," "manufactured construction material," "Recovery Act designated country construction material," "steel," and "unmanufactured construction material," as used in this provision, are defined in the clause of this solicitation entitled "Required Use of Iron, Steel, and Manufactured Goods--Buy American statute--Construction Materials Under Trade Agreements" (Federal Acquisition Regulation (FAR) clause 52.225-23).

(b) *Requests for determination of inapplicability* . An offeror requesting a determination regarding the inapplicability of section 1605 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act) or the Buy American statute should submit the request to the Contracting Officer in time to allow a determination before submission of offers. The offeror shall include the information and applicable supporting data required by paragraphs (c) and (d) of FAR clause 52.225-23 in the request. If an offeror has not requested a determination regarding the inapplicability of section 1605 of the Recovery Act or the Buy American statute before submitting its offer, or has not received a response to a previous request, the offeror shall include the information and supporting data in the offer.

(c) *Evaluation of offers* . (1) If the Government determines that an exception based on unreasonable cost of domestic construction material applies in accordance with FAR 25.604, the Government will evaluate an offer requesting exception to the requirements of section 1605 of the Recovery Act or the Buy American statute by adding to the offered price of the contract-

(i) 25 percent of the offered price of the contract, if foreign manufactured construction material is included in the offer based on an exception for the unreasonable cost of comparable manufactured domestic construction material; and

(ii) 20 percent of the cost of foreign unmanufactured construction material

included in the offer based on an exception for the unreasonable cost of comparable domestic unmanufactured construction material.

(2) If the solicitation specifies award on the basis of factors in addition to cost or price, the Contracting Officer will apply the evaluation factors as specified in paragraph (c)(1) of this provision and use the evaluated cost or price in determining the offer that represents the best value to the Government.

(3) Unless paragraph (c)(2) of this provision applies, if two or more offers are equal in price, the Contracting Officer will give preference to an offer that does not include foreign construction material excepted at the request of the offeror on the basis of unreasonable cost.

(d) Alternate offers. (1) When an offer includes foreign construction material, other than Recovery Act designated country construction material, that is not listed by the Government in this solicitation in paragraph (b)(3) of FAR clause 52.225-23, the offeror also may submit an alternate offer based on use of equivalent domestic or Recovery Act designated country construction material.

(2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer and a separate cost comparison table prepared in accordance with paragraphs (c) and (d) of FAR clause 52.225-23 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.

(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of FAR clause 52.225-23 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic or Recovery Act designated country construction material, and the offeror shall be required to furnish such domestic or Recovery Act designated country construction material. An offer based on use of the foreign construction material for which an exception was requested—

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or
(ii) May be accepted if revised during negotiations.

(End of provision)

647

****(WHEN USING RECOVERY ACT FUNDS, USE BELOW WITH FAR 52.225-24, IF INSUFFICIENT TIME IS AVAILABLE TO PROCESS A DETERMINATION REGARDING THE INAPPLICABILITY OF THE BUY AMERICAN ACT PRIOR TO RECEIPT OF OFFERS FOR ACQUISITIONS VALUED AT $7,032,000 OR MORE, BUT LESS THAN $12,001,460.)****

Alternate I (May 2014), **FAR Clause 52.225-24, Notice of Required Use of American Iron, Steel, and Manufactured Goods-Buy American Statute-Construction Materials under Trade Agreements** (Jan 2021).

As prescribed in 25.1102(e), substitute the following paragraph (b) for paragraph (b) of the basic provision:

(b) *Requests for determination of inapplicability* . An offeror requesting a determination regarding the inapplicability of section 1605 of the American Recovery and Reinvestment Act of 2009 (Pub. L. 111-5) (Recovery Act) or the Buy American statute shall submit the request with its offer, including the information and applicable supporting data required by paragraphs (c) and (d) of FAR clause 52.225-23.

648

****(WHEN USING RECOVERY ACT FUNDS, USE BELOW IN SOLICITATIONS FOR CONSTRUCTION PERFORMED IN THE UNITED STATES AND VALUED AT $7,032,000 OR MORE, BUT LESS THAN $12,001,460.)****

Alternate II (Mar 2009), **FAR Clause 52.225-24, Notice of Required Use of American Iron, Steel, and Manufactured Goods-Buy American Act-Construction Materials under Trade Agreements** (Jan 2021).

As prescribed in 25.1102(e), add the definition of "Bahrainian, Mexican, or Omani construction material" to paragraph (a) and substitute the following paragraph (d) for paragraph (d) of the basic provision:

(d) *Alternate offers.* (1) When an offer includes foreign construction material, except foreign construction material from a Recovery Act designated country other than Bahrain, Mexico, or Oman that is not listed by the Government in this solicitation in paragraph (b)(3) of FAR clause 52.225-23, the offeror also may submit an alternate offer based on use of equivalent domestic or Recovery Act designated country construction material other than Bahrainian, Mexican, or Omani construction material.

(2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer and a separate cost comparison table prepared in accordance

with paragraphs (c) and (d) of FAR clause 52.225-23 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.

(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of FAR clause 52.225-23 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic or Recovery Act designated country construction material other than Bahrainian, Mexican, or Omani construction material. An offer based on use of the foreign construction material for which an exception was requested—

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or
(ii) May be accepted if revised during negotiations.

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****(USE BELOW IN NEGOTIATED FIXED-PRICE REQUIREMENTS (excluding Architect and Engineering, and Construction contracts) WHERE PERFORMANCE-BASED CONTRACT FINANCING WILL BE PROVIDED.)****

29. **Invitation to Propose Performance-Based Payments, FAR 52.232-28** (Mar 2000).

(a) The Government invites the offeror to propose terms under which the Government will make performance-based contract financing payments during contract performance. The Government will consider performance-based payment financing terms proposed by the offeror in the evaluation of the offeror's proposal. The Contracting Officer will incorporate the financing terms of the successful offeror and the FAR clause, Performance-Based Payments, at FAR 52.232-32, in any resulting contract.

(b) In the event of any conflict between the terms proposed by the offeror and the terms in the clause at FAR 52.232-32, Performance-Based Payments, the terms of the clause at FAR 52.232-32 shall govern.

(c) The Contracting Officer will not accept the offeror's proposed performance-based payment financing if the financing does not conform to the following limitations:

(1) The Government will make delivery payments only for supplies delivered and accepted, or services rendered and accepted in accordance with the payment terms of this contract.

(2) The terms and conditions of the performance-based payments must-

(i) Comply with FAR 32.1004;

(ii) Be reasonable and consistent with all other technical and cost information included in the offeror's proposal; and

(iii) Their total shall not exceed 90 percent of the contract price if on a whole contract basis, or 90 percent of the delivery item price if on a delivery item basis.

(3) The terms and conditions of the performance-based financing must be in the best interests of the Government.

(d) The offeror's proposal of performance-based payment financing shall include the following:

(1) The proposed contractual language describing the performance-based payments (see FAR 32.1004 for appropriate criteria for establishing performance bases and performance-based finance payment amounts).

(2) A listing of-

(i) The projected performance-based payment dates and the projected payment amounts; and

(ii) The projected delivery date and the projected payment amount.

(3) Information addressing the Contractor's investment in the contract.

(e) Evaluation of the offeror's proposed prices and financing terms will include whether the offeror's proposed performance-based payment events and payment amounts are reasonable and consistent with all other terms and conditions of the offeror's proposal.

(End of provision)

650

****(USE BELOW WITH 52.232-28 (above) IN COMPETITIVE NEGOTIATED SOLICITATIONS (excluding Architect and Engineering, and Construction contracts) IF THE GOVERNMENT INTENDS TO ADJUST PROPOSED PRICES FOR PROPOSAL EVALUATION PURPOSES (See FAR 32.1004(e).)****

Alternate I (Mar 2000), **FAR Clause 52.232-28, Invitation to Propose Performance-Based Payments** (Mar 2000).

As prescribed in FAR 32.1005(b)(2), add the following paragraph (f) to the basic provision:

(f) The Government will adjust each proposed price to reflect the cost of providing the proposed performance-based payments to determine the total cost to the Government of that particular combination of price and performance-based financing. The Government will make the adjustment using the procedure described in FAR 32.205(c).

651

****(USE BELOW IN ALL SOLICITATIONS FUNDED WITH APPROPRIATED BIO-DEFENSE FUNDS.

Note: *At this time, may only be applicable to NIAID projects* .

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

30. **Prohibition on Contractor Involvement with Terrorist Activities**

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

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****(INCLUDE BELOW IN SOLICITATIONS WHEN IT HAS BEEN DETERMINED THAT:

- CONTRACTOR PERSONNEL MAY REQUIRE ACCESS TO HHS-CONTROLLED FACILITIES AND/OR INFORMATION SYSTEMS, INCLUDING SENSITIVE DATA/INFORMATION, IN ORDER TO PERFORM THE CONTRACT/ORDER SOW/PWS, AND/OR ;
- THE HOMELAND SECURITY PRESIDENTIAL DIRECTIVE'S (HSPD-12) MORE STRINGENT ACCESS PROCEDURES ARE EXPECTED TO APPLY, BECAUSE ACCESS WILL BE ROUTINE AND OF LONG-TERM DURATION, OR IS ROUTINE AND OF SHORT-TERM DURATION, BUT GREATER ACCESS CONTROLS ARE DEEMED NECESSARY.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

1. For more information, see HHS OCIO Program Policies at: https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/information-security-privacy-program/index.html.
2. The Contract Specialist, Project Officer, I/C Information Systems Security Officer (ISSO), and/or Privacy Officer can assist the acquisition staff in tailoring the language in the below Article. If additional guidance is needed, contact the individual responsible for Contracts (Security Language) - located in the NIH Office of the Chief Information Officer (OCIO) - Phone: 301-496-1168 and Email: nihciocommunications@mail.nih.gov.

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

Second paragraph: Select "Technical" or "Business" as appropriate from the drop-down box.

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

HHS Security and Privacy Language for Information and Information Technology Procurements is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the _____ Technical/Business] Proposal entitled "Information Security."

The Homeland Security Presidential Directive (HSPD)-12 and the Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, Contractor (including subcontractor), or other source.

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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 for Position Sensitivity Designations. To determine the designation, the Position Designation Tool (PDT) discussion is found at: https://ors.od.nih.gov/ser/dpsac/administrators/onboarding-new-staff/Pages/position-designation-tool.aspx .

The requiring activity representative, in conjunction with Personnel Security, shall use the OPM Position Sensitivity Designation automated tool (https://pdt.nbis.mil/) to determine the sensitivity designation for background investigations. After making those determinations, include all applicable position sensitivity designations.

32. **INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY**

A. **POSITION SENSITIVITY DESIGNATIONS**

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 and 732of Title 5, Code of Federal Regulations (CFR). To determine the designation, the Position Designation Tool (PDT) discussion is found at: https://ors.od.nih.gov/ser/dpsac/administrators/onboarding-new-staff/Pages/position-designation-tool.aspx and the link to access the tool is found at: https://pdt.nbis.mil/. The following position sensitivity designation levels apply to this solicitation/contract:

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

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

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

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

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

HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

The Contractor (and/or any subcontractor) and its employees must comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; FIPS 201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; and Executive Order 13467, Part 1 §1.2.
For additional information, see HSPD-12 policy at: https://www.dhs.gov/homeland-security-presidential-directive-12

Roster-

1. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster shall be submitted to the COR and/or CO within fourteen (14) calendar days after the effective date of this contract. Any revisions to the roster as a result of staffing changes shall be submitted within seven (7) calendar days of the change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j.
2. If the Contractor is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.
3. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

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

B. **Assessment and Authorization (A&A)-** A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) shall work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s) within three (3) months after contract award. The Contractor shall conduct the A&A requirements in accordance with HHS IS2P, NIST SP 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach (latest revision).

For an existing ATO, Contracting Officer Representative must make a determination if the existing ATO provides appropriate safeguards or if an additional ATO is required for the performance of the contract and state as such.

NIH acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the system security and privacy controls are implemented and operating effectively.

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

- **System Security Plan (SSP) -** due within 30 days after contract award. The SSP shall comply with the NIST SP 800-18, Guide for Developing Security Plans for Federal Information Systems, the Federal Information Processing Standard (FIPS) 200, Recommended Security Controls for Federal Information Systems, and NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline requirements, and other applicable NIST guidance as well as HHS and NIH policies and other guidance. The SSP shall be consistent with and detail the approach to IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The SSP shall provide an overview of the system environment and security requirements to protect the information system as well as describe all applicable security controls in place or planned for meeting those requirements. It should provide a structured process for planning adequate, cost-effective security protection for a system. The Contractor shall update the SSP at least annually thereafter.
- **Security Assessment Plan/Report (SAP/SAR) -** due 30 days after the contract award. The security assessment shall be conducted by the assessor and be consistent with NIST SP 800-53A, NIST SP 800-30, and HHS and NIH policies. The assessor will document the assessment results in the SAR.

  The NIH should determine which security control baseline applies and then make a determination on the appropriateness/necessity of obtaining an independent assessment. Assessments of controls can be performed by contractor, government, or third parties, with third party verification considered the strongest. If independent assessment is required, include statement below.

  Thereafter, the Contractor, in coordination with the NIH shall conduct/assist in the assessment of the security controls and update the SAR at least annually.

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

- **POA&M -** due 30 days after contract award. The POA&M shall be documented consistent with the HHS Standard for Plan of Action and Milestones and NIH policies.
  All findings/weaknesses shall be documented in the POA&M and remediated/mitigated from the date the weaknesses are formally identified and documented by the timelines below:
    - Critical within 30 days;
    - High within 60 days;
    - Medium within 1 year; and
    - Low within 1 year.

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

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

- **E-Authentication Questionnaire -** The Contractor (and/or any subcontractor) shall collaborate with government personnel to ensure that an E-Authentication Threshold Analysis (E- auth TA) is completed to determine if a full E-Authentication Risk Assessment (E-auth RA) is necessary. System documentation developed for a system using E-auth TA/E-auth RA methods shall follow OMB 04-04 and NIST SP 800-63, Rev. 2, Electronic Authentication Guidelines.

  Based on the level of assurance determined by the E- Auth, the Contractor (and/or subcontractor) must ensure appropriate authentication to the system, including remote authentication, is in- place in accordance with the assurance level determined by the E-Auth (when required) in accordance with HHS policies.

E. **Reporting and Continuous Monitoring**

Following the initial ATOs, the Contractor (and/or any subcontractor) must perform the minimum ongoing continuous monitoring activities specified below, submit required deliverables by the specified due dates, and meet with the system/ service owner and other relevant stakeholders to discuss the ongoing continuous monitoring activities, findings, and other relevant matters. The CSP will work with the agency to schedule ongoing continuous monitoring activities.

- **Information Security Continuous Monitoring-** Upon the government issuance of an Authority to Operate (ATO), the Contractor (and/or subcontractor)- owned/operated systems that input, store, process, output, and/ or transmit government information, shall meet or exceed the Information Security Continuous Monitoring (ISCM) requirements in accordance with FISMA and NIST SP 800- 137, Information Security Continuous Monitoring (ISCM) for Federal Information Systems and Organizations, and HHS IS2P. The following are the minimum requirements for ISCM:
- **Annual Assessment/ Pen Test -** Assess the system security and privacy controls (or ensure an assessment of the controls is conducted) at least every two (2) years on high-risk systems, to determine the implemented security and privacy controls are operating as intended and producing the desired results. This may involve penetration testing conducted by the agency or independent third- party. In addition, review all relevant A& A documentation (SSP, POA& M, Contingency Plan, etc.) and provide updates by specified due date provided by the Contracting Officer Representative.
- **Asset Management -** Using any available Security Content Automation Protocol (SCAP)- compliant automated tools for active/ passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing HHS- owned information/ data. It is anticipated that this inventory information will be required to be produced at least 60 days after contract award. IT asset inventory information shall include IP address, machine name, operating system level, security patch level, and SCAP- compliant format information. The Contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.
- **Configuration Management -** Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The Contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.
- **Vulnerability Management -** Use SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process government information. Contractors shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS policy. Automated tools shall be compliant with NIST-specified

SCAP standards for vulnerability identification and management. The Contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP- compliant automated tools and report to the agency at least within 30 days of the contract award.

- **Patching and Vulnerability Remediation -** Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeframes.
- **Secure Coding -** Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
- **Boundary Protection -** The Contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).
- A security control assessment must be conducted by a FedRAMP third- party assessment organization (3PAO) for the initial ATO and annually thereafter or whenever there is a significant change to the system's security posture in accordance with the FedRAMP Continuous Monitoring Plan.
- At a minimum, the Contractor must provide the following artifacts/ deliverables on a monthly basis as directed by the Contracting Officer/ Contracting Officer Representative.
    1. Operating system, database, Web application, and network vulnerability scan results;
    2. Updated POA&Ms;
    3. Any updated authorization package documentation as required by the annual attestation/ assessment/ review or as requested by the NIH System Owner or AO; and
    4. Any configuration changes to the system and/ or system components or CSP's cloud environment, that may impact HHS/ NIH's security posture. Changes to the configuration of the system, its components, or environment that may impact the security posture of the system under this contract must be approved by the agency.

F. **Configuration Baseline**

The Contractor shall certify that applications are fully functional and operate correctly as intended on systems using the US Government Configuration Baseline (USGCB), DISA Security Technical Implementation Guides (STIGs), Center for Information Security (CIS) Security Benchmarks or any other HHS- identified configuration baseline. The standard installation, operation, maintenance, updates, and/ or patching of software shall not alter the configuration settings from the approved HHS/NIH.

- The Contractor shall configure its computers that contain HHS data with the latest applicable United States Government Configuration Baseline (USGCB) and/or other

approved HHS IT Security Configurations. (See: https://usgcb.nist.gov/). Note: Approved security configurations include, but are not limited to, those published by the Department, the NIH, and the National Institute of Standards and Technology (NIST) . NIH may have security configurations that are more stringent than the minimum baseline set by the Department or NIST. When incorporating such security configuration requirements in solicitations and contracts, the NIH CISO and/or Information System Security Officer (ISSO) shall be consulted to determine the appropriate configuration reference for a particular system or services acquisition.)

- The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS and must adhere to all NIH configuration standards and policies (See: https://ocio.nih.gov/InfoSecurity/Policy/Pages/CM.aspx.
- The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)- validated tools with USGCB Scanner capability to ensure its products operate correctly with USGCB configurations and do not alter USCGB settings - (See: http://scap.nist.gov/validation). The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest USGCB major version and subsequent major versions.
- The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.
- The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.
- The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (See: http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf), Homeland Security
  Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.
- The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.
- The Contractor shall use Security Content Automation Protocol (SCAP) validated tools with configuration baseline scanner capability to certify their products operate correctly with HHS and NIST defined configurations and do not alter these settings.

G. **Standard for Encryption**

The Contractor (and/or any subcontractor) shall:

1. Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.

2. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-3 validated encryption solution.
3. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and NIH- specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).
4. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-3. The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer Technical Representative within 15 days of the validation.
5. Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys. Encryption keys shall be provided to the COR upon request and at the conclusion of the contract.

H. **Applicability**

The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:

1. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.
2. Operate a Federal System Containing Information: A Contractor (and/or any subcontractor) will operate a federal system and information technology containing data that supports the HHS mission. In addition to the Federal Acquisition Regulation (FAR) Subpart 2.1 definition of "information technology" (IT), the term as used in this section includes computers, ancillary
equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services), and related resources.

I. **Safeguarding Information and Information Systems**

In accordance with the Federal Information Processing Standards Publication (FIPS) 199, Standards for Security Categorization of Federal Information and Information Systems, the Contractor (and/ or any subcontractor) must protect government information and information systems in order to ensure:

- **Confidentiality,** which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;
- **Integrity** , which means guarding against improper information modification or destruction, and ensuring information non- repudiation and authenticity; and
- **Availability** , which means ensuring timely and reliable access to and use of information.
    - Provide security for any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor on behalf of HHS regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or Contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, within one (1) hour or less, bring the situation to the attention of the other party.
    - Adopt and implement the policies, procedures, controls, and standards required by the HHS Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the HHS Information Security Program security requirements, outlined in the HHS Information Security and Privacy Policy (IS2P), by contacting the CO/ COR or emailing fisma@hhs.gov
    - Comply with the Privacy Act requirements.

J. **Information Security Categorization** - In accordance with FIPS 199 and National Institute of Standards and Technology (NIST) Special Publication (SP) 800- 60, Volume II: Appendices to Guide for Mapping Types of Information and Information Systems to Security Categories, Contractor Non- Disclosure Agreement and based on information provided by the ISSO, CISO, or other security representative, the risk level for each Security Objective and the Overall Risk Level, which is the highest watermark of the three factors (Confidentiality, Integrity, and Availability) of the information or information system are the following:

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

Based on information provided by the ISSO, Privacy Office, system/data owner, or other security or privacy representative, it has been determined that this solicitation/contract involves:

[ ] No PII [ ] Yes

Personally Identifiable Information (PII). Per the Office of Management and Budget (OMB) Circular A-130, "PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is

linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: social security number, date and place of birth, mother's maiden name, biometric records, etc.

Confidentiality Impact Level has been determined to be:

[ ] Low [ ] Moderate [ ] High

K. **Contract Initiation and Expiration**

1. **General Security Requirements-** The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the Contractor shall follow the HHS EPLC framework and methodology or and in accordance with the HHS Contract Closeout Directive (2018) located at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HHS-Closeout-Directive-2018.pdf . HHS Enterprise Architecture (EA) requirements are located at: https://www.hhs.gov/sites/default/files/eplc-policy-dec-2016.pdf
2. **System Documentation-** Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-160, Systems Security Engineering: Considerations for a Multidisciplinary Approach in the Engineering of Trustworthy Secure Systems, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.
3. **Sanitization of Government Files and Information-** As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation in accordance with the NIH Media Sanitization and Disposal Policy to the CO and/ or COR to certify that, at the government's direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800- 88, Guidelines for Media Sanitization.
4. **Notification-** The Contractor (and/or any subcontractor) shall notify the CO and/ or COR and system ISSO within fifteen days before an employee stops working under this contract.
5. **Contractor Responsibilities Upon Physical Completion of the Contract-** The Contractor (and/or any subcontractors) shall return all government information and IT resources (i.e., government information in non- government-owned systems, media, and backup systems) acquired during the term of this contract to the CO and/or COR. Additionally, the Contractor shall provide a certification that all government information has been properly sanitized and

purged from Contractor-owned systems, including backup systems and media used during contract performance, in accordance with HHS and/or NIH policies.

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

L. TRAINING

1. Mandatory Training for All Contractor Staff- All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable HHS/ NIH Contractor Information Security Awareness, Privacy, and Records Management training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, the employees shall complete NIH Information Security Awareness, Privacy, and Records Management training at least annually, during the life of this contract. All provided training shall be compliant with HHS training policies.
2. Role- based Training- All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role- based training annually commensurate with their role and responsibilities in accordance with HHS policy and the HHS Role- Based Training (RBT) of Personnel with Significant Security Responsibilities Memorandum. Read further guidance about the NIH Role- based Training: https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/index.html
3. Training Records- The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS policy. A copy of the training records shall be provided to the CO and/or COR within 30 days after contract award and annually thereafter or upon request.

M. RULES OF BEHAVIOR

1. The Contractor (and/ or any subcontractor) shall ensure that all employees performing on the contract comply with the HHS Information Technology General Rules of Behavior, and comply with the NIH Information Technology General Rules of Behavior https://ocio.nih.gov/aboutus/publicinfosecurity/securitytraining/Pages/NIH_IT_GeneralRulesofBehavior.aspx , which are contained in the NIH Information Security Awareness Training Course http://irtsectraining.nih.gov

2. All Contractor employees performing on the contract must read and adhere to the Rules of Behavior before accessing Department data or other information, systems, and/ or networks that store/ process government information, initially at the beginning of the contract and at least annually thereafter, which may be done as part of annual NIH Information Security Awareness Training. If the training is provided by the contractor, the signed Rules of Behavior must be provided as a separate deliverable to the CO and/ or COR per defined timelines above.

N. **INCIDENT RESPONSE**

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams within one(1) hour of discovery, whether the response is positive or negative.

FISMA defines an incident as " an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cyber security and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines a breach as "a suspected or confirmed incident involving PII".

1. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-3 validated encryption.
2. DO NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send NIH approved notifications to affected individuals in accordance with https://wiki.ocio.nih.gov/wiki/index.php/US-CERT_Federal_Incident_Notification_Guidelines .
3. Report all suspected and confirmed information security and privacy incidents and breaches to the NIH Incident Response Team (IRT) via email at IRT@mail.nih.gov , COR, CO, the NIH Office of the SOP (or his or her designee), and other

stakeholders, including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable NIH and HHS policy and procedures, NIST standards and guidelines, as well as US- CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contract information, impact classifications/ threat vector, and the type of information compromised. In addition, the Contractor shall:

- cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
- not include any sensitive information in the subject or body of any reporting e- mail; and
- encrypt sensitive information in attachments to email, media, etc.

4. Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.
5. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to Contractor facilities during a breach/ incident investigation within an hour of discovery.

O. **Vulnerability Scanning Reports-**

The Contractor shall report the results of the required monthly special vulnerability scans no later than 10 days following the end of each reporting period. If required monthly, this report may be included as part of the Technical Progress Report. Otherwise, this report shall be submitted under a separate cover on monthly basis.

P. **Confidentiality and Nondisclosure of Information-**

Any information provided to the Contractor (and/ or any subcontractor) by HHS or collected by the Contractor on behalf of HHS shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor

employee or any of its subcontractors to whom any HHS records may be made available or disclosed shall be notified inwriting by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein. The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and NIH policies. Unauthorized disclosure of information will be subject to the HHS/ NIH sanction policies and/ or governed by the following laws and regulations:

18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);

18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and

44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

Each employee, including subcontractors, having access to non- public Department information under this acquisition shall complete the " Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf . A copy of each signed and witnessed Non- Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

654

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

33. **Electronic and Information Technology Accessibility Notice,** HHSAR 352.239-73 (December 2015).

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

b. Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508 . The complete text of the Section 508 Final Provisions can be accessed at https://www.access-board.gov/ict.html .

c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility. In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://www.hhs.gov/web/508 . In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

The "HHS Section 508 Product Assessment Template" is included in SECTION J - List of Attachments, of this solicitation.

655

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

34. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1** (Feb 1998).

This Solicitation incorporates one or more solicitation provisions by

reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

656

****(USE BELOW IN ALL SOLICITATIONS EXCEPT AS PROVIDED IN FAR 4.1102 (a).)****
ADDITIONAL INFORMATION TO COMPLETE THIS ITEM.

- **Alternate I:** Include for contracts to support unusual or compelling needs (FAR 4.1102(a)(5).

a. System for Award Management, FAR Provision 52.204-7 (Oct 2018).

Alternate I (Oct 2018) [is/is not] applicable to this solicitation.

657

****(USE BELOW IN ALL SOLICITATIONS THAT DO NOT CONTAIN THE PROVISION AT FAR 52.204-7, System for Award Management (See FAR 4.1102(a) for additional information.) OR MEET A CONDITION AT FAR 4.605(c)(2).)****

b. Unique Entity Identifier, FAR Provision 52.204-6 (Oct 2016).

658

****(USE BELOW WHEN THE TRADE AGREEMENT ACT OR THE NORTH AMERICAN FREE TRADE AGREEMENT ACT (NAFTA) APPLIES TO THIS REQUIREMENT. THE FOLLOWING CLAUSE MAY ALSO BE INCLUDED IF THE CO DECIDES THAT THEY ARE NECESSARY.)****

c. Submission of Offers in the English Language, FAR Clause 52.214-34, (Apr 1991).

659

****(USE BELOW WHEN THE TRADE AGREEMENT ACT OR THE NORTH AMERICAN FREE TRADE AGREEMENT ACT (NAFTA) APPLIES TO THIS REQUIREMENT. THE FOLLOWING CLAUSE MAY ALSO BE INCLUDED IF THE CO DECIDES THAT THEY ARE NECESSARY.)****

d. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (Apr 1991).

660

****(USE BELOW ONLY IF FACSIMILE PROPOSALS ARE AUTHORIZED.)****

Note: *Careful consideration should be given before allowing facsimile proposals. They SHOULD NOT be used for R&D proposals or any proposal that requires submission to more than one destination. Also, the anticipated size of the proposal should be considered. Large proposals may not be appropriate for faxing.*

IMPORTANT: MAKE SURE TO INCLUDE THE FAX NUMBER ON THE FACE PAGE OF THE SOLICITATION IF FACSIMILE PROPOSALS ARE AUTHORIZED.

e. Facsimile Proposals, FAR Clause 52.215-5, (Oct 1997).

661

****(USE BELOW IN SOLICITATIONS WHICH MAY RESULT IN CONTRACTS WITH COMMERCIAL ORGANIZATIONS.)****

f. Facilities Capital Cost of Money, FAR Clause 52.215-16, (June 2003).

662

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

g. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (Oct 1997).

663

****(USE BELOW IN ALL SOLICITATIONS WHEN THE ESTIMATED CONTRACT OR ORDER VALUE IS EXPECTED TO EXCEED THE SIMPLIFIED ACQUISITION THRESHOLD **AND** THE CONTEMPLATED CONTRACT TYPE IS EXPECTED TO BE A COST-REIMBURSEMENT CONTRACT. THIS PROVISION SHALL ALSO BE USED IN ALL OTHER SOLICITATIONS WHERE FAR CLAUSE 52.215-23, Limitations on Pass-Through Charges, IS INCORPORATED.)****

h. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22, (Oct 2009).

664

****(USE BELOW IN SOLICITATIONS FOR INDEFINITE-QUANTITY CONTRACTS THAT MAY RESULT IN MULTIPLE CONTRACT AWARDS.)****

i. Single or Multiple Awards, FAR Clause 52.216-27, (Oct 1995).

665

****(USE THE PROVISION BELOW IN SOLICITATIONS FOR NON-COMMERCIAL ITEMS CONTEMPLATING USE OF A TIME-AND-MATERIALS OR LABOR-HOUR TYPE OF CONTRACT IF THE PRICE IS EXPECTED TO BE BASED ON ADEQUATE PRICE COMPETITION.)****

j. Time-and-Materials/Labor-Hour Proposal Requirements-Non-Commercial Item Acquisitions with Adequate Price Competition, FAR Clause 52.216-29, (Nov 2021).

666

****(USE THE PROVISION BELOW IN SOLICITATIONS CONTEMPLATING USE OF A COMMERCIAL TIME-AND-MATERIALS OR LABOR-HOUR TYPE OF CONTRACT.)****

k. Time-and-Materials/Labor-Hour Proposal Requirements-Commercial Item Acquisition, FAR Clause 52.216-31, (Nov 2021).

667

****(USE BELOW IN ALL SOLICITATIONS EXPECTED TO RESULT IN A CONTRACT OF $10,000,000 OR OVER.)****

l. Preaward On-Site Equal Opportunity Compliance Evaluation, ($10,000,000 or Over), FAR Clause 52.222-24, (Feb 1999).

668

****(USE BELOW IN SOLICITATIONS FOR NEGOTIATED CONSTRUCTION CONTRACTS.)****

m. Notice of Requirement for Affirmative Action to Ensure Equal Employment Opportunity for Construction, FAR 52.222-23, (Feb 1999).

669

****(USE BELOW IN ALL SOLICITATIONS ASSOCIATED WITH LARGE SCALE (OVER $25 MILLION) CONSTRUCTION PROJECTS, WHEN IT IS DETERMINED THAT A PROJECT LABOR AGREEMENT WILL BE REQUIRED. See FAR Subpart 22.5.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Alternate I** : Include when the submission of a project labor agreement from only the apparent successful offeror will be required.
2. **Alternate II** : Include when the submission of a project labor agreement will be allowed after contract award.

n. Notice of Requirement for Project Labor Agreement, FAR Clause 52.222-33 (May 2010).

Alternate I (May 2010) [is/is not] applicable to this solicitation.

Alternate II (May 2010 [is/is not] applicable to this solicitation.

670

(USE BELOW IN SOLICITATIONS WHEN IT IS POSSIBLE THAT AT LEAST $500,000 OF THE VALUE OF THE CONTRACT PERFORMED OUTSIDE THE UNITED STATES HAS AN ESTIMATED VALUE THAT EXCEEDS $550,000; AND THE ACQUISITION IS NOT ENTIRELY FOR COMMERCIALLY AVAILABLE OFF-THE-SHELF ITEMS.)

o. Certification Regarding Trafficking in Persons Compliance Plan, FAR Provision 52.222-56 (Oct 2020).

671

****(USE BELOW IN SOLICITATIONS FOR NEGOTIATED CONSTRUCTION CONTRACTS.)****

p. Preparation of Proposals--Construction, FAR Clause 52.236-28, (Oct 1997).

672

****(USE BELOW IN SOLICITATIONS OVER THE SIMPLIFIED ACQUISITION THRESHOLD FOR PROFESSIONAL OR TECHNICAL SERVICES TO BE ACQUIRED ON THE BASIS OF THE NUMBER OF HOURS TO BE PROVIDED, I.E. LEVEL OF EFFORT.)****

q. Identification of Uncompensated Overtime, FAR Clause 52.237-10, (Mar 2015).

673

****(USE THIS PROVISION WHEN IT IS QUESTIONABLE WHETHER OR NOT THIS REQUIREMENT INVOLVES ANTI-TERRORIST TECHNOLGY PRODUCT(S)
OR SERVICES WHICH MAY BE APPROPRIATE FOR SAFETY ACT PROTECTIONS AND:

1. AFTER CONSULTATION WITH DEPARTMENT OF HOMELAND SECURITY (DHS), THE AGENCY HAS DETERMINED THAT SAFETY ACT PROTECTIONS ARE NOT APPLICABLE; OR
2. DHS HAS DENIED APPROVAL OF A PRE-QUALIFICATION DESIGNATION NOTICE.)****

r. SAFETY Act Coverage Not Applicable, FAR Clause 52.250-2, (Feb 2009).

674

****(USE THIS PROVISION WHEN THE DEPARTMENT OF HOMELAND SECURITY (DHS) HAS ISSUED A BLOCK DESIGNATION/CERTIFICATION FOR THE SOLICITED TECHNOLOGIES.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Alternate I** : Use with Alternate I when contingent offers are authorized in accordance with FAR 50.205-3.
2. **Alternate II** : Use with Alternate II when offers presuming SAFETY Act designation or certification are authorized in accordance with FAR 50.205-4. If this alternate is used, the Contracting Officer may alter the number of days within which offerors must submit their SAFETY Act designation or certification application.

s. SAFETY Act Block Designation/Certification, FAR Clause 52.250-3, (Feb 2009).

Alternate I (Feb 2009) [is/is not] applicable to this solicitation.

Alternate II (Feb 2009) [is/is not] applicable to the solicitation.

[Note to Offerors: The DHS SAFETY Act block designation or block certification is attached to this solicitation and contains essential information. Offerors should read this information carefully to make sure they comply with its terms if they plan to take advantage of SAFETY Act coverage for their technology(ies).]

675

****(USE THIS PROVISION IN A SOLICITATION FOR WHICH THE DEPARTMENT OF HOMELAND SECURITY (DHS) HAS ISSUED A PRE-QUALIFICATION DESIGNATION NOTICE.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

1. **Alternate I** : Use with Alternate I when contingent offers are authorized in accordance with FAR 50.205-3.
2. **Alternate II** : Use with Alternate II when offers presuming SAFETY Act designation or certification are authorized in accordance with 50.205-4. If this Alternate is used, the Contracting Officer may alter the number of days within which offerors must submit their SAFETY Act designation or certification application.

t. SAFETY Act Pre-qualification Designation Notice, FAR Clause 52.250-4, (Feb 2009).

Alternate I (Feb 2009) [is/is not] applicable to this solicitation.

Alternate II (Feb 2009) [is/is not] applicable to the solicitation.

[Note to Offerors: The DHS SAFETY Act block pre-qualification designation notice is attached to this solicitation and contains essential information. Offerors should read this information carefully to make sure they comply with its terms if they plan to take advantage of SAFETY Act coverage for their technology(ies).]

676

****(USE BELOW IF THE PROVISION AT 52.250-3 IS USED WITH ITS ALTERNATE II OR THE PROVISION AT 52.250-4 IS USED WITH ITS ALTERNATE II. See previous two items above.)****

u. SAFETY Act--Equitable Adjustment, FAR Clause 52.250-5, (Feb 2009).

677

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

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The

technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

Note to Offerors: Beginning May 25, 2008, the offeror shall include the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

678

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

1. **Technical Discussions**

The technical discussion included in the technical proposal should respond to the items set forth below:

679

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

a. **Statement of Work**

1. Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. Review pertinent work already published which is relevant to this project and your proposed approach. This should support the scope of the project as you perceive it.

2. Approach

The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. Proposals which merely restate the requirements of the Government's scope of work will not be eligible for award.

Use as many subparagraphs, appropriately titled, as needed to clearly outline the general plan of work. Discuss phasing of research and, if appropriate, include experimental design and possible or probable outcome of approaches proposed.

3. Methods

   Describe in detail the methodologies you will use for the project, indicating your level of experience with each, areas of anticipated difficulties, and any unusual expenses you anticipate.

4. Schedule

   Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments of work, as applicable, by contract year as well as for the overall contract. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

680

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

b. **Personnel**

Describe the experience and qualifications of personnel who will be assigned for direct work on this program. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar equipment or programs. Special mention shall be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for this program.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS FOR MORE THAN A TOTAL OF 100% OF THEIR TIME. IF THE SITUATION ARISES WHERE IT IS DETERMINED THAT A PROPOSED EMPLOYEE IS COMMITTED FOR MORE THAN 100% OF HIS OR HER TIME, THE GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.

681

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

1. Single Principal Investigator/Project Director

   List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

682

****(USE BELOW WHEN THE SOLICITATION HAS BEEN SELECTED TO INCLUDE THE OPTION FOR PROPOSING MULTIPLE PRINCIPAL INVESTIGATORS UNDER THE CONTRACT.)****

2. Multiple Principal Investigators

   The NIH now provides offerors the opportunity to propose a multiple Principal Investigator (PI) model on research and development contracts. The multiple PI model is intended to supplement, and not replace, the traditional single PI model. The NIH chose this RFP as a candidate for the multiple PI model. Ultimately, the decision to submit a proposal using the multiple PI versus single PI is the decision of the investigators and their institutions. The decision should be consistent with and justified by the scientific goals of the project.

   It is essential that organizations consider all aspects of this approach before submitting a proposal. While there are some projects that clearly are appropriate for the multiple PI model, the "fit" of other projects may not be so clear. Offerors should base the selection of either the single PI or multiple PI option on the research proposed, to ensure optimal facilitation of the science. Projects suitable for the multiple PI model could include as few as two PIs who are jointly responsible for the scientific and technical direction of the project. The multiple PI option is based on the proposed project, not on the number of performance sites or the number of participating institutions.

   Multiple PIs under research contracts shall use the Subcontract Model. In this approach, offerors submit a single proposal, and a single award is made to the prime contractor. The prime contractor, when appropriate, will award subcontracts to fund the components of the project at the other institutions. The relationship between the Contractor and subcontractors must be designed to support all components of the project.

To facilitate communication with the NIH, the offeror must designate a Contact PI at the time of proposal submission. The Contact PI must be employed at the prime contractor's organization. The designation of the Contact PI may rotate on an annual basis. However, this rotation is restricted to PIs located at the prime contractor's organization. The Contact PI is responsible for: relaying communications between all of the PIs and the NIH, and coordinating progress reports for the project. Being named Contact PI does not confer any special authority for the project.

Leadership Plan

Offerors proposing multiple PIs will need to submit a Leadership Plan as part of the Technical Proposal. The Leadership Plan shall describe the governance and organizational structure of the research project including communication plans, process for making decisions on scientific direction, allocation of resources, publications, intellectual property issues, and procedures for resolving conflicts. The Leadership Plan shall follow the Table of Contents provided below:

I. Rationale
   Include a discussion of how the project will be enhanced by the multiple PI approach.
II. Identification of all proposed PIs
   Identify the proposed PIs, their point of contact information and affiliated organizations, and the percentages of time proposed for this project. Identify the Contact PI and plans for rotation of that role, if any.
III. Roles and Responsibilities
   Identify both the scientific and administrative roles and responsibilities of all named PIs.
IV. Approach to Fiscal and Management Coordination
   Describe how the project will be performed and monitored from a fiscal and management perspective. Discuss organizational administrative coordination and support.
V. Project Direction and Resource Allocation
   Address how decisions will be made regarding scientific direction, and, how resources will be allocated and redistributed if needed during performance. Address plans for shared resources such as IT or other shared data considerations. If joint standard operating procedures will be developed, describe this process.
VI. Communication and Lines of Authority
   Address communication and lines of authority within and among PIs and within and among organizations.

VII. Data sharing, Intellectual Property, Publication, and other Proprietary Considerations
Data sharing plans, intellectual property considerations, publication agreements, and any other proprietary or confidential information sharing should be addressed in this section.

VIII. Conflict Resolution
Address how conflicts will be avoided, identified, and resolved.

IX. Other
Address any other information relative to the leadership approach to Multiple PI projects.

Offerors submitting single PI proposals do not need to submit a Leadership Plan.

683

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

3. Other Investigators

List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

684

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

4. Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

1. The specific items or expertise they will provide.
2. Their availability to the project and the amount of time anticipated.
3. Willingness to act as a consultant.
4. How rights to publications and patents will be handled.

685

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

5. Resumes

Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

686

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

2. **Other Considerations**

Record and discuss specific factors not included elsewhere which support your proposal. Using specifically titled subparagraphs, items may include:

a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
d. Other factors you feel are important and support your proposed research.
e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

687

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

3. **Technical Evaluation**

Proposals will be technically evaluated in accordance with SECTION M - Evaluation Factors for Award of this solicitation.

688

****(USE BELOW WHEN HUMAN SUBJECTS WILL BE INVOLVED IN THE PROJECT. BY DEFINITION THIS INCLUDES INTERVIEWS AS WELL AS STUDIES AND TRIALS.)****

Note: *This item consists of the subparagraphs a. through l. that should be selected as appropriate for the SOLICITATION* .

4. **Human Subjects**

IMPORTANT NOTE TO OFFERORS: The following subparagraphs shall be addressed, as applicable, in a SEPARATE FILE of the Technical Proposal entitled, "HUMAN SUBJECTS."

689

****(INCLUDE IN ALL SOLICITATIONS THAT INVOLVE HUMAN SUBJECTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

Alternate I : Use when the agency is prescribing a date later than the proposal submission by which the offeror must have an approved FWA. Delete if this is not needed.

a. **Notice to Offerors of Requirements, Protection of Human Subjects, HHSAR 352.270-4(a)** (December 2015).

(a)The Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR part 46, are available on the Office for Human Research Protections (OHRP) Web site at: http://www.hhs.gov/ohrp/index.html .These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of human subjects participating in research activities supported or conducted by HHS.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable public information through intervention or interaction with the individual, or identifiable private information. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. 45 CFR part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.

(c) Activities which involve human subjects in one or more of the categories set forth in 45 CFR 46.101(b)(1)-(6) are exempt from complying with 45 CFR part 46. See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal.

(e) In accordance with 45 CFR part 46, offerors considered for award shall file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board shall ensure that: The risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46 .111 for additional requirements regarding initial and continuing review. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP Web site (at http://www.hhs.gov/ohrp/assurances/index.html).

(f) Offerors may consult with OHRP only for general advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. ONLY the contracting officer may offer information concerning a solicitation.

(g) The offeror shall document in its proposal the approved FWA from OHRP, related to the designated Institutional Review Board (IRB) reviewing and overseeing the research. If the offeror does not have an approved FWA from OHRP, the offeror must obtain an FWA before the deadline for proposal submission. When possible, the offeror shall also certify the IRB's review and approval of the research. If the offeror cannot obtain this certification by the time of proposal submission they must include an explanation in their proposal. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.

(End of provision).

Alternate I (Dec 2015).

As prescribed in HHSAR 370.303(a), the Contracting Officer shall substitute the following paragraph (g) for paragraph (g) of the basic clause.

(g) The offeror's proposal shall document that it has an approved or active FWA from OHRP, related to the designated IRB reviewing and overseeing the research. When possible the offeror shall also certify the IRB has reviewed and approved the research. If the offeror cannot make this certification at the time of proposal submission, its proposal must include an explanation. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB. If the offeror does not have an active FWA from OHRP, the offeror shall take all necessary steps to obtain an FWA prior to the deadline for proposal submission. If the offeror cannot obtain an FWA before the proposal submission date, the proposal shall indicate the steps/actions the offeror will take to obtain OHRP approval within(Contracting Officer must insert a time period in which the FWA must be obtained). Upon obtaining FWA approval, submit the approval notice to the Contracting Officer.

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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
   1. Human Subjects Involvement, Characteristics, and Design :
      i. Briefly describe the overall study design in response to the solicitation.
      ii. Describe the subject population(s) to be included in the study; the procedures for assignment to a study group, if relevant; and the anticipated numbers of subjects for each study group.

iii. List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research.

2. Study Procedures, Materials, and Potential Risks
    i. Describe all planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data, and/or records, will be obtained; and whether any private identifiable information will be collected in the proposed research project.
    ii. For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials.
    iii. Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects.
    iv. Where appropriate, describe alternative treatments and procedures, including their risks and potential benefits. When alternative treatments or procedures are possible, make the rationale for the proposed approach clear.

b. Adequacy of Protection Against Risks
    1. Recruitment and Informed Consent:
        i. Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent. The informed consent document for the Contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the Contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.
            1. For research involving children: If the proposed studies will include children, describe the process for meeting HHS regulatory requirements for parental

permission and child assent (45 CFR 46.408). See the HHS page on Research with Children FAQs and the NIH page on Requirements for Child Assent and Parent/Guardian Permission.

2. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver.

2. Protection Against Risk:
    i. Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
    ii. Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
    iii. In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.
3. **Vulnerable Subjects, if relevant to your study** - Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. 'Prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers).
    i. <u>Pregnant Women, Fetuses, and Neonates or Children</u> - If the study involves vulnerable subjects subject to additional protections under Subparts B and D (pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements.
        1. HHS' Subpart B - Additional Protections for Pregnant Women, Fetuses, and Neonates
        2. HHS' Subpart D - Additional Protections for Children
        3. OHRP Guidance on Subpart D Special Protections for Children as Research Subjects and the HHS 407 Review Process

c. Potential Benefits of the Proposed Research to the Subjects and Others
    1. Discuss the potential benefits of the research to the subjects and others.
    2. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

3. Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

   Note: Financial compensation of subjects should not be presented as a benefit of participation in research.

d. Importance of the Knowledge to be Gained
   1. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
   2. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

      Note : If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

      Collaborating Site(s)

      When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

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****(USE BELOW WHEN HUMAN SUBJECTS WILL BE INVOLVED IN THE PROJECT. BY DEFINITION THIS INCLUDES INTERVIEWS AS WELL AS STUDIES AND TRIALS.)****

c. **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 and amended September 24,

2010, at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html . Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH Office of Extramural Research (OER) on-line tutorial, entitled "Protecting Human Research Participants" at: https://phrptraining.com/ . This course is also available in Spanish under the title "Protección de los participantes humanos de la investigación" at: https://phrptraining.com/ . You may take the tutorials on-line or download the information in PDF form at no cost. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual, entitled, "Protecting Study Volunteers in Research," can be obtained through CenterWatch, Inc. at: https://www.centerwatch.com/products/category/1060-training-guides .

If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

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d. **Inclusion of Women and Minorities in Research Involving Human Subjects**

NIH-conducted and supported clinical research must conform to the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research in accord with Public Health Service Act sec. 4928 U.S.C. sec 289a-2. The policy requires that women and members of minority groups and their subpopulations must be included in all NIH-conducted or supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant NIH Institute/Center (IC) Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an IC Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

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

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

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research."

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation.

The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report" (see Section J, Attachments)

NOTE 1 : *For all proposals, use the ethnic and racial categories and complete the "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report" in accordance with the Office of Management and Budget (OMB) for all Application Packages after January 25, 2018, which may be found at*: https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm .

NOTE 2 : *If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in FAR 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.*

Standards for Collecting Data . When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in Appendix A- Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity at: https://nces.ed.gov/programs/handbook/data/pdf/Appendix_A.pdf . The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate

questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials *** require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect ((see NIH Guide:

https://grants.nih.gov/policy/inclusion/women-and-minorities/guidelines.htm, Glossary/Definitions - Significant Difference). *The definition of an " **NIH-Defined Phase III clinical trial** " can also be found at this website.) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all Contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups,

  OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups,

  OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form entitled, "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report," <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, "PHS Human Subjects and Clinical Trials Information Form/Cumulative 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 18 years.

All Offerors proposing research involving human subjects should read the "Inclusion of Children in Clinical Research: Change in NIH Definition " which was

published in the NIH guide notice on October 13, 2015 and is available at the following URL address:

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-010.html

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

1. The objective of the solicitation is not relevant to children.
    a. There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
    b. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
    c. A separate, age-specific study in children is warranted and preferable. Examples include:

i. The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
ii. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
iii. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
iv. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
v. Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
vi. Other special cases justified by the offeror and found acceptable to the review group and the Institute Director.

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 18 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 18) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

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f. **Research Involving Prisoners as Subjects**

A. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: http://www.hhs.gov/ohrp/policy/prisoner.html.

B. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:
   a. to describe the prevalence or incidence of a disease by identifying all cases, or
   b. to study potential risk factor associations for a disease, and
2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2 7) and determined and documented that:
   a. the research presents no more than minimal risk, and
   b. no more than inconvenience to the prisoner subjects, and
   c. prisoners are not a particular focus of the research.

For more information about this Waiver see http://www.gpo.gov/fdsys/pkg/FR-2003-06-20/html/03-15580.htm.

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****(USE BELOW WHEN HUMAN FETAL TISSUE WILL BE INVOLVED IN THE SOLICITATION)****
The Contracting Officer shall submit an HFT justification, HFT Compliance Assurance, and a draft Informed Consent form from each from all offerors still being considered for award to the Ethics Advisory Board for review and recommend whether, in light of ethical consideration, NIH should fund the research project.

g. **Research Involving Human Fetal Tissue**

Research involving Human Fetal Tissue (HFT) must be conducted in accordance with applicable Federal, State and local laws, regulations, and policies. Selected Federal statutes, regulations, and policies are provided below:

42 U.S.C. 289g-1 a 289g-2 set forth specific requirements and prohibitions on research involving human fetal tissue. For example, among other prohibitions, 42 U.S.C. 289g-2 provides:

"Prohibitions regarding Human Fetal Tissue:

a. Purchase of tissue

It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human fetal tissue for valuable consideration if the transfer affects interstate commerce."

The full text of 42 U.S.C. 289g-1 is available at:
http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap6A-subchapIII-partH-sec289g-1.htm.

The full text of 42 U.S.C. 289g-2 is available at:
http://www.gpo.gov/fdsys/pkg/USCODE-2010-title42/html/USCODE-2010-title42-chap6A-subchapIII-partH-sec289g-2.htm.

Research involving HFT is also subject to the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B). The following provisions may be specifically relevant:

§ 46.204 Research involving pregnant women or fetuses.
~ (a) - (g)

h. No inducements, monetary or otherwise, will be offered to terminate a pregnancy;
i. Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and
j. Individuals engaged in the research will have no part in determining the viability of a neonate.

§ 46.206 Research involving, after delivery, the placenta, the dead fetus or fetal material.

a. Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable federal, state, or local laws and regulations regarding such activities.
b. If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals are research subjects and all pertinent subparts of this part are applicable.

The full text of the HHS Regulations for the Protection of Human Subjects is available at:
https://www.hhs.gov/ohrp/sites/default/files/ohrp/policy/ohrpregulations.pdf .

Furthermore, per NOT-OD-16-033 at:
https://grants.nih.gov/grants/guide/notice-files/not-od-16-033.html , when obtaining primary HFT for research purposes, NIH expects offerors to maintain appropriate documentation, such as an attestation from the health care provider or a third- party supplier, that informed consent was obtained at the time of tissue collection.

Non-Transplantation Research on Fetal Tissue Obtained from Elective Abortions

a. By signing the face page of the proposal, the offeror (authorized institutional official) certifies that the research involving HFT is in compliance with applicable federal, state, or local laws, regulations, and policies, including 42 USC 289g-1 and g-2, the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B), and NOT-OD-16-033.

Human Fetal Tissue Obtained from Elective Abortions

Offerors shall include a justification for its use as a separate attachment (see Section J for a link to the template used for the justification) and include an HFT Compliance Assurance and draft Informed Consent form as described below. Offerors shall address HFT requirements as outlined in NOT- OD-19-128. Offerors who fail to include a justification for the use of HFT obtained from elective abortions, an HFT Compliance Assurance, and a draft Informed Consent form, will be non- responsive to the solicitation and withdrawn from further consideration.

Offerors shall include the following information in the justification package:

- Use the specific heading: "Human Fetal Tissue Obtained from Elective Abortions Justification". The justification should be in detail for review by NIH.
- The Offeror must include the following in the justification:
    1. Indicate why the research goals cannot be accomplished using an alternative to HFT (including, but not limited to, induced pluripotent cells not developed from HFT, organoids not developed from HFT, neonatal human tissue, human tissue obtained from adults, HFT not derived from elective abortion, animal models, and *in vitro* models that are not developed from HFT, and computational models).
    2. Indicate the methods used to determine that no alternatives to HFT can be used (including, but not limited to, literature review and preliminary experiments).
    3. Describe results from a literature review used to provide justifications.
    4. Describe plans for the treatment of HFT and the disposal of HFT when research is complete.
    5. Describe planned written, voluntary, informed consent process for cell/tissue donation, or description and documentation of process if cells/tissue were already obtained. Include a draft informed consent form for planned use under the proposed research. The informed consent for donation of HFT for use in research requires language that acknowledges informed consent for donation of HFT was obtained by someone other than the person who obtained the informed consent for abortion, occurred after the informed consent for abortion, and will not affect the method of abortion; no enticements, benefits, or financial incentives were used at any level of the process to incentivize abortion or the donation of HFT; and to be signed by both the woman and the person who obtains the informed consent.
    6. Budget Justification: Describe and document the quantity, type, and source of the HFT, and include a line item cost for the

acquisition of HFT or indicate the cost is $0 if using donated or existing HFT. The line item cost shall also be included in the offeror's separate Business proposal.

7. HFT Compliance Assurance: Offeror shall provide a letter signed by the Program Director/Principal Investigator assuring the HFT donating organization or clinic adheres to the requirements of the informed consent process and documentation that HFT was not obtained or acquired for valuable consideration.

Research using HFT shall be in compliance with all applicable federal, state, or local laws, regulations, and policies, including 42 USC 289g-1 and g-2, the HHS Regulations for the Protection of Human Subjects (45 CFR 46 Subparts A and B), NOT-OD-16-033, and NOT-OD-19-128.

Research on Transplantation of Human Fetal Tissue

Sections 498A and 498B of the PHS Act (42 U.S.C. 289g-1 and 289g-2) contain additional requirements for research on the transplantation of human fetal tissue for therapeutic purposes conducted or supported by NIH. Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local laws as well as the following NIH guidance.

Under section 498A, the official who signs the application is certifying that the research on transplantation of human fetal tissue will adhere to the following provisions. The woman who donates the fetal tissue must sign a statement declaring that the donation is being made:

- for therapeutic transplantation research
- without any restriction regarding the identity of individuals who may receive the transplantation, and
- without the donor knowing the identity of the recipient.

The attending physician must sign a statement that they have:

- obtained the tissue in accordance with the donor's signed statement and
- fully disclosed to the donor their intent, if any, to use the tissue in research and any known medical risks to the donor or risks to her privacy associated with the donation that are in addition to risks associated with the woman's medical care.

In the case of tissue obtained pursuant to an induced abortion, the physician's statement also must state that they:

- obtained the woman's consent for the abortion before requesting or obtaining consent for the tissue to be used;

- did not alter the timing, method, or procedures used to terminate the pregnancy solely for the purpose of obtaining the tissue for research; and
- performed the abortion in accordance with applicable State and local laws.

The Program Director/Principal Investigator (PD/PI) must sign a statement certifying that they are aware that the tissue is human fetal tissue obtained in a spontaneous or induced abortion, or pursuant to a stillbirth and that the tissue was donated for research purposes. The PD/PI also must certify that this information has been shared with others who have responsibilities regarding the research and, before eliciting informed consent from the transplantation recipient, will obtain written acknowledgment that the patient is aware of the aforementioned information. The PD/PI must certify in writing that they have had no part in any decisions as to the timing, method, or procedures used to terminate the pregnancy.

In submitting an application to NIH, the individual that signs the application is certifying that, if research on the transplantation of human fetal tissue is conducted under the grant-supported project, the organization will make available for audit by the HHS Secretary or designee, the physician statements, the PD/PI's statements, and informed consents required by subsections 498A(b)(2) and (c) of the PHS Act or will ensure HHS access to those records, if maintained by an entity other than the recipient. This requirement is in addition to the requirements concerning human subjects in research.

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****(USE BELOW IN ALL SOLICITATIONS THAT INVOLVE HUMAN SUBJECTS, INCLUDING RESEARCH INVOLVING HUMAN SPECIMENS, SAMPLES, AND/OR DATA.)****
SEE NIH NOTICE NOT-OD-22-001, NIH Implementation of the Revised Common Rule Provision Regarding Public Health Surveillance Activities Deemed Not to Be Research at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-22-001.html .

h. **Public Health Surveillance Exclusion**

An Offeror may request an exclusion from applicability of the "revised Common Rule"[1] if it believes that NIH-funded or -conducted activities associated with this solicitation should be considered "public health surveillance activities deemed not to be research" for the purposes of the revised Common Rule. All requests for the public health surveillance exclusion from the revised Common Rule for NIH-funded research-whether conducted or supported-must receive NIH approval, as per the process outlined below, to be considered a public health surveillance activity deemed not to be research under the revised Common Rule's Sections §46.102(k), Public health authority, and §46.102(l)(2), Public

health surveillance activities. NIH expects that NIH-supported or -conducted research will be determined to be a public health surveillance activity only in extremely rare cases. **Please note that NIH will not consider any NIH-defined clinical trials for a public health surveillance exclusion request. In addition, NIH will not consider studies that contain any activity that does not meet the requirements for an exclusion for a public health surveillance determination, including any intent to store specimens and/or data for future use.**

Requesting a Determination that NIH-Funded or -Conducted Activities be Considered Public Health Surveillance:

Offerors shall provide a compelling justification as to why NIH-funded or -conducted activities should be considered public health surveillance activities deemed not to be research for the purposes of the revised Common Rule. Refer to the attached template in Section J. All activities for which approval of the exclusion will be sought must be disclosed and described.

The justification shall include information that demonstrates **all three (3)** of the following:

a) The proposed activity is strictly limited to only that necessary for NIH to identify, monitor, assess, or investigate:
   i. Potential public health signals; or
   ii. Onsets of disease outbreaks; or
   iii. Conditions of public health importance (including trends, signals, risk factors, or patterns in diseases).

AND

b) The activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

AND

c) The activities will directly inform NIH public health decision-making or action.

Note: An Offeror shall submit its compelling justification for exclusion with its technical proposal as a separate attachment, so that the justification can be detached from and evaluated apart from the Offeror's technical proposal. The Government reserves the right to not consider any public health surveillance exclusion requests if the justification is not provided at the time of original

proposal submission.

Offerors shall complete and submit the PHS Human Subjects and Clinical Trials Information Form, following instructions in the solicitation, as applicable. Offerors should not assume that approval of an exclusion will be granted when completing the PHS Human Subjects and Clinical Trials Information Form.

Note that the proposed budget in the proposal must reflect all necessary/required costs for the full and proper conduct of research involving human subjects, in complete compliance with all applicable laws, protocols, rules, and/or regulations at all levels, without approval of any exclusion. Offerors should not assume that approval of an exclusion will be granted when considering the costs to include in any proposed budget and therefore, must respond and price accordingly.

Notice of Approval or Disapproval of Request for Exclusion

Exclusion requests will be considered separate from the NIH peer review of technical proposals. Offerors will be issued written notification of approval or denial by the NIH Contracting Officer of any request(s) for exclusion prior to award. Any decision by NIH on an Offeror's request for a Public Health Surveillance Exclusion shall be final.

The award budget may then be adjusted accordingly if approval of an exclusion is granted by NIH.

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[1] Code of Federal Regulations (CFR) Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects, Revised 19 January 2017, Effective 19 July 2018, with a General Compliance Date of 21 January 2019 (45 CFR part 46)), and not its predecessor, the Pre-2018 Common Rule (Common Rule). The revised Common Rule is also known or referred to as the "2018 Requirements" or the "2018 Rule."

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****USE BELOW WHEN RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES WILL BE ADMINISTERED TO HUMAN SUBJECTS.)****

i. **Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Including Human Gene Transfer Research)**

All research projects (both NIH-funded and non-NIH-funded) involving recombinant or synthetic nucleic acid molecules that are conducted at or sponsored by an entity in the U.S. that receives any support for recombinant or synthetic nucleic acid research from NIH shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*) (see http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines). All NIH-funded projects conducted abroad that involve research with recombinant or synthetic nucleic acid molecules must also comply with the NIH Guidelines. In addition to biosafety and containment requirements, the *NIH Guidelines* delineate points to consider in the development and conduct of human gene transfer clinical trials, including ethical principles and safety reporting requirements.

Prior to beginning any clinical trial involving the transfer of recombinant or synthetic nucleic acid molecules into humans, the trial must be registered with the NIH Office of Science Policy (OSP) and, if applicable, reviewed by the NIH Recombinant DNA Advisory Committee (RAC). If this contract involves a human gene transfer trial raising unique and/or novel issues, the trial may be discussed by the RAC in a public forum (see Appendix M-I-B of the *NIH Guidelines* for the specific criteria for the selection of protocols for RAC review and discussion). Approval of an Institutional Biosafety Committee (IBC) and the Institutional Review Board (IRB) are necessary before the Contracting Officer's Representative (COR) and Contracting Officer (CO) may approve the protocol prior to the start of the research. IBC approval may not occur until the protocol registration process with NIH is complete. If the trial is reviewed by the RAC, IBC approval may not occur before the RAC has concluded its review of the protocol and the protocol registration process with NIH is complete.

For human gene transfer research, Appendix M-I-C-4 of the NIH Guidelines requires any serious adverse events (SAEs) that are both unexpected and possibly associated with the human gene transfer product to be reported to NIH OSP and an IBC within 15 days, or within 7 days if the event was life-threatening or resulted in a death. A copy of the report must also be filed with the COR and CO. SAE reports must also be submitted within their mandated time frames to the IRB, Food and Drug Administration (FDA), and, if applicable, the Health and Human Services (HHS) Office for Human Research Protections (OHRP). In addition, annual reports must be submitted to NIH OSP covering certain information about human gene transfer protocols. Further information about the content of these reports can be found in Appendix M-I-C-3 of the NIH Guidelines. Additional information on the requirements that pertain to human gene transfer can be found in a series of Frequently Asked Questions at: https://osp.od.nih.gov/biotechnology/nih-guidelines-faqs/.

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or

termination of the contract for any work related to recombinant or synthetic nucleic acid research or a requirement for the CO to approve any or all recombinant or synthetic nucleic acid molecule projects under this contract. This includes the requirement for the institution to have an IBC registered with NIH OSP that complies with the requirements of the *NIH Guidelines* . Further information about compliance with the *NIH Guidelines* can be found on the NIH OSP website at: https://osp.od.nih.gov/biotechnology/nih-guidelines/.

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****(USE BELOW WHEN HUMAN SUBJECTS WILL BE INVOLVED IN THE PROJECT.)****

j. **Human Stem Cell Research**

On March 9, 2009, the President issued Executive Order (EO) 13505: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells. The NIH has published Guidelines on Human Stem Cell Research at: https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research . The Guidelines implement EO 13505 with regard to extramural NIH-funded human stem cell research, establish policy and procedure under which the NIH will fund such research, and help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.

To facilitate research using human embryonic stem cells, the NIH has established a Human Embryonic Stem Cell Registry ("the NIH Registry") that lists the human embryonic stem cells that are currently eligible for use in NIH-funded research. This registry is available at: https://grants.nih.gov/stem_cells/registry/current.htm . Proposed human embryonic stem cell line(s) must be on the NIH Registry at the time of proposal submission. Any possible changes to the proposed cell line must be discussed in the proposal. Offerors wishing to have Human Embryonic Stem Cell Lines added to the NIH Human Embryonic Stem Cell Registry must submit the request on Form NIH 2890 through the following website: https://hescregapp.od.nih.gov/NIH_Form_2890_Login.htm .

See Section H of this solicitation for more details.

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****(USE BELOW FOR ALL RFPs THAT WILL RESULT IN THE CONDUCT OF CLINICAL TRIALS.)****

NOTE: The following language may be modified to incorporate an IC's alternate and comparable approach to expressing the NIH policy regarding Data and Safety Monitoring in Clinical Trials.

k. **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

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

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Contracting Officer Representative (COR).

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP))

convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

For any proposed clinical trial, NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial, its size, and its complexity. Provide a description of the DSMP, including:

- The overall framework for safety monitoring and what information will be monitored.
- The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
- The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), will be managed and reported, as required, to the IRB, the person or group responsible for monitoring, the awarding IC, the NIH Office of Biotechnology Activities, and the Food and Drug Administration.
- The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the DSMP will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:
    - PD/PI: While the PD/PI must ensure that the trial is conducted according to the approved protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PD/PI to also be responsible for carrying out the DSMP.
    - Independent safety monitor/designated medical monitor: a physician or other expert who is independent of the study.
    - Independent Monitoring Committee or Safety Monitoring Committee: a small group of independent experts.
    - Data and Safety Monitoring Board (DSMB): a formal independent board of experts including investigators and biostatisticians. NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally, for all Phase III clinical trials, although Phase I and Phase II clinical trials may also need DSMBs. If a DSMB is used, please describe the general composition of the Board without naming specific individuals.

The NIH Policy for Data and Safety Monitoring at: http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB- approved monitoring plan as part of the proposal submission.

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****(USE BELOW IN RFPs FOR HIV ANTIRETROVIRAL TREATMENT TRIALS THAT WILL TAKE PLACE IN WHOLE OR IN PART IN DEVELOPING COUNTRIES - Defined as the Low-and-Middle Income Economies, using WORLD BANK CLASSIFICATIONS.)****

I. **HIV Antiretroviral Treatment Trials**

The NIH is committed to conducting HIV/AIDS research in an effort to improve the health of people living with this disease, particularly people in countries most affected by the epidemic. It is important that individuals who volunteer to participate in NIH funded HIV antiretroviral trials be given the option to continue to receive antiretroviral treatment following their completion of the trial. In order to accomplish this, the Contractor must work with the host countries' authorities and other stakeholders to identify sources available, if any, in the country for the provision of such treatment. It is noted that NIH cannot provide this treatment following the completion of the research. See NIH Guide Notice, " Guidance for Addressing the Provision of Antiretroviral Treatment for Trial Participants Following Their Completion of NIH Funded HIV Antiretroviral Treatment Trials in Developing Countries ," located at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-038.html.

The offeror's proposal must address a plan that describes the following:

- A description of available sources, if any (e.g., name of source, location, contact person of facility/organization) for the provision of antiretroviral treatment and care following the completion of the trial;
- A summary of the offeror's interaction with the providers;
- Documents, if any, from available sources/ providers regarding plans for implementation; and
- A description of how this information will be conveyed to the trial participants.

If there are no sources for antiretroviral treatment in or available to the country in which the treatment trials will take place, the offeror must provide:

1. A statement confirming that at the time of the offer, no sources of antiretroviral treatment could be identified;
2. A description of how this information will be conveyed to the trial participants; and

3. A commitment to continue to explore potential sources as the trial proceeds.

This plan or the documentation provided regarding the lack of available sources of antiretroviral treatment will be evaluated by the Contracting Officer Representative (COR) as a part of the overall review of the proposal. While an offeror's documentation of the lack of available sources for antiretroviral treatment will not, of itself, constitute denial of a contract award, priority for contract awards may be given to those offerors who identify sources for the provision of antiretroviral treatment following the completion of the trial.

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****(USE BELOW IN SOLICITATIONS FOR APPLICABLE CLINICAL TRIALS AS FOLLOWS:)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- For information about how to determine "applicable clinical trials," see Step 1 of the following link: http://grants.nih.gov/ClinicalTrials_fdaaa/index.htm#whatsteps

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

m. **Registration of and Results Reporting for Applicable Clinical Trials in ClinicalTrials.gov**

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

(a) The registration of certain "applicable clinical trials" in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
(b) The reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

The resultant contract will support one or more applicable clinical trial subject to FDAAA.

The "responsible party" is the entity responsible for registering and reporting trial results in ClinicalTrials.gov.

1. Where the Contractor is the IND/IDE holder, the Contractor will be considered the Sponsor, therefore the "Responsible Party."
2. Where there is no IND/IDE holder or where the Government is the IND/IDE holder, the Government will generally be considered the "Sponsor" and may designate the Contractor's Principal Investigator (PI) as the "Responsible Party."
3. For Multi-Center trials where there is no IND/IDE holder or where the Government is the IND/IDE holder, the "Responsible Party" will be designated at one site (generally the lead clinical site) and all other sites will be responsible for providing necessary data to the "Responsible Party" for reporting in the database.

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

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

Note: When reviewing a contract proposal funding a new clinical trial in whole or in part, an award cannot be issued until a plan for the dissemination of clinical trial information has been submitted by the offeror, and the Contracting Officer (CO) has approved the plan. Offerors are required to submit a plan for the dissemination of NIH-funded clinical trial information in the proposal submitted on or after January 18, 2017, that addresses how the policy expectations will be met. If a plan is not included in the proposal, the CO shall request the plan from the offeror prior to award. An award cannot be made until the plan is accepted and approved by the CO. Once approved, the plan is incorporated as a term and condition of award.

n. **PLAN FOR THE DISSEMINATION OF INFORMATION OF NIH-FUNDED CLINICAL TRIAL**

Offerors are required to submit a plan for the dissemination of NIH-funded clinical trial information in the proposal. At a minimum, the plan must contain sufficient information to assure that:

1. The Contractor shall register and submit results information to https://clinicaltrials.gov/ as outlined in the NIH policy on the Dissemination of NIH-Funded Clinical Trial Information and according to the specific timelines stated in the policy (this can be a brief statement);

2. Informed consent documents for the clinical trial(s) shall include a specific statement relating to posting of clinical trial information at https://clinicaltrials.gov/ ; and
3. The Contractor has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with NIH policy on the Dissemination of NIH-Funded Clinical Trial Information requirements.

If the Offerors plan does not meet these minimum standards, or is otherwise not acceptable as determined by the Contracting Officer, the contract award cannot be issued until an approved plan has been submitted.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHERE MORE THAN ONE DOMESTIC SITE WILL CONDUCT THE SAME PROTOCOL INVOLVING NON-EXEMPT HUMAN SUBJECTS RESEARCH.)****
SEE NIH NOTICE- NOT-OD-16-094.

o. **IDENTIFICATION OF SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)**

Offerors are required to identify the name of the Single Institutional Review Board (sIRB) in an attachment to the technical proposal for each protocol involving more than one domestic site. At a minimum, the Offeror shall provide confirmation of the following:

1. Participating sites will adhere to the sIRB Policy;
2. Sites and the sIRB will adhere to the communication plan described in the authorization/reliance agreement; and
3. If, in the case of restricted award an sIRB has not yet been identified, include a statement that the offeror will follow the sIRB Policy and communicate plans to select a registered IRB of record. This information must be provided to the Contracting Officer prior to initiating recruitment for a multi-site study.

The Offeror may request direct cost funding for the additional costs associated with the establishment and review of the multi-site study by the sIRB, with appropriate justification; all such costs must be reasonable and consistent with cost principles, in accordance with the Federal Acquisition Regulation Part 31, as applicable to your contract.

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS WHERE MORE THAN ONE DOMESTIC SITE WILL CONDUCT THE SAME PROTOCOL INVOLVING NON-EXEMPT HUMAN SUBJECTS RESEARCH.)****
SEE NIH NOTICE- NOT-OD-16-094.

p. **EXCEPTIONS TO THE SINGLE INSTITUTIONAL REVIEW BOARD (sIRB) POLICY**

In the technical proposal, Offerors may request an exception to the sIRB policy for one or more studies.

1. For sites for which Federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions):
   (a) The Offeror shall identify any site that meets the requirements for the Single IRB policy but is required to have local IRB review because of a federal, state, or tribal law, regulation or policy; and
   (b) The Offeror shall provide specific citation for policy-based exceptions.
2. Time Limited Exception: ancillary studies to ongoing research without a sIRB- new multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use the sIRB of record until the parent study is expected to comply with the sIRB policy. The Offeror shall provide the parent contract number to request an exception.
3. *Other exceptions* when Offeror believes that one or more research sites should be exempt from use of the single IRB of record to conduct local IRB review based on compelling justification:
   (a) Offerors should request an exception in the sIRB plan attachment within the contract proposal (section 3.2 in the Study Record: PHS Human Subjects and Clinical Trials Information form).
   (b) Offerors must include the name of the site(s) for which an IRB other than the sIRB of record is proposed to review the study for the sites(s).
   (c) Offerors must substantiate their exception request with sufficient information that demonstrates a compelling justification for *other exceptions* to the sIRB policy. The rationale should include why the sIRB of record cannot serve as the reviewing IRB for the site(s), and why the local IRB is uniquely qualified to be the reviewing IRB for the specific site(s).
   - For instance, the justification may consider ethical or human subjects protections issues, population needs, or other compelling reasons that IRB review for the site(s) cannot be provided by the single IRB of record.

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

Post-Award Exception Requests

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

Notice of Approval or Disapproval of *Other Exception* Requests

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

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

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****(USE BELOW INSTRUCTIONS IN ALL SOLICITATIONS THAT INVOLVE HUMAN SUBJECTS, INCLUDING RESEARCH INVOLVING HUMAN SPECIMENS AND/OR DATA).****

q. **PHS HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM**

Offerors shall submit the "PHS Human Subjects and Clinical Trials Information Form" with each technical proposal for work involving human subjects.

FORM SUBMISSION INSTRUCTIONS

1. The PHS Human Subjects and Clinical Trials Information Form must be submitted with your technical proposal.

2. Offerors must use the form and follow the associated instructions posted on the website at: https://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files.

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

r. **INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS**

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

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

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

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

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

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****(USE BELOW IN SOLICITATIONS AND CONTRACTS THAT INVOLVE HUMAN SUBJECTS. BY DEFINITION THIS INCLUDES INTERVIEWS AS WELL AS STUDIES AND TRIALS.)****

s. **POSTING CLINICAL TRIAL INFORMED CONSENT FORMS TO CLINICALTRIALS.GOV**

The Revised Common Rule sections 46.102(b) and 46.116(h) requires Contractors with to post one IRB-approved version of an Informed Consent Form that has been used to enroll participants on a public federal website designated for posting such Consent Forms. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database https://clinicaltrials.gov/ . Note: ClinicalTrials.gov only accepts Informed Consent Forms written in English; non-English language forms must be submitted to https://www.regulations.gov/ .

1. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database https://clinicaltrials.gov/
2. The Informed Consent Form must be posted after recruitment closes, and no later than 60 days after the final study visit.
3. The Contracting Officer (CO) and/or Contracting Officer Representative (COR) may permit or require redactions as appropriate.
4. Informed Consent Forms for the clinical trial(s) shall include a specific statement relating to posting of clinical trial information at https://clinicaltrials.gov/
5. Informed Consent Forms must be compliant with the HHS Policy for the Protection of Human Research Subjects (45 CFR 46).

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****(USE BELOW IN SOLICITATIONS THAT INVOLVE LIVE VERTEBRATE ANIMALS.)****

5. **Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, HHSAR 352.270-5(a)** (December 2015).

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization

shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, MD 20892-6910 (Email: olaw@od.nih.gov ; Phone: 301-496-7163).

The PHS Policy is available on the internet at: https://olaw.nih.gov/ .

(End of provision).

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****(USE BELOW IN R&D SOLICITATIONS INVOLVING LIVE VERTEBRATE ANIMALS (INCLUDING THEIR USE AS A SOURCE OF TISSUES.)****

6. **Research Involving Live Vertebrate Animals**

It is intended that live vertebrate animals will be used during performance of this contract. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (authority derived from the Health Research Extension Act of 1985) specifies that certain information is required from offerors in contract proposals submitted to the NIH that will use live vertebrate animals.

The following criteria must be addressed in a separate section of the Technical Proposal titled "Vertebrate Animal Section" (VAS):

1. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to

be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.

2. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
3. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
4. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

A concise (no more than 1-2 pages), complete description addressing these criteria must be provided. The description must be cohesive and include sufficient information to allow evaluation by reviewers and NIH staff. For more discussion regarding the VAS, see NIH Guide Notice NOT-OD-16-006 at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html.

The Contract Proposal VAS Worksheet is provided as an Attachment in SECTION J of this solicitation to assist in the preparation of the VAS as part of the Technical Proposal. It can be accessed at: https://grants.nih.gov/grants/olaw/vascontracts.pdf.

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****(USE BELOW IN ALL NIAID SOLICITATIONS AND/OR WHEN CONTRACT PERFORMANCE WILL INVOLVE POSSESSION, USE, OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS.

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

7. **Possession, Use and Transfer of Select Biological Agents or Toxins**

Notice to Offerors of Requirements of Select Agents Regulations - August 25, 2020 (https://www.selectagents.gov/regulations/index.htm): 42 CFR Part 73, Possession , Use, and Transfer of Select Agents and Toxins (relating to public health and safety): 7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins (relating to plant health or plant products) (and, 9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins (relating to human and animal health, animal health or animal products)

These regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the Agricultural Bioterrorism

Protection Act of 2002. They are designed to improve the ability of the United States Government to prevent, prepare for, and respond to bioterrorism and other public health emergencies. These regulations establish requirements regarding registration, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications.

Listings of HHS and USDA Select Agents and Toxins, and overlap Select Agents or Toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at https://www.selectagents.gov/ and https://www.selectagents.gov/sat/list.htm. For foreign institutions, see the NIAID Select Agent Award information at: https://www.niaid.nih.gov/grants-contracts/select-agent-terms-award-niaid-grants .

If the proposed contract will not involve the possession, use or transfer Select Agents or Toxins, the offeror must include a statement in its technical proposal that the work does not now nor will it in the future (i.e. throughout the life of the award) involve the possession, use or transfer Select Agents or Toxins.

Domestic Institutions

For prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, the domestic institution must:

i. Include details about the Select Agent in their technical proposal, including the quantity proposed to be used during contract performance.
ii. Describe the proposed use of the Select Agent or Toxin, including any restricted experiments.
iii. Comply with 42 CFR part 73, 7 CFR part 331 and/or 9 CFR part 121 at: https://www.selectagents.gov/regulations/index.htm , as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

Foreign Institutions

For prime or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, the foreign institution must:

i. Include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.

ii. Describe the proposed use of the Select Agent or Toxin, including any restricted experiments.

iii. When requested during negotiations, provide information satisfactory to the NIAID/NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: https://www.selectagents.gov/regulations/index.htm for U.S. institutions are in place and will be administered on behalf of all Select Agent work under the resulting contract. The process for making this determination includes a site visit to the foreign laboratory facility by an NIAID representative. During this visit, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. Laboratory site visits are conducted every three years for the life of the contract.

An NIAID chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the site visit , the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: https://www.selectagents.gov/regulations/index.htm . The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime Contractor of the approval status of the foreign institution. No NIH funds can be used for research involving a Select Agent or Toxin at a foreign institution until NIAID grants this approval.

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****(USE BELOW IN ALL SOLICITATIONS INVOLVING RESEARCH AND DEVELOPMENT INCLUDING SBIRs.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- Under Relevant Biological variables, variables may be added, but sex cannot be deleted unless justified by the IC.

8. **Enhancing Reproducibility through Rigor and Transparency**

The offeror shall demonstrate compliance with the NIH Policy on enhancing Reproducibility through Rigor and Transparency as described in NIH Guide Notice NOT- OD-15-103 . Specifically, the offeror shall describe in its technical proposal the information described below:

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****(USE PARAGRAPH a. BELOW IN ALL BROAD AGENCY ANNOUCEMENTS UNLESS SCIENTIFIC PREMISE WAS ADDRESSED DURING CONCEPT REVIEW.)****

For RFPs, Program staff need to determine if the scientific premise has been addressed by the Government in formulating the contract requirement(s) or if it should be addressed by the Offerors and evaluated in peer review.
IF NOT USING PARAGRAPH a., RENUMBER PARAGRAPH b. THROUGH d. AS APPROPRIATE.
ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- In paragraph c. insert additional variables as needed.

a. Compliance Factors

1. Describe the scientific premise for the Technical Proposal. The scientific premise is the research that is used to form the basis for the proposed research. Offerors should describe the general strengths and weaknesses of the prior research being cited by the offeror as crucial to support the proposal. It is expected that this consideration of general strengths and weaknesses could include attention to the rigor of the previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources.
2. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.
3. Explain how relevant biological variables, including sex, [if deemed necessary by the IC, additional variables may be included here] are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for proposals proposing to study only one sex. If your proposal involves human subjects, the sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion and justify the proposed proportions of individuals (such as males and females) in the sample. Refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.
4. If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in

the proposal. Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.

Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals. If the Technical Proposal does not propose the use of key biological and/or chemical resources, a plan for authentication is not required, and the offeror should so state in its proposal.

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

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- For a list of applicable agents or toxins, refer to Section 6 of the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern: http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf .

9. **Dual Use Research of Concern**

The offeror shall demonstrate compliance with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) or "DURC" policy. Additional National Institutes of Health information is found at: https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research . The offeror shall provide in its technical proposal each of the following items:

a. Identification of the agents or toxins subject to the DURC policy.
b. A description of the categories of experiments in which the identified agents or toxins produces or aims to produce or can be reasonably anticipated to produce one or more of the effects identified in Section 6 of the DURC policy.
c. For projects involving any of the agents listed in the DURC policy and that involve or are anticipated to involve any of the categories of experiments listed in the DURC policy, an indication of whether or not the project meets the definition of "dual use research of concern" in Section 4C of the policy.

d. For projects meeting the definition of "dual use research of concern," a draft risk mitigation plan.
e. Certification that the offeror is or will be in compliance with all aspects of the DURC policy prior to use of pertinent agents or toxins.

The Government shall not award a contract to an offeror who fails to certify compliance or whose draft risk mitigation plan is unsatisfactory to the Government. If selected for award, an approved risk mitigation plan shall be incorporated into the contract.

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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.)****

10. **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guidelines for Recipients of NIH Research Grants and Policy," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any

contract awarded from this solicitation. It can be found at the following website: http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf .

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****(USE BELOW IN ALL SOLICITATIONS WHERE RESEARCH DATA, INCLUSIVE OF GENOMIC DATA, WILL BE GENERATED. IN ACCORDANCE WITH "FINAL NIH POLICY FOR DATA MANAGEMENT AND SHARING," NOTICE NOT-OD-21-013 WITH A RELEASE DATE OF 29 OCTOBER 2020 AND AN EFFECTIVE DATE OF 25 JANUARY 2023, NOT-OD-22-189, IMPLEMENTATION DETAILS FOR THE NIH DATA MANAGEMENT AND SHARING PLAN, AND NOT-OD-22-198, IMPLEMENTATION CHANGES FOR GENOMIC DATA SHARING PLANS INCLUDED WITH APPLICATIONS DUE ON OR AFTER JANUARY 25, 2023, AS APPLICABLE, INCLUDE THE FOLLOWING IN ALL SOLICITATIONS RELEASED AFTER 01 JULY 2022 WITH AN ORIGINAL PROPOSAL RECEIPT DATE OF 25 JANUARY 2023 OR LATER, AND ANY CONTRACTS RESULTING FROM THESE SOLICITATIONS WITH RESEARCH DATA GENERATION REQUIREMENTS.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Last Paragraph:** Include this bracketed (" **[…]** ") paragraph for Multi-Center Clinical Trials or Epidemiological Studies. Make sure to delete this paragraph if it is not applicable.

a. **Management and Sharing of Research Data**

[Note: This policy applies to **all** NIH contracts, regardless of dollar value or level or type of funding, degree of funding (whole or partial), or type of NIH funding mechanism, that are expected to generate research data. **]**

NIH encourages, to the maximum extent practicable, the sharing of final research data to expedite the translation of research results into knowledge, products, services, and/or procedures to improve the human health condition. This contract is anticipated to generate such research data. Therefore, the Offeror shall submit to the Contracting Officer (CO) its Data Management and Sharing Plan, which also includes genomic data, as an attachment to its technical proposal or state why such data sharing is not possible. If data sharing is limited, the Offeror shall explain the rationale and nature of such limitations in its Data Management and Sharing Plan. An Offeror's Data Management and Sharing Plan, including those that include genomic data, will no longer undergo peer review but be subject to NIH staff review and acceptance prior to award. NIH's Data Management and Sharing Policy may be found at the following Web site:

NOT-OD-21-013: Final NIH Policy for Data Management and Sharing.

NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources are found at: https://grants.nih.gov/policy/sharing.htm .

[If the resultant contract is part of a collaborative program involving multiple sites, all data management and sharing shall be governed by a data management, sharing, and dissemination plan to be jointly developed prior to award. A Coordinating Center's proposal shall describe the methods by which to coordinate such data management, sharing, and dissemination planning and implementation efforts. In its proposal the Coordinating Center shall include a budget with all proposed costs and justification for/of any costs of such collaborative effort(s). **]**

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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 (https://grants.nih.gov/policy/sharing.htm) also referred to as NIH Principles and Guidelines for Sharing of Biomedical Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042 at: (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html), dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066 at: (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html), the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Offerors must include in their technical proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR provide appropriate reasons why such sharing is restricted or not

possible. A reasonable time frame for periodic disposition of material and associated data must be specified in the proposal. In addition, the plan must address if, or how, offerors will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following:

1. Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) at: https://www.ott.nih.gov/sites/default/files/documents/pdfs/slaform.pdf ; for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (https://autm.net/surveys-and-tools/agreements/material-transfer-agreements/mta-toolkit/uniform-biological-material-transfer-agreement) .
2. How will inappropriate "reach-through" requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?
3. How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

Offerors may request funds in their cost proposal to defray reasonable costs associated with sharing materials or data or transfer of model organisms and associated data to appropriate repositories.

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****(USE BELOW IN ALL SOLICITATIONS AND CONTRACTS INVOLVING NIH -FUNDED RESEARCH THAT GENERATES LARGE-SCALE HUMAN GENOMIC DATA ON OR AFTER JANUARY 25, 2015.)****

c. **Data Sharing Policy for Large-Scale Human Genomic Data**

1. Pursuant to the NIH Genomic Data Sharing Policy located at: https://sharing.nih.gov/ , all offerors proposing NIH-funded research that generates large-scale human genomic data shall provide:

    a. a plan for submission of genomic data to the NIH-designated data repository, and
    b. an Institutional Certification.

As an alternative, Contractors may provide an appropriate justification on why submission to the repository is not possible with the proposal submission to the Contracting Officer for approval.

2. Pursuant to the NIH Genomic Data Sharing Policy located at: https://sharing.nih.gov/ , Contractors who request access to controlled-access genomic data in the NIH repository for proposed research will be reviewed by the NIH Data Access Committees (DACs). NIH DACs will accept requests for proposed research uses beginning one month prior to the anticipated data release date. The access period for all controlled-access data is one year; at the end of each approved period, data users can request an additional year of access or close out the project. Additionally, Contractors requesting access to the data shall abide by the database of Genotypes and Phenotypes (dbGaP) Approved User Code of Conduct (https://dbgap.ncbi.nlm.nih.gov/aa/GWAS_Code_of_Conduct.html). Large-scale data include genome-wide association studies, single nucleotide polymorphisms arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism.

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****FOR USE IN ALL SOLICITATIONS AND CONTRACTS THAT INCLUDE HeLa CELL WHOLE GENOME SEQUENCE DATA****

d. **Sharing HeLa Cell Whole Genome Sequence Data and Family Acknowledgement**

1. Offerors proposing to generate HeLa Cell Whole Genome Sequence Data shall include a plan for submission of this data with the proposal pursuant to the HeLa Whole Genome Sequence Data guidance in NIH Guide Notice NOTOD-13-099, available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-099.html
2. Offerors who have generated and submitted HeLa cell whole genome sequence data from DNA or RNA to dbGaP must submit a data access request if they plan to use these data in any analyses. The process for accessing these data is outlined on the HeLa Cell Genome Sequencing Studies page (available at https://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/study.cgi?study_id=phs000640.v10.p1) .
3. The following acknowledgment, or a variation of it that has been reviewed by the HeLa Genome Data Access Working Group, shall be made in any dissemination of research findings:

"The genome sequence described/used in this research was derived from a HeLa cell line (URL to dbGaP). Henrietta Lacks, and the HeLa cell line that was established from her tumor cells without her knowledge or consent in 1951, have made significant contributions to scientific progress and advances in human health. We are grateful to Henrietta

Lacks, now deceased, and to her surviving family members for their contributions to biomedical research. This study was reviewed by the NIH HeLa Genome Data Access Working Group."

Contact helagenome@nih.gov for acknowledgement variation requests.

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****(USE BELOW IN SOLICITATIONS ABOVE THE MICROPURCHASE THRESHOLD WHEN THE ACQUISITION UTILIZES A PRODUCT OR SERVICE CODE DESIGNATED BY HHS AS HAVING SUSTAINABLE ACQUISITION ATTRIBUTES.)****

11. **Instructions to Offerors-Sustainable Acquisition** , HHSAR Provision **352.223-71** (December 2015).

Offerors must include a Sustainable Acquisition Plan in their technical proposals. The Plan must describe their approach and the quality assurance mechanisms in place for applying FAR 23.1 Sustainable Acquisition Policy (and other Federal Laws, regulations and Executive Orders governing sustainable acquisition purchasing) to this acquisition. the Plan shall clearly identify those products and services included in Federal sustainable acquisition preference programs by categorizing them along with their respective price/cost in the following eight groups: Recycled Content, Energy Efficient, Biobased, Environmentally Preferable, Electronic Product Environment Assessment Tool, Water-Efficient, Non-Ozone Depleting Substances, and Alternative Fuels.

(End of provision).

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****(USE BELOW IN SOLICITATIONS THAT INVOLVE THE ACQUISITION OF COMMUNICATIONS PRODUCTS AND SERVICES, INCLUDING CONTENT IN ANY FORMAT, SUCH AS REPORTS, DOCUMENTS, CHARTS, POSTERS, PRESENTATIONS, OR VIDEO MATERIAL THAT IS SPECIFICALLY INTENDED FOR PUBLICATION ON, OR DELIVERY VIA, AN HHS-OWNED OR FUNDED WEB SITE. See HHSAR 311.7000.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

Text Box:

Include the Section 508 accessibility standards which apply to the content or communications material identified in the Statement of Work or Performance Work Statement.

Notes:

1. In accordance with HHSAR Part 311, the Project Officer shall list the applicable accessibility standards of the Access Board Final Rule (36 CFR Part 1194) (e.g., "36 CFR 1194.21(a)-(j).")
2. Most Web-based text and communication must meet the accessibility standards in 36 CFR 1194.22, "Web-based intranet and Internet information and applications."
3. Additionally, 36 CFR 1194.41, "Information, documentation and support," and 36 CFR 1194.24 "Video and multimedia products" apply to all written, graphical, or broadcast video materials or products produced for HHS, including training.

36 CFR 1194.41(c) specifies that support services for products shall accommodate the communication needs of end-users with disabilities.

12. **Section 508 accessibility standards for HHS Web Site Content and Communications Materials**

Regardless of format, all Web content or communications materials specifically produced for publication on, or delivery via, HHS Web sites, including text, audio, or video, under this contract shall conform to applicable Section 508 accessibility standards. Remediation of any materials that do not comply with the applicable accessibility standards of 36 CFR Part 1194 as set forth herein shall be the responsibility of the Contractor.

The following Section 508 accessibility standards apply to the content or communications material identified in this Statement of Work Performance Work Statement:

_____

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****(USE BELOW IN ALL SOLICITATIONS. THE RESULTING BASIC COST/PRICE INFORMATION WILL BE USED FOR SUCH PURPOSES AS ENSURING THAT THE OFFEROR FULLY UNDERSTANDS THE REQUIREMENT AND FOR DETERMINING THAT THE INDIRECT RATE(S) ARE BEING APPLIED CORRECTLY. IT DOES NOT PRECLUDE OBTAINING MORE COMPREHENSIVE INFORMATION, INCLUDING COST OR PRICING DATA, IN APPROPRIATE CIRCUMSTANCES.)****

c. **BUSINESS PROPOSAL INSTRUCTIONS**

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

1. **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

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****(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 $2,000,000 AND Adequate Price Competition IS NOT expected;
2. Proposals will be BELOW $2,000,000 AND Adequate Price Competition IS expected BUT The CO concludes that unusual circumstances make it necessary to obtain Data Other Than Certified Cost or Pricing Data to determine Price Reasonableness;
3. Proposals will EXCEED $2,000,000 AND the CO obtains a waiver from the Certified Cost or Pricing Data Requirement in accordance with FAR 15.403-1(b)(4).)****

Note: *It will be necessary for the Contracting Officer to determine the level of data other than certified cost or pricing data required based on the needs and expectations of each solicitation.*

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Last sentence (in Brackets):**
  INCLUDE: Normally, the offeror should be allowed to submit this information in their own format. In this case the bracketed sentence should be INCLUDED in the SOLICITATION.
  DELETE: If the Contracting Officer deems that a specific format for the submission of this information is in the best interest of the Government, DELETE the bracketed sentence below and set forth the necessary format as the final sentence/paragraph of this item.

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3. **Data Other than Certified Cost or Pricing Data**

a. Data submitted shall be sufficient to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., data to support an analysis of material costs (when sufficient data on labor and overhead rates is already available), or data on prices and quantities at which the offeror has previously sold the same or similar items.

Data submitted must support the price proposed. The offeror shall include sufficient detail or cross references to clearly establish the relationship of the data provided to the price proposed. The offeror shall support any data provided with explanations or supporting rationale, as needed, to permit the Contracting Officer and authorized representative to evaluate the documentation.

[Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

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****(USE BELOW WHEN THE CONTRACTING OFFICER WANTS TO SPECIFY THE LEVEL OF DETAIL OF DATA OTHER THAN CERTIFIED COST AND PRICING DATA.)****
Note: *The information below may NOT be appropriate for all solicitations. The CO should evaluate each requirement individually, determine the level of detail the offeror should provide, and modify the paragraphs below based on the needs of the solicitation*.

b. The data submitted shall be at the level of detail described below.

1. **Direct Labor**

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

2. **Materials**

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

3. **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced

or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $750,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. **Raw Materials**

   Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

   Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

   Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

   If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

9. **Travel**

   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

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****(USE BELOW WHEN SUBMISSION OF CERTIFIED COST OR PRICING DATA IS REQUIRED.)****

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- **Paragraph 3:** If you plan to use one of the formats set forth in Table 15.2 of FAR 15.408, delete this paragraph and replace it with the appropriate language from Table 15.2. Also, if you use the language contained in Table 15.2, you will not need to add Alternate I of clause 52.215-20, immediately following this item.

4. **Certified Cost or Pricing Data**
   a. **General Instructions**
      A. You must provide the following information on the first page of your pricing proposal:
         1. Solicitation, contract, and/or modification number;
         2. Name and address of offeror;
         3. Name and telephone number of point of contact;
         4. Name of contract administration office (if available);
         5. Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);
         6. Proposed cost; profit or fee; and total;
         7. Whether you will require the use of Government property in the performance of the contract, and, if so, what property. See Item 16. Other Administrative Data, subparagraph a.2. Government Property of this Section L.2.c of this solicitation;
         8. Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
         9. The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the

instructions in FAR 15.403 5(b)(1) and Table 15 2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;

10. Date of submission; and
11. Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the certified cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, certified cost or pricing data (as defined at FAR 2.101). You must clearly identify on your cover sheet that certified cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including:
    1. The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
    2. The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries'' section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.

G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the

proposal, you must, under the conditions stated in FAR 15.406 2, submit a Certificate of Current Cost or Pricing Data.

b. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. **Materials and services** . Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when certified cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own certified cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor certified cost or pricing data as part of your own certified cost or pricing data as required in paragraph A.2. below. These requirements also apply to all subcontractors if required to submit certified cost or pricing data.

1. *Adequate Price Competition* . Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205 26(e)).
2. *All Other* . Obtain certified cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of certified cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the

lower of either $12.5 million or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. Also submit any information reasonably required to explain your estimating process (including the judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data, and the nature and amount of any contingencies included in the price). The Contracting Officer may require you to submit certified cost or pricing data in support of proposals in lower amounts. Subcontractor certified cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime Contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the certified cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's certified cost or pricing data is required as described in this paragraph, it must be included, along with your own certified cost or pricing data submission, as part of your own certified cost or pricing data. You must also submit any other certified cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor** . Provide a time phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.
C. **Indirect Costs** . Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.
D. **Other Costs** . List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties** . If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:
    1. Name and address of licensor.
    2. Date of license agreement.
    3. Patent numbers.
    4. Patent application serial numbers, or other basis on which the royalty is payable.
    5. Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
    6. Percentage or dollar rate of royalty per unit.
    7. Unit price of contract item.
    8. Number of units.
    9. Total dollar amount of royalties.
    10. If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.202 and 31.205-37).

F. **Facilities Capital Cost of Money** . When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB CMF and show the calculation of the proposed amount (see FAR 31.205 10).

c. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

d. **General Information**

A. There is a clear distinction between submitting certified cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of certified cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later

information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of certified cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

B. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

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****(USE BELOW IN SOLICITATIONS IF IT IS REASONABLY CERTAIN THAT CERTIFIED COST OR PRICING DATA OR DATA OTHER THAN CERTIFIED COST OR PRICING DATA WILL BE REQUIRED.)****

5. **Requirements for Certified Cost or Pricing Data and Data Other than Certified Cost or Pricing Data, FAR Clause 52.215-20** (Nov 2021).

(a) Exceptions from certified cost or pricing data.

(1) In lieu of submitting certified cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following paragraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) *Identification* of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) *Commercial product and commercial service exception.* For a commercial product and commercial service exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include:

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) *Requirements for certified cost or pricing data.* If the offeror is not granted an exception from the requirement to submit certified cost or pricing data, the following applies:

(1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall

submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision).

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****(USE BELOW IF CERTIFIED COST AND PRICING DATA WILL BE REQUIRED TO BE SUBMITTED USING THE FORMAT SPECIFIED SECTION L.2.c.4. Certified Cost or Pricing Data, subparagraph 3. OF THIS WORKFORM.)****

Note: *If you will be requiring the submission of Certified Cost or Pricing Data in a format other than the format specified in Section L.2.c.4. Certified Cost or Pricing Data, subparagraph 3. of this workform, the language in Alternate I, below, should be modified to be consistent with the format you require.*

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- Make sure to check that the paragraph numbering within the brackets in paragraph (b)(1) below is consistent with your SOLICITATION. Change if necessary.

Alternate I (October 2010) of FAR Clause **52.215-20, Requirements for Certified Cost or Pricing Data and Data Other than Cost or Pricing Data** (Nov 2021).

As prescribed in 15.408(l)(and see 15.403-5(b)(1)), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in the following format:

[Insert description of the data and format that are required, and include access to records necessary to permit an adequate evaluation of the proposed price in accordance with 15.408 , Table 15-2 *, Note 2. The description may be inserted at the time of issuing the solicitation, or the* Contracting Officer *may specify that the offeror's format will be acceptable, or the description may be inserted as the result of negotiations.]*

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****(USE BELOW IN ALL SOLICITATIONS WHEN A COST-REIMBURSEMENT, FIXED-PRICE LEVEL OF EFFORT, TIME-AND-MATERIALS, OR LABOR HOUR CONTRACT IS CONTEMPLATED.)****

6. **Salary Rate Limitation**

Offerors are advised that no NIH funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II*. The Executive Schedule, Level II* annual salary rate limitation also applies to individuals proposed under subcontracts and to consultants. **LINK TO EXECUTIVE SCHEDULE RATES OF PAY:**

https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/
(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

***Note to Offerors** : The current Fiscal Year Executive Level II Salary Rate shall be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year Executive Level II Salary rates.

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****(USE BELOW IN ALL SOLICITATIONS THAT WILL RESULT IN THE AWARD A MULTI-YEAR CONTRACT THAT WILL NOT BE FULLY FUNDED (FAR 17.1).)****

ADDITIONAL INFORMATION TO COMPLETE THIS ARTICLE:

1. **Subparagraph c:** Include estimated amount of the cancellation ceiling.
   Note: *In establishing cancellation ceilings, the Contracting Officer should estimate nonrecurring costs which would be incurred by an average Contractor and would be applicable to the products/services furnished under the contract. Nonrecurring costs are those costs which are generally incurred on a one-time basis and include such costs as preproduction or startup, plant or equipment relocation, special tooling and special test equipment, preproduction engineering, and specialized workforce training.*
   In most cases, when procuring professional services, the nonrecurring costs (i.e., the cancellation ceiling) will be $0.00.

7. **Multi-year Contract**

a. **General**

The Government intends to award any contract resulting from this solicitation under the terms and conditions of Federal Acquisition Regulation (FAR) Subpart 17.1, Multi-year Contracting. A multi-year contract may provide that performance under the contract during the second and subsequent years of the contract is contingent upon the appropriation of funds. It also may provide for a cancellation payment to be made to the Contractor if appropriations are not made.

Funding will be obligated to cover performance of the first program year plus cancellation liability, if any. Thereafter, performance will be funded as specified in Section B of the contract.

b. **Proposal Preparation and Evaluation**

In accordance with FAR 17.106-2, contract award will not be made on less than the requirements of the first program year; therefore, the offeror's proposal shall specifically identify the costs for the first program year, each subsequent program year, and the total multi-year contract.

Proposals will be evaluated in accordance with the evaluation factors set forth in Section M of this solicitation. The evaluation will consider the offeror's price and ability to perform the first program year as well as the total multi-year requirement. Award will be made based on the best overall value to the government.

If the Government determines before award that only the first program year requirements are needed, the Government's evaluation of the price or estimated cost and fee, if applicable, shall consider only the first year.

c. **Cancellation Ceiling**

In accordance with FAR Subpart 17.1, Multi-year Contracting, cancellation ceiling established for this contract is $ _____ . This amount, which is negotiable, will be reduced at the conclusion of each program year to reflect the contractor's recovery of non-recurring costs as performance progresses.

The first program year is not subject to cancellation. Cancellation dates for each succeeding program year will be included in the resultant contract and will indicate the specific calendar date by which funding for these requirements will be established. The cancellation dates will generally be the last day of each program year.

Offerors shall submit detailed estimates, by program year as well as for the total multi-year requirement, for any preproduction or startup, labor learning, and other nonrecurring costs that will be incurred in the execution of the proposed contract (see FAR 17.106-1). This information shall be provided in a format similar to below, and shall be included in a clearly identified section of the business proposal. The Government may use the offeror's proposed estimates to revise the cancellation ceiling established by the Government. The cancellation ceiling will not be an evaluation factor for award.

FORMAT FOR SUBMISSION OF PROPOSED CANCELLATION CEILING

The total proposed cancellation ceiling for this contract is $ _____ . After completion of Program Year 1, the proposed ceiling amount is $ _____ ; after completion of Program Year 2, the proposed ceiling amount is $ _____ ; after the completion of Year 3, the proposed ceiling amount is $ _____ ; and after completion of Program Year 4, the proposed ceiling amount is $ _____ .

Instructions:

1. **Adjust accordingly for the number of years proposed.**
2. **Provide basis and support for all costs proposed.**

732

****(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 IN SOLICITATIONS OR CONTRACTS OVER $750,000 (OR $1.5 Million for construction of Public Facilities) when the FAR Clause 52.219-9 Small Business Subcontracting Plan is incorporated or referenced in the Solicitation or Contract.)****

NOTE: An offeror must submit their respective subcontracting plan electronically using the U.S. Department of Health and Human Services (HHS) Small Business Customer Experience (SBCX) system at https://osdbu.hhs.gov. The form will be generated by the portal when the offerors submit their information for each specific proposal. The offeror must follow the instructions outlined in the SBCX Industry Guide at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j .

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- Last Paragraph: This paragraph identifies the minimum subcontract plan goals for the SOLICITATION and MUST be filled in for EVERY SOLICITATION that requires submission of a Subcontract Plan.

9. **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $750,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation. In accordance with FAR 19.704 and FAR Clause 52.219-9, the submission of a subcontracting plan by other than small business offeror(s) is a requirement as a part of the proposal submission process and is to be submitted separately from the technical and cost proposals. An offeror's subcontracting plan must be determined to be acceptable, by the Contracting Officer, prior to the contract award.

1. An offeror is to submit their respective subcontracting plan electronically using the U.S. Department of Health and Human Services (HHS) Small Business Customer Experience (SBCX) system at https://osdbu.hhs.gov. The offeror must follow the instructions outlined in the SBCX Industry Guide instructions outlined in the SBCX Industry Guide at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j to successfully submit their subcontracting plan by the proposal submission deadline.

2. The official point of receipt for determining timely submission of an offeror's subcontracting plan is the SBCX system and/or email notification. Once the subcontracting plan is successfully submitted in the SBCX system the offeror

should receive an email notification and confirmation message of completion upon submission.

3. If an offeror's subcontracting plan is not confirmed as received within the SBCX system by the proposal submission date specified in the solicitation, it will be considered late in accordance with subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offeror—Competition Acquisition. Disposition of late submittals of a subcontracting plan by an offeror via the SBCX system is at the discretion of the Contracting Officer.

4. Any technical questions regarding the use of the SBCX system may be submitted via email message to the SBCX help desk at client.support@apexlogic.com. The client support hours of operation are Monday – Friday, 6:00 a.m. – 8:00 p.m. Eastern Standard Time (EST). Note: help desk tickets can be submitted 24 hours a day / 7 days a week and a representative will respond within the presented client support hours of operation for assistance.

    a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
    b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
    c. The offeror understands that:
        i. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
        ii. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
        iii. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation

process to allow the Contractor to modify the plan within the time limits prescribed.

iv. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

v. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

vi. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:

i. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

ii. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

iii. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

iv. A description of the method used to develop the subcontracting goals.

v. A description of the method used to identify potential sources for solicitation purposes.

vi. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-

Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

vii. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

viii. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

ix. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $750,000 adopt a plan similar to the plan agreed upon by the offeror.

x. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government.

xi. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

32% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

734

****(USE BELOW IN ANY SOLICITATION THAT INCLUDES THE FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN.)****

10. **Mentor-Protégé Program, HHSAR 352.219-70** (December) 2015**.**

a. Large business prime Contractors serving as mentors in the HHS Mentor-Protege Program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU) approved mentor-protege agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protege firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at https://www.esrs.gov/ . The mentor firm and protege firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a $10,000 subcontract awarded to a protege firm and provision of $5,000 of developmental assistance as $15,000 of subcontracting plan credit.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.

b. The program consists of--

1. Mentor firms--large businesses that:
   (i) Demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and
   (ii) Have a Mentor-Protege agreement approved by HHS' OSDBU;
2. Protege firms--firms that:
   (i) Seek developmental assistance;
   (ii) Qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned small businesses; and
   (iii) Have a Mentor-Protege agreement approved by HHS' OSDBU; and
3. Mentor-Protege agreements--joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision).

735

****(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 https://www.sba.gov/federal-contracting/contracting-assistance-programs/hubzone-program .

736

****(USE BELOW FOR SOLICITATIONS WHICH WILL RESULT IN A CONTRACT FOR SERVICES WHICH WILL EXCEED $700,000 AND THE SERVICE TO BE PROVIDED WILL REQUIRE MEANINGFUL NUMBERS OF PROFESSIONAL EMPLOYEES.)****

12. **Total Compensation Plan**

a. **Instructions**

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. **Evaluation**

1. **Total Compensation Plan (Professional Employees)**
In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished

and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. **Cost (Professional Compensation)**
   Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3. **Other (Labor Relations)**
   An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4. **Federal Acquisition Regulation Clauses incorporated by Reference**
   FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees.

737

****(USE BELOW IN SOLICITATIONS FOR CONTRACTS THAT WILL REQUIRE THE CONTRACTOR TO USE AN EARNED VALUE MANAGEMENT SYSTEM (EVMS), WHETHER FULL OR PARTIAL, WHEN THE GOVERNMENT REQUIRES AN INTEGRATED BASELINE REVIEW (IBR) PRIOR TO AWARD.)****

ADDITIONAL INFORMATION ABOUT THIS ITEM:

- EVM IS APPLICABLE TO SOLICITATIONS FOR CONTRACTS THAT USE DEVELOPMENT, MODERNIZATION AND ENHANCEMENT (DME) FUNDS.

Note: *Funds used to develop, plan, modernize, or enhance an IT system are considered DME. DME does not include maintenance of existing IT Systems (including technology refreshment hardware and software.* For more information about EARNED VALUE MANAGEMENT (EVM) See HHSAR Subpart 334.2.

13. **Notice of Earned Value Management System - Pre-Award IBR**

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Business Proposal entitled, "Earned Value Management System."

a. The offeror shall provide documentation that its proposed Earned Value Management System (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard-748 (current version at time of solicitation).
b. If the offeror proposes to use a system that currently does not meet the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the guidelines.
    1. The plan shall:
        i. Describe the EVMS the offeror intends to use in performance of the contract;
        ii. Distinguish between the offeror's existing management system and modifications proposed to meet the guidelines;
        iii. Describe the management system and its application in terms of the EVMS guidelines;
        iv. Describe the proposed procedure for application of the EVMS requirements to subcontractors;
        v. Provide documentation describing the process and results, including Government participation if applicable, of any third- party evaluation or self- evaluation of the system's compliance with the EVMS guidelines; and
        vi. Provide a schedule of events leading up to formal validation and Government acceptance of the offeror's EVMS, if the value of the offeror's proposal, including options, is $25 million or more.
    2. The offeror shall provide information and assistance, as required by the Contracting Officer, to support review of the plan.

3. The Contracting Officer will review the offeror's EVMS implementation plan prior to contract award.
4. The offeror's EVMS plan must provide milestones indicating when the offeror anticipates that the EVMS will be compliant with the ANSVEIS Standard- 748 guidelines.

c. The offeror shall identify in its offer the subcontractors, or subcontracted effort if subcontractors have not been identified, to which the requirements of EVMS will be applied. Prior to contract award, the offeror and HHS shall agree on the subcontractors, or subcontracted effort, subject to the EVMS requirement.

d. HHS will conduct an Integrated Baseline Review (IBR) prior to contract award. The offeror shall be compensated as set forth elsewhere in this solicitation for its preparation for and participation in the IBR.

Offerors **[ ] Will** , **[ ] Will Not** be directly compensated for the costs of participating in a pre-award IBR.

738

****(USE BELOW IN SOLICITATIONS FOR CONTRACTS THAT WILL REQUIRE THE CONTRACTOR TO USE AN EARNED VALUE MANAGEMENT SYSTEM (EVMS), WHETHER FULL OR PARTIAL, WHEN THE GOVERNMENT REQUIRES AN IBR AFTER CONTRACT AWARD.
EVM APPLIES TO CONTRACTS THAT USE DEVELOPMENT, MODERNIZATION AND ENHANCEMENT (DME) FUNDS).)****

Note: *For more information about Earned Value Management (EVM) see HHSAR Subpart 334.2*.

14. **Notice of Earned Value Management System - Post-Award IBR**

a. The offeror shall provide documentation that its proposed Earned Value Management System (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard-748 (current version in effect at time of solicitation).

b. If the offeror proposes to use a system that currently does not meet the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the guidelines.
    1. The plan shall:
        i. Describe the EVMS the offeror intends to use in performance of the contract;
        ii. Distinguish between the offeror's existing management system and modifications proposed to meet the guidelines;

iii. Describe the management system and its application in terms of the EVMS guidelines;
iv. Describe the proposed procedure for application of the EVMS requirements to subcontractors;
v. Provide documentation describing the process and results, including Government participation if applicable, of any third-party evaluation or self-evaluation of the system's compliance with the EVMS guidelines; and
vi. Provide a schedule of events leading up to formal validation and Government acceptance of the offeror's EVMS, if the value of the offeror's proposal, including options, is $25 million or more.

2. The offeror shall provide information and assistance, as required by the Contracting Officer, to support review of the plan.

3. The Contracting Officer will review the offeror's EVMS implementation plan prior to contract award.

4. The offeror's EVMS plan must provide milestones indicating when the offeror anticipates that the EVM system will be compliant with the ANSI/EIA Standard-748 guidelines.

c. The offeror shall identify in its offer the subcontractors, or subcontracted effort if subcontractors have not been identified, to which the requirements of EVMS will be applied. Prior to contract award, the offeror and HHS shall agree on the subcontractor's) subcontracted effort, subject to the EVMS requirement.

739

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

15. **Other Administrative Data**

740

a. **Property**

741

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

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government

property be provided, other than that specified under "Government Furnished Property," below , the proposal must include a comprehensive justification addressing the following items:

a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

742

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

2. Government Property

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);

b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;

c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and

d. A description of the offeror's property management system, plan, and any customary commercial practices, voluntary consensus standards, or industry-leading practices and standards to be used in the offeror in managing Government property.

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from an offeror or Contractor possessing Government property. This will be done by adjusting the offers by applying, for evaluation purposes only, a rental equivalent evaluation factor, as specified in FAR 52.245-9.

743

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

ADDITIONAL INFORMATION TO COMPLETE THIS ITEM:

- Select the appropriate statement from the drop down box.

3. Government-Furnished Property

   [No Government Furnished Property is offered for this acquisition/A Listing of Government Furnished Property is provided in Section J - Solicitation Attachments of this solicitation].

744

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

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "Appendix Q, HHS Contracting Guide for Contract of Government Property," which can be found at: https://oamp.od.nih.gov/sites/default/files/DGS/HHS Contracting Guide for Contract of Government Property-Appendix Q.pdf.

745

****(USE BELOW WHEN IT IS ANTICIPATED THAT ROYALTIES MAY BE PAID IN CONNECTION WITH CONTRACT WORK.)****

b. **Royalties**

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

746

****(USEBELOW IN ALL SOLICITATIONS.)****

c. **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (Jul 2013).

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232

34, Payment by Electronic Funds Transfer Other than System for Award Management.

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

(End of provision).

747

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

d. **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

748

****(USE IN ALL SOLICITATIONS EXCEPT THOSE THAT WILL RESULT IN A FIRM-FIXED-PRICE CONTRACT.)****

e. **Adequate Accounting System**

FAR Part 16 sets forth the requirements and limitations for consideration of contract type. As stated in Section L.1., General Instructions of this solicitation, the resultant contract will not be Firm-Fixed Price. Therefore, the offeror's/contractor's accounting system and practices must be adequate and suitable for accumulating costs under government contracts.

To be considered for an award under this solicitation, the offeror shall include, in the Business Proposal, the following Certification:

"By submission of its signed offer, the Offeror certifies that its accounting system:

1. Complies with Generally Accepted Accounting Principles (GAAP).
2. Provides for:
    a. Proper segregation of direct costs from indirect costs.
    b. Identification and accumulation of direct costs by contract.
    c. A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
    d. Accumulation of costs under general ledger control.
    e. A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
    f. A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
    g. Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
    h. Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions.
    i. Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.
    j. Segregation of preproduction costs from production costs, if applicable.
3. Accounting system provides financial information:
    a. Required by contract clause concerning limitation of cost (FAR 52.232-20) or limitation on payments (FAR 52.216-16).
    b. Required to support requests for progress payments.
4. Accounting system was designed, and records are maintained in such a manner that adequate, reliable data are developed for use in pricing follow-on acquisitions.
5. Accounting system is currently in full operation.

The Contracting Officer reserves the right to request, with the Final Proposal Revision (FPR), a current (within 18 months) CPA opinion confirming that the Offeror's accounting system is compliant as certified above.

749

****(USE BELOW IF THE RESULTANT CONTRACT WILL BE INCREMENTALLY FUNDED.)****

f. **Incremental Funding**

An incrementally funded contract is a contract in which funds are obligated, as they become available, to cover specific periods of performance.

750

****(USE BELOW WHEN A COST-REIMBURSEMENT CONTRACT FOR SEVERABLE SERVICES USING INCREMENTAL FUNDING IS CONTEMPLATED.)****

ADDITIONAL INSTRUCTIONS TO COMPLETE THIS ITEM:

- Insert the appropriate period or increment of performance in the text box.

Incremental Funding, HHSAR 352.232-70 (December 2015).

The Government intends to negotiate and award a cost-reimbursement contract using incremental funding as described in the clauses at FAR 52.232-22, "Limitation of Funds." The initial obligation of funds under the contract is expected to cover _____ . The Government intends to obligate additional funds up to and including the full estimated cost of the contract for the remaining years of performance by unilateral contract modification. However, the Government is not required to reimburse the Contractor for costs incurred in excess of the total amount obligated, nor is the Contractor required to perform beyond the level supported by the total amount obligated.

(End of provision).

751

****(USE BELOW IF COMMERCIAL ORGANIZATIONS MIGHT RESPOND TO THE SOLICITATION.)****

g. **Facilities Capital Cost of Money, FAR 52.215-16,** (Jun 2003).

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of provision).

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] Fac Cap Cost of Money (Has) The prospective Contractor **has** specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] Fac Cap Cost of Money (Has Not) The prospective Contractor **has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

752

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

16. **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a. **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b. **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement

of Work in this RFP.

c. **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d. **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

753

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

17. **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a. Willingness to perform as a subcontractor for specific duties (list duties).

b. What priority the work will be given and how it will relate to other work.
c. The amount of time and facilities available to this project.
d. Information on their cognizant field audit offices.
e. How rights to publications and patents are to be handled.
f. A complete cost proposal in the same format as the offeror's cost proposal.

754

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

18. **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

756

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

19. **Travel Costs/Travel Policy**

757

****(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.

758

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

b. **Travel Policy**

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If

an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

758

****(USE BELOW IN ALL SOLICITATIONS FUNDED WITH APPROPRIATED BIO-DEFENSE FUNDS.

Note: *At this time, may only be applicable to NIAID projects* .

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

20. **Certification of Visas for Non-U.S. Citizens**

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.