SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Requisition or other Purchase Authority: Public Law 81-692 as amended.

<table>
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<th>2. Request for Proposal (RFP) Number:</th>
<th>3. Issue Date:</th>
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<tr>
<td>NIAID-DAIT-NIHAI201800017</td>
<td>09/26/2018</td>
<td>[X] No</td>
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<td></td>
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<td>[ ] Yes See Part IV Section L</td>
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</table>

5. Title: NIH Tetramer Core Facility

6. ISSUED BY:
   - Office of Acquisitions
   - National Institute of Allergy and Infectious Diseases
   - National Institutes of Health
   - 5601 Fishers Lane
   - Rockville, MD 20852

7. SUBMIT OFFERS TO:
   See Part III, Section J, "Packaging and Delivery of the Proposal,"
   ATTACHMENT 1 of this Solicitation.
   The due date for all questions relating to this solicitation are due by 12/17/18.

8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 3:00pm EST on 1/9/2019. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.

9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS.

   IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition," LOCATED IN SECTION L.1. OF THIS SOLICITATION.

10. Offeror must be registered in the System for Award Management (SAM) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at [http://www.sam.gov](http://www.sam.gov)

11. FOR INFORMATION CALL: Maribel Miranda
    PHONE: 240-669-5139
    e-MAIL: maribel.miranda@nih.gov
    COLLECT CALLS WILL NOT BE ACCEPTED.

5601 Fishers Lane
Rockville, MD 20852
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<td>2.</td>
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<td>HUMAN SUBJECT EVALUATION</td>
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<td>LIVE VERTEBRATE ANIMALS EVALUATION</td>
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PART I - THE SCHEDULE

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

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The National Institute of Allergy and Infectious Diseases (NIAID) Division of Allergy, Immunology, and Transplantation (DAIT), Division of Microbiology and Infectious Diseases (DMID), Division of AIDS (DAIDS), and Division of Intramural Research (DIR); and the National Cancer Institute (NCI) support the NIH Tetramer Core Facility. The funding for this needed program permits tetramer-related technology development, MHC allele gene expression and protein purification, tetramer production and quality control testing, order tracking, and website maintenance. Investigators requesting reagents incur the cost of peptide production, shipping of the peptides to the NIH Tetramer Core Facility, and shipping of the tetramer reagents to their institution.

The NIH Tetramer Core Facility Contractor will be involved with the synthesis and distribution of soluble MHC-peptide tetramer and related reagents to the global research community, and performance of research and development to improve tetramer technologies and increase the types of products available to the biomedical research community.

ARTICLE B.2. PRICES/COSTS

a. This is an Indefinite Quantity contract as contemplated by FAR 16.504. The Contractor shall be reimbursed by the Government in an amount not less than a total of $50,000 (minimum) nor more than a total of $50,000,000 (maximum) for successful performance of this contract.

b. The costs set forth in this ARTICLE will cover the contract period 12/20/2019 through 12/19/2026.

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

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Conferences & Meetings, 2) Food for Meals, Light Refreshments & Beverages, 3) Promotional Items, 4) Acquisition, by purchase or lease, of any interest in real property; 5) Special rearrangement or alteration of facilities; 6) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 7) Travel Costs including Foreign Travel; 8) Consultant Costs; 9) Subcontract Costs; 10) Patient Care Costs; 11) Accountable Government Property; 12) Printing costs; and 13) Research Funding.
SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated August 1, 2018, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

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

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

a. Technical Progress Reports

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

For proposal preparation purposes only, it is estimated that the selected reports will be required as follows:

[X] Quarterly- Task Area A
[X] Annually- Task Area A
[X] Final- Upon final completion of the contract - All Task Areas

2. Summary of Salient Results

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

b. Other Reports/Deliverables

1. Reporting of Financial Conflict of Interest (FCOI)

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

45 CFR Part 94 is available at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45. See Part 94.5, Management and reporting of financial conflicts of interest for complete information on reporting requirements.

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

2. **Section 508 Annual Report**

The contractor shall submit an annual Section 508 report in accordance with the schedule set forth by the Contracting Officer (CO)/Contracting Officer's Representative (COR). The Section 508 Report Template and instructions for completing the report are available at: http://www.hhs.gov/web/508/contracting/technology/vendors.html under "Vendor Information and Documents."

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

All reports required herein shall be submitted in electronic format. All electronic contract deliverables shall be submitted via the NIAID electronic Report Deliverable Submission (eRDS) Site, available at the following website: https://erds.niaid.nih.gov/. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

**ARTICLE C.3. INVENTION REPORTING REQUIREMENT**

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

The first annual utilization report shall be due on or before the 30th Calendar day following the calendar year of the contract. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

- Contracting Officer
- National Institutes of Health
- National Institute of Allergy and Infectious Diseases
- Office of Acquisitions
- 5601 Fishers Lane
- Rockville, MD 20852

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

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

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

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

b. For the purpose of this SECTION, the Contracting Officer’s Representative (COR) is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:
   National Institutes of Health
   National Institute of Allergy and Infectious Diseases
   Division of Allergy, Immunology, and Transplantation
   5601 Fishers Lane
   Rockville, MD 20852

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

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

   FAR Clause 52.246-9, Inspection of Research and Development (Short Form) (April 1984).
SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract shall be from 12/20/2019 through 12/19/2026.

ARTICLE F.2. DELIVERIES

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

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified in each Task Order.

b. All electronic reports and deliverables shall be submitted through the NIAID Electronic Reports and Deliverables System, available here: https://erds.niaid.nih.gov/

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989)

Alternate I (April 1984) is applicable to this contract.
SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER’S REPRESENTATIVE (COR)

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

To be specified prior to award.

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

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

The Government may unilaterally change its COR designation.

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

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

(End of Clause)

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

<table>
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<th>Name</th>
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ARTICLE G.3. TASK ORDER PROCEDURE

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

a. General

Only the Contracting Officer may issue Task Orders to the Contractor, providing specific authorization or direction to perform work within the scope of the contract and as specified in the Statement of Work. Unless specifically authorized by the Contracting Officer, the Contractor shall not commence work until a fully executed Task Order has been awarded. The Contractor may incur costs under this contract in performance of task orders and task order modifications issued in accordance with this ARTICLE.
No other costs are authorized unless otherwise specified in the contract or expressly authorized by the Contracting Officer.

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

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

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

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

c. Evaluation and Award of Task Order Proposals

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

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

ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

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

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

National Institutes of Health
Office of Financial Management
Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

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

Contracting Officer
Office of Acquisitions
National Institutes of Health
National Institute of Allergy and Infectious Diseases
5601 Fishers Lane
Rockville, MD 20852

TBD

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

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

a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Institute of Allergy and Infectious Diseases.

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

c. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the Central Contractor Registration (CCR) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.] If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.

d. Invoice Matching Option. This contract requires a two-way match.

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

f. The Contract Title is:
NIH Tetramer Core Facility

g. Contract Line Items as follows:

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

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

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

ARTICLE G.5. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

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

b. The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.

c. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of Clause)

ARTICLE G.6. INDIRECT COST RATES

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

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

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.7. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real
property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at: http://oamp.od.nih.gov/sites/default/files/appendix_q_hhs_contracting_guide.pdf.

ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually to coincide with the anniversary date of the contract.

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

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

b. Electronic Access to Contractor Performance Evaluations

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

http://www.cpars.gov
SECTION H - SPECIAL CONTRACT REQUIREMENTS

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

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

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

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

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

e. (End of clause)

ARTICLE H.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:


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

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

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

ARTICLE H.3. 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:


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

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

ARTICLE H.4. HUMAN MATERIALS

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

ARTICLE H.5. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.
The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

ARTICLE H.6. RESEARCH INVOLVING HUMAN FETAL TISSUE

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

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

ARTICLE H.7. RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (Including Human Gene Transfer Research)

All research projects (both NIH-funded and non-NIH-funded) involving recombinant or synthetic nucleic acid molecules that are conducted at or sponsored by an entity in the U.S. that receives any support for recombinant or synthetic nucleic acid research from NIH shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) available at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines. All NIH-funded projects abroad that include recombinant or synthetic nucleic acid molecules must also comply with the NIH Guidelines.

The NIH Guidelines stipulate biosafety and containment measures for recombinant or synthetic nucleic acid research, which is defined in the NIH Guidelines as research with (1) molecules that a) are constructed by joining nucleic acid molecules and b) can replicate in a living cell, i.e. recombinant nucleic acids, or (2) nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e. synthetic nucleic acids, or (3) molecules that result from the replication of those described in (1) or (2). The NIH Guidelines apply to both basic and clinical research. Specific guidance for the conduct of human gene transfer studies appears in Appendix M of the NIH Guidelines.

Failure to comply with the NIH Guidelines may result in suspension, limitation, or termination of the contract for any work related to recombinant or synthetic nucleic acid research or a requirement for the Contracting Officer to approve any or all recombinant or synthetic nucleic acid molecule projects under this contract. This includes the requirement for the institution to have an Institutional Biosafety Committee (IBC) registered with the NIH Office of Science Policy that complies with the requirements of the NIH Guidelines. Further information about compliance with the NIH Guidelines can be found on the NIH Office of Science Policy website available at: http://osp.od.nih.gov/.

ARTICLE H.8. NIH POLICY ON ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

Contractors shall adhere to the NIH policy of enhancing reproducibility through rigor and transparency by addressing each of the four areas of the policy in performance of the Statement of Work and in publications, as applicable:
1) Scientific Premise; 2) Scientific Rigor; 3) Consideration of Relevant Biological Variables, including Sex; and 4) Authentication of Key Biological and/or Chemical Resources. This policy applies to all NIH funded research and development, from basic through advanced clinical studies. See NIH Guide Notice, NOT-OD-15-103, "Enhancing Reproducibility through Rigor and Transparency" and NOT-OD-15-102, "Consideration of Sex as a Biological Variable in NIH-funded Research" for more information. In addition, publications are expected to follow the guidance at http://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research, whether preclinical or otherwise, as appropriate. More information is available at http://grants.nih.gov/reproducibility/index.htm, including FAQs and a General Policy Overview.

ARTICLE H.9. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.


ARTICLE H.10. NEEDLE EXCHANGE, HHSAR 352.270-12 (December 2015)

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

(End of clause)

ARTICLE H.11. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

ARTICLE H.12. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

a. The Contractor shall not use any funds obligated under this contract for any abortion.

b. The Contractor shall not use any funds obligated under this contract for the following:

   1. The creation of a human embryo or embryos for research purposes; or

   2. Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

c. The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR part 46 as of the date
of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.

d. The Contractor shall not use any Federal funds for the cloning of human beings.

(End of clause)

ARTICLE H.13. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

ARTICLE H.14. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015)

a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United States Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 2.11, or from a source that is exempt from licensing under those sections.

c. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c)above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor’s name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov; Web site: (http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare).

(End of clause)
ARTICLE H.15. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: http://grants1.nih.gov/grants/olaw/references/phspol.htm

In addition, the research involving live vertebrate animals shall be conducted in accordance with the description set forth in the Vertebrate Animal Section (VAS) of the contractor's technical proposal, as modified in the Final Proposal Revision (FPR), dated TBD, which is incorporated by reference.

ARTICLE H.16. INTRODUCTION OF RODENTS AND RODENT PRODUCTS

No rodent or rodent product shall be delivered into the NIH, NIAID environment (NIH) directly, or through collaborative research or holding facilities under contract to NIAID except by permit. Direct shipments to NIH from a Division of Veterinary Resources (DVR), Office of Research Services (ORS) approved source will be considered exempt. Non-exempt sources must be approved by permit issued through the DVR, ORS. The permit must be obtained by the Contractor prior to the shipment to NIH of the rodents and/or rodent products. The Contractor must be sure that this permit exists and is current before transferring rodents or rodent products into the NIH, NIAID environment. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Applications for permits should be submitted by facsimile not less than 30 days prior (60 days in situations where quarantine is likely) to shipping date to: NIH Division of Veterinary Resources (DVR), Office of Research Services (ORS), Building 14G, Service Rd. South, Room 102, BETHESDA MD 20892-5210, (301)496-2527, FAX: (301) 402-0352.

ARTICLE H.17. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL:


ARTICLE H.18. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

ARTICLE H.19. GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

ARTICLE H.20. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-9, Option to Extend the Term of the Contract set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost of the contract will be increased as set forth in the ESTIMATED COST Article in SECTION B of this contract.

ARTICLE H.21. SUBCONTRACTING PROVISIONS

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

2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

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

1. Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

   April 30th
   October 30th
   Expiration Date of Contract

2. Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

   October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:

   TBD
   Contracting Officer

ARTICLE H.22. HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS

ARTICLE H.22.1. INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

A. Baseline Security Requirements

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

   a. 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.

   b. 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.

2. **Safeguarding Information and Information Systems** - In accordance with the Federal Information Processing Standards Publication (FIPS) 199, Standards for Security Categorization of Federal Information and Information Systems, the Contractor (and/or any subcontractor) shall:

   a. 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.

   b. 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.

   c. 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.

   d. Comply with the Privacy Act requirements.

3. **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**: [X] Low [ ] Moderate [ ] High
   - **Integrity**: [ ] Low [X] Moderate [ ] High
   - **Availability**: [X] Low [ ] Moderate [ ] High
   - **Overall Risk Level**: [ ] Low [X] 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:

   [X] No PII [ ] Yes PII

**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.

PII Confidentiality Impact Level has been determined to be: [ ] Low [X] Moderate [ ] High

4. Controlled Unclassified Information (CUI) - CUI is defined as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Contractor (and/or any subcontractor) must comply with Executive Order 13556, Controlled Unclassified Information, implemented at 3 CFR, part 2002, when handling CUI. As implemented the term "handling" refers to "...any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, shall be:

a. Marked appropriately;
b. Disclosed to authorized personnel on a Need-To-Know basis;
c. Protected in accordance with NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations if handled by internal Contractor system; and
d. Returned to HHS control, destroyed when no longer needed, or held until otherwise directed. Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

5. Protection of Sensitive Information - For security purposes, information is or may be sensitive because it requires security to protect its confidentiality, integrity, and/or availability. The Contractor (and/or any subcontractor) shall protect all government information that is or may be sensitive in accordance with OMB Memorandum M-06-16, Protection of Sensitive Agency Information by securing it with a FIPS 140-2 validated solution.

6. 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 in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

The confidentiality, integrity, and availability of such information 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:

a. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
b. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and

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:

8. **Government Websites**- All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS shall enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. For internal-facing websites, the HTTPS is not required, but it is highly recommended.

9. **Contract Documentation**- The Contractor shall use provided templates, policies, forms and other agency documents provided by the Contracting Officer and the Contracting Officer’s Representative to comply with contract deliverables as appropriate.

10. **Standard for Encryption**- The Contractor (and/or any subcontractor) shall:

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

    b. 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 140-2 validated encryption solution.

    c. 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).

    d. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer’s Technical Representative within 15 days of the validation.

    e. 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.

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

12. **Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA)**- The Contractor shall assist the NIH Office of the Senior Official for Privacy (SOP) or designee with conducting a PTA for the information system and/or information handled under this contract to determine whether or not a full PIA needs to be completed. The NIH PIA guide is located at [https://oma.od.nih.gov/forms/Privacy%20Documents/Documents/NIH%20PIA%20Guide.pdf](https://oma.od.nih.gov/forms/Privacy%20Documents/Documents/NIH%20PIA%20Guide.pdf).
a. If the results of the PTA show that a full PIA is needed, the Contractor shall assist the OpDiv SOP or designee with completing a PIA for the system or information within 60 days after completion of the PTA and in accordance with HHS policy and OMB M-03-22, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.

b. The Contractor shall assist the NIH Office of the SOP or designee in reviewing the PIA at least every three years throughout the system development lifecycle (SDLC)/information lifecycle, or when determined by the agency that a review is required based on a major change to the system, or when new types of PII are collected that introduces new or increased privacy risks, whichever comes first.

B. 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://ocio.nih.gov/aboutus/publicinfosecurity/securitytraining/Pages/rolebasedtraining.aspx

3. Training Records- The Contractor (and/or any subcontractor) shall maintain training records for all its employees working under this contract in accordance with HHS policy. A copy of the training records shall be provided to the CO and/or COR within 30 days after contract award and annually thereafter or upon request.

C. RULES OF BEHAVIOR

1. The Contractor (and/or any subcontractor) 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/InfoSecurity/training/Pages/nihitrob.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.

D. 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 24 hours, whether the response is positive or negative.

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

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

In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) shall:

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 140-2 validated encryption.
2. 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://ocio.nih.gov/InfoSecurity/IncidentResponse/Pages/ir_guidelines.aspx
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:
   a. cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
   b. not include any sensitive information in the subject or body of any reporting e-mail; and
   c. 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.
E. POSITION SENSITIVITY DESIGNATIONS

All Contractor (and/or any subcontractor) employees must obtain a background investigation commensurate with their position sensitivity designation that complies with Parts 1400 and 731 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/contract:

[ ] Level 6: Public Trust - High Risk. Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[X] Level 5: Public Trust - Moderate Risk. Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[ ] Level 1: Non-Sensitive. Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

F. HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

The Contractor (and/or any subcontractor) and its employees shall 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-

a. 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://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx.

b. 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.

c. 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.

d. 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.
e. 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.

f. 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.

g. 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).

h. 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).

i. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.

j. 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.

G. 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 Guide (2012).

   HHS EA requirements may be located here: https://www.hhs.gov/ocio/ea/documents/proplans.html

2. System Documentation- Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, Security Considerations in the System Development Life Cycle, 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
NIH Contractor Employee Separation Checklist https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/ Documents/Emp-sep-checklist.pdf when an employee terminates work under this contract within 2 days of
the employee's exit from the contract. All documentation shall be made available to the CO and/or COR upon
request.

H. RECORDS MANAGEMENT AND RETENTION

The Contractor (and/or any subcontractor) shall maintain all information in accordance with Executive Order 13556 --
Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies
and schedules and HHS/NIH policies and shall not dispose of any records unless authorized by HHS/NIH.
In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper
authorization, it shall be documented and reported as an incident in accordance with HHS/NIH policies.

ARTICLE H.23. 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

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

ARTICLE H.24. CONFIDENTIALITY OF INFORMATION

a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

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

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

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

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

The following information is covered by this article:

All data provided by the Government to the contractor.
ARTICLE H.25. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site:  

http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45

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

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

1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;

2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and

2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

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

c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the NIH-funded research.

d. Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for NIH-funded research. Require that each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time
period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to NIH-funded research when the Institution, thorough its designated official(s), reasonably determines that the significant financial interest: Could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

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

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

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

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

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

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

If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.
ARTICLE H.26. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause 352.227-70, Publications and Publicity incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. [to be specified at time of award]"

a. Advanced Copies of Press Releases

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the Contracting Officer's Representative (COR) has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

ARTICLE H.27. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is 1-800-HHS-TIPS (1-800-447-8477). All telephone calls will be handled confidentially. The website to file a complaint on-line is: http://oig.hhs.gov/fraud/hotline/ and the mailing address is:

US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.28. SHARING RESEARCH DATA

A data sharing plan must be submitted with the proposal and must be approved by the Office of Acquisitions. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

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


NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

ARTICLE H.29. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control
guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at: http://apps.usfa.fema.gov/hotel/.

**ARTICLE H.30. CONSTITUTION DAY**

Each educational institution that receives Federal funds for a fiscal year shall hold an educational program on the United States Constitution on September 17 of such year for the students serviced by the educational institution in accordance with Public Law 108-447.
PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

THE FOLLOWING ARTICLE I.1. GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP:

The complete listing of these clauses may be accessed at:

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT
ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

a. **Alternate II** (August 2016) of FAR Clause 52.215-2, Audit and Records--Negotiation (October 2010) is added.

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

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

d. FAR Clauses 52.249-6, Termination (Cost-Reimbursement) (May 2004) and 52.249-14, Excusable Delays (April 1984), are deleted in their entirety and FAR Clause 52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions) (August 2016), is substituted therefore.
ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses by reference, (unless otherwise noted), with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

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

1. FAR Clause 52.203-13, Contractor Code of Business Ethics and Conduct (October 2015).

2. FAR Clause 52.203-14, Display of Hotline Poster(s) (October 2015).

   “....(3) Any required posters may be obtained as follows:

<table>
<thead>
<tr>
<th>Poster(s)</th>
<th>Obtain From</th>
</tr>
</thead>
</table>

3. FAR Clause 52.209-10, Prohibition on Contracting With Inverted Domestic Corporations (November 2015).

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

5. FAR Clause 52.219-28, Post-Award Small Business Program Rerepresentation (July 2013).

6. FAR Clause 52.224-1, Privacy Act Notification (April 1984).

7. FAR Clause 52.224-2, Privacy Act (April 1984).

8. FAR Clause 52.227-14, Rights in Data - General (May 2014).

9. FAR Clause 52.227-16, Additional Data Requirements (June 1987).

10. FAR Clause 52.242-3, Penalties for Unallowable Costs (May 2014).

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:

1. HHSAR Clause 352.211-2, Conference Sponsorship Request and Conference Materials Disclaimer (December 2015)

2. HHSAR Clause 352.211-3, Paperwork Reduction Act (December 2015)
3. HHSAR Clause **352.223-70, Safety and Health** (December 2015)

4. HHSAR Clause **352.231-70, Salary Rate Limitation** (December 2015)

   **Note:** The Salary Rate Limitation is at the Executive Level II Rate.


   (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.)
ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. Any contract awarded from this solicitation will contain the following:

This contract incorporates the following clauses in full text.

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

1. FAR Clause 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (July 2013)

As prescribed in 9.104-7(c), insert the following clause:

a. The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIIS) on a semi-annual basis, throughout the life of the contract, by posting the required information in the System for Award Management (SAM) database at http://www.acquisition.gov.

b. As required by section 3010 of the Supplemental Appropriations Act, 2010 (Pub. L. 111-212), all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIIS consists of two segments--

1. The non-public segment, into which Government officials and the Contractor post information, which can only be viewed by--

   i. Government personnel and authorized users performing business on behalf of the Government; or

   ii. The Contractor, when viewing data on itself; and

2. The publicly-available segment, to which all data in the non-public segment of FAPIIS is automatically transferred after a waiting period of 14 calendar days, except for--

   i. Past performance reviews required by subpart 42.15;
   
   ii. Information that was entered prior to April 15, 2011; or

   iii. Information that is withdrawn during the 14-calendar-day waiting period by the Government official who posted it in accordance with paragraph (c)(1) of this clause.

b. The Contractor will receive notification when the Government posts new information to the Contractor's record.

   1. If the Contractor asserts in writing within 7 calendar days, to the Government official who posted the information, that some of the information posted to the non-public segment of FAPIIS is covered by a disclosure exemption under the Freedom of Information Act, the Government official who posted the information must within 7 calendar days remove the posting from FAPIIS and resolve the issue in accordance with agency Freedom of Information procedures, prior to reposting the releasable information. The contractor must cite 52.209-9 and request removal within 7 calendar days of the posting to FAPIIS.

   2. The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.
3. As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.

d. Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.

(End of clause)

2. FAR Clause 52.216-18, Ordering (October 1995).

a. Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from 12/20/2019 through 12/19/2026.

b. All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

c. If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of clause)

3. FAR Clause 52.216-19, Order Limitations (October 1995)

a. Minimum Order. When the Government requires supplies or services covered by this contract in an amount of less than $50,000 the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

b. Maximum Order. The Contractor is not obligated to honor--

1. Any order for a single item in excess of $100 million.

2. Any order for a combination of items in excess of $100 million; or

3. A series of orders from the same ordering office within 30 days that together call for quantities exceeding the limitation in subparagraph (1) or (2) above.

c. If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) above.

d. Notwithstanding paragraphs (b) and (c) above, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 30 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

4. FAR Clause 52.216-22, Indefinite Quantity (October 1995)

a. This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.
b. Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."

c. Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

d. Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after 12/19/2027.

(End of clause)
## PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

### SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

### SOLICITATION ATTACHMENTS

<table>
<thead>
<tr>
<th>Attachment No.</th>
<th>Title</th>
<th>Location</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attachment 1:</td>
<td>Packaging and Delivery of Proposal (R &amp; D)</td>
<td>See attachment section at the end of this RFP</td>
</tr>
<tr>
<td>Attachment 2:</td>
<td>Proposal Intent Response Sheet</td>
<td>See attachment section at the end of this RFP</td>
</tr>
<tr>
<td>Attachment 3:</td>
<td>Statement of Work for Base Contract</td>
<td>See attachment section at the end of this RFP</td>
</tr>
<tr>
<td>Attachment 4:</td>
<td>Statement of Work and Reporting Requirements for Task Order A-1</td>
<td>See attachment section at the end of this RFP</td>
</tr>
<tr>
<td>Attachment 5:</td>
<td>Statement of Work and Reporting Requirements for Sample Task Order B-1</td>
<td>See attachment section at the end of this RFP</td>
</tr>
<tr>
<td>Attachment 6:</td>
<td>Additional Technical Proposal Instructions, Format for Technical Proposal and Table of Contents</td>
<td>See attachment section at the end of this RFP</td>
</tr>
<tr>
<td>Attachment 7:</td>
<td>Additional Business Proposal Instructions and Uniform Cost Assumptions</td>
<td>See attachment section at the end of this RFP</td>
</tr>
<tr>
<td>Attachment 8:</td>
<td>Section K - Representations, Certifications, and Other Statements of Offerors</td>
<td>See Section K</td>
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### TECHNICAL PROPOSAL ATTACHMENTS

<table>
<thead>
<tr>
<th>Attachment No.</th>
<th>Title</th>
<th>Location</th>
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<tbody>
<tr>
<td>Attachment 11:</td>
<td>Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310)</td>
<td><a href="http://www.hhs.gov/ohrp/sites/default/files/ohrp/assurances/forms/optional310form.rtf">http://www.hhs.gov/ohrp/sites/default/files/ohrp/assurances/forms/optional310form.rtf</a></td>
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## BUSINESS PROPOSAL ATTACHMENTS

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<th>Title</th>
<th>Location</th>
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<tr>
<td>Attachment 16:</td>
<td>Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet</td>
<td><a href="https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee-and-labor-hours">https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee-and-labor-hours</a></td>
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<td><a href="https://oamp.od.nih.gov/sites/default/files/DFASDocs/buscntrctprpsprdsht08-2014_508.xlsx">https://oamp.od.nih.gov/sites/default/files/DFASDocs/buscntrctprpsprdsht08-2014_508.xlsx</a></td>
</tr>
<tr>
<td>Attachment 18:</td>
<td>Disclosure of Lobbying Activities, OMB Form SF-LLL</td>
<td><a href="http://www.gsa.gov/portal/forms/download/116430">http://www.gsa.gov/portal/forms/download/116430</a></td>
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## INFORMATIONAL ATTACHMENTS

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<th>Location</th>
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</table>
**PART IV - REPRESENTATIONS AND INSTRUCTIONS**

**SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS**

**IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :**

1. Go to the **System for Award Management (SAM)** and complete the Representations and Certifications. The SAM website may be accessed at: [http://www.sam.gov](http://www.sam.gov); and

2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**
   **SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS**

   which is included as an Attachment in Section J-LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation.

   If you are unable to access this **SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS** electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

3. **FAR Clause 52.204-19 Incorporation by Reference of Representations and Certifications** (December 2014).

   The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

(End of Clause)
SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Provision 52.215-1 (January 2017)]

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

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

(3) It is the only proposal received.

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

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

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

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

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

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

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

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

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
(d) Offer expiration date. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) Restriction on disclosure and use of data.

(1) The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification)."

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

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

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) Contract award.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) A summary of the rationale for award.

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

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

(End of Provision)

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

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.
b. **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 541714.
2. The small business size standard is 1000.

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

1. It is anticipated that one award will be made from this solicitation and that the award(s) will be made on/ about December, 2019.
2. It is contemplated that an Indefinite Delivery, Indefinite Quantity (IDIQ) type contract comprised of cost reimbursement, term/completion type orders will be awarded 12/20/2019 to 12/19/2026.
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.

d. **LEVEL OF EFFORT**

The Government's requirement for the work set forth in the Statement of Work of this solicitation is 22,776 direct labor hours. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

<table>
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<tr>
<th>Labor Category</th>
<th>Year 1</th>
<th>Year 2</th>
<th>Year 3</th>
<th>Year 4</th>
<th>Year 5</th>
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e. **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.

f. **PROMOTING EFFICIENT SPENDING**

On September 21, 2011, the Office of Management and Budget issued Memorandum M-11-35, entitled, “Eliminating Conference Spending and Promoting Efficiency in Government,” emphasizing the President’s priority to ensure that the Government operates with the utmost efficiency and eliminates unnecessary or wasteful spending. This was followed by the Executive Order on Delivering an Efficient, Effective, and Accountable Government (EO 13576) and the Executive Order on Promoting Efficient Spending (EO 13589). On January 3, 2012, the Department of Health and Human Services (DHHS) issued the memorandum “HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings,
Food, Promotional Items, and Printing, and Publications” (See http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html).

In support of these directives, the NIH issued a January 30, 2012, Memorandum, entitled, “NIH Guidance Related to the HHS Policies on Promoting Efficient Spending: Use of Appropriated Funds for Conferences, Conference Grants and Meetings, Food, Promotional Items, and Printing and Publications." (See http://oamp.od.nih.gov/)

Any contract awarded as a result of this solicitation will:

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

g. 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.

h. 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.

i. PREPARATION COSTS

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

j. SERVICE OF PROTEST (SEPTEMBER 2006) - FAR 52.233-2

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

Tom Bahrami, Contracting Officer
Office of Acquisitions
National Institute of Allergy and Infectious Diseases
National Institutes of Health
5601 Fishers Lane
Rockville, MD 20852

(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)

k. 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.
2. INSTRUCTIONS TO OFFERORS

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.

1. Contract Type and General Clauses

   It is contemplated that an Indefinite Delivery, Indefinite Quantity (IDIQ) type contract comprised of cost reimbursement, term/completion type orders 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.

2. Authorized Official and Submission of Proposal

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

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

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

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

3. Proposal Summary and Data Record (NIH-2043)

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

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

5. Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

6. Evaluation of Proposals

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

7. 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.

8. 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.

9. 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.

10. 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.

11. 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 NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID 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 NIAID 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 NIAID requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

12. Institutional Responsibility Regarding Investigator Conflicts of Interest

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any Investigator financial conflicts of interest. The Institution shall comply with all requirements of 45 CFR Part 94 at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45.

13. 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.

14. Certification of Filing and Payment of Taxes

None of the funds appropriated or otherwise made available by the Consolidated Appropriations Act of FY 2014, may be used to enter into a contract in an amount greater than $5,000,000 unless the prospective contractor certifies in writing to the agency awarding the contract that, to the best of its knowledge and belief, the contractor has filed all Federal tax returns required during the 3 years preceding the certification, has not been convicted of a criminal offense under the Internal Revenue Code of 1986, and 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.

15. Past Performance Information

a. Offerors shall submit the following information as part of their Business proposal.

A list of the last 5 contracts completed during the past Three years and the last 3 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 $700,000.

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

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.
16. HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS

16. 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 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.

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 of Title 5, Code of Federal Regulations (CFR). The following position sensitivity designation levels apply to this solicitation/contract:

[X] Level 5: Public Trust - Moderate Risk. Contractor/subcontractor employees assigned to Level 5 positions with no previous investigation and approval shall undergo a Suitability Determination and a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

[X] Level 6: Public Trust - High Risk. Contractor/subcontractor employees assigned to Level 6 positions shall undergo a Suitability Determination and Background Investigation (MBI).

[ ] Level 1: Non-Sensitive. Contractor/subcontractor employees assigned to Level 1 positions shall undergo a Suitability Determination and National Check and Inquiry Investigation (NACI).

1. HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

The Contractor (and/or any subcontractor) and its employees shall 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-

a. 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://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx
b. 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.

c. 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.

d. 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.

e. 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.

f. 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.

g. 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).

h. 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).

i. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.

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

- **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 high-risk weaknesses must be mitigated within 30 days and all medium weaknesses must be mitigated within 60 days from the date the weaknesses are formally identified and documented. 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

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

   • **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 annually to determine the implemented security and privacy controls are operating as intended and producing the desired results (this may involve penetration testing conducted by the agency or independent third-party. In addition, review all relevant SA&A documentation (SSP, POA&M, Contingency Plan, etc.) and provide updates by specified due date provided by the Contracting Officer's 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.

2. At a minimum, the Contractor must provide the following artifacts/deliverables on a monthly basis as directed by the Contracting Officer/Contracting Officer’s Representative.

   a. Operating system, database, Web application, and network vulnerability scan results;
   b. Updated POA&Ms;
   c. Any updated authorization package documentation as required by the annual attestation/assessment/review or as requested by the NIH System Owner or AO; and
   d. 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**

1. 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/](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](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 USGCB settings - (See: [http://scap.nist.gov/validation](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.

2. 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:

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

b. 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 140-2 validated encryption solution.

c. 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).

d. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative within 15 days of the validation.

e. 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:

a. 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.

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

I. Safeguarding Information and Information Systems- In accordance with the Federal Information Processing Standards Publication (FIPS)199, Standards for Security Categorization of Federal Information and Information Systems, the Contractor (and/or any subcontractor) shall:

a. 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.

b. 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.

c. 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.

d. 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:  [X] Low  [ ] Moderate  [ ] High

   Integrity:       [ ] Low  [X] Moderate  [ ] High

   Availability:   [X] Low  [ ] Moderate  [ ] High

   Overall Risk Level:  [ ] Low  [X] 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:

   [X] No PII  [ ] Yes PII
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.

PII Confidentiality Impact Level has been determined to be: [ ] Low [X] 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 in accordance with the HHS Contract Closeout Guide (2012). HHS EA requirements may be located here: [https://www.hhs.gov/ocio/ea/documents/proplans.html](https://www.hhs.gov/ocio/ea/documents/proplans.html)

2. **System Documentation** - Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, Security Considerations in the System Development Life Cycle, 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 NIH Contractor Employee Separation Checklist [https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf](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/](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://ocio.nih.gov/aboutus/publicinfosecurity/securitytraining/Pages/rolebasedtraining.aspx](https://ocio.nih.gov/aboutus/publicinfosecurity/securitytraining/Pages/rolebasedtraining.aspx)

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/InfoSecurity/training/Pages/nihitrob.aspx](https://ocio.nih.gov/InfoSecurity/training/Pages/nihitrob.aspx), which are contained in the NIH Information Security Awareness Training Course [http://irtsectraining.nih.gov](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 24 hours, whether the response is positive or negative.

FISMA defines an incident as “an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. 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 140-2 validated encryption.

2. **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 individuals in accordance with https://ocio.nih.gov/InfoSecurity/IncidentResponse/Pages/ir_guidelines.aspx

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:

a. cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;

b. not include any sensitive information in the subject or body of any reporting e-mail; and

c. encrypt sensitive information in attachments to email, media, etc.

Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.

4. Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.

5. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation within an hour of discovery.

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

P. **Confidentiality and Nondisclosure of Information**- Any information provided to the contractor (and/or any subcontractor) by HHS or collected by the contractor on behalf of HHS shall be used only for the purpose of carrying out the provisions of this contract and shall not be disclosed or made known in any manner to any persons except as may be necessary in the performance of the contract. The Contractor assumes responsibility for protection of the confidentiality of Government records and shall ensure that all work performed by its employees and subcontractors shall be under the supervision of the Contractor. Each Contractor employee or any of its subcontractors to whom any HHS records may be made available or disclosed shall be notified in writing by the Contractor that information disclosed to such employee or subcontractor can be used only for that purpose and to the extent authorized herein.

The confidentiality, integrity, and availability of such information 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);
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.

17. **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.


   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 supplies 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.

18. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

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

**FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):**

a. System for Award Management, FAR Provision 52.204-7 (October 2016).

   **Alternate I** (July 2013) is not applicable to this solicitation.

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


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

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.

1. **Technical Discussions**

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

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.

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.

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.

2. 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.

3. Additional Personnel

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

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

4. 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.

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.

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

4. **Human Subjects**

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

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](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](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](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](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.

b. Instructions to Offerors Regarding Protection of Human Subjects

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

a. Risks to the subjects

   • Human Subjects Involvement, Characteristics, and Design :
     ◦ Briefly describe the overall study design in response to the solicitation.
     ◦ 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.
     ◦ 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.
• Study Procedures, Materials, and Potential Risks

  ◦ 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.

  ◦ 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.

  ◦ 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.

  ◦ 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

  • Recruitment and Informed Consent:

  ◦ Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. 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.

    - 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.

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

  • Protection Against Risk:

  ◦ Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

  ◦ Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

**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).

- **Pregnant Women, Fetuses, and Neonates or Children** - If the study involves vulnerable subjects subject to additional protections under Subparts B and D (pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements.
  - HHS' Subpart B - Additional Protections for Pregnant Women, Fetuses, and Neonates
  - HHS' Subpart D - Additional Protections for Children
  - 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

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

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

d. Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

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

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

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html). Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

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

Curricula that are readily available and meet the educational requirement include the NIH Office of Extramural Research (OER) on-line tutorial, entitled "Protecting Human Research Participants" at: [http://phrp.nihtraining.com](http://phrp.nihtraining.com). This course is also available in Spanish under the title "Protección de los participantes humanos de la investigación" at: [http://pphi.nihtraining.com](http://pphi.nihtraining.com). You may take the tutorials on-line or download the information in PDF form at no cost. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual, entitled, "Protecting Study Volunteers in Research," can be obtained through Centerwatch, Inc. at: [http://store.centerwatch.com/c-29-training-guides.aspx](http://store.centerwatch.com/c-29-training-guides.aspx).

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

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

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:


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) Directive No. 15, which may be found at: http://www.whitehouse.gov/omb/fedreg_notice_15.

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

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these
required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials** require that:

* a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide:


  "The definition of an "NIH-Defined Phase III clinical trial" can also be found at this website.)

  by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and

  b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

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

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

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

  OR

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

  OR

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

**Use the form entitled, "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report," when preparing your response to the solicitation requirements for inclusion of women and minorities. (See Section J-List of Documents, Exhibits and Other Attachments of the RFP)**

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)
Use the form entitled, "PHS Human Subjects and Clinical Trials Information Form/ Cumulative Inclusion Enrollment Report," for reporting in the resultant contract.

e. Inclusion of Children in Research Involving Human Subjects

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are clear and compelling reasons not to include them. (See examples of Justifications for Exclusion of Children below). For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

All offerors proposing research involving human subjects should read the “NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects” which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:


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

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

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

Justifications for Exclusion of Children

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

- The objective of the solicitation is not relevant to children.
  - There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
  - The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
  - A separate, age-specific study in children is warranted and preferable. Examples include:
- The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or

- The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or

- Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or

- Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or

- Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);

- Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

**Definition of a Child**

For the purpose of this solicitation, a child is defined as an individual under the age of 21 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

**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](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) 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.


f. Research Involving Human Fetal Tissue

Human Fetal Tissue means tissue or cells obtained from a dead human fetus, including human embryonic stem cells, human pluripotent stem cells and human embryonic germ cells.

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

By signing the face page of the proposal, the offeror (authorized institutional official) certifies that researchers using human fetal tissue are in compliance with 42 USC 289g 2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to profit, and does not include reasonable payment for costs associated with the collection processing, preservation, storage, quality control or transportation of these tissues.

Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local law.

g. 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](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 (see Appendix M of the NIH Guidelines).

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: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/institutional-biosafety-committees/faq.

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 web site: at: http://osp.od.nih.gov/office-biotechnology-activities/rdna_ibc/ibc.html.

h. 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: http://stemcells.nih.gov/policy/pages/2009guidelines.aspx. 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: [http://grants.nih.gov/stem_cells/registry/current.htm](http://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: [http://hescregapp.od.nih.gov/NIH_Form_2890_Login.htm](http://hescregapp.od.nih.gov/NIH_Form_2890_Login.htm).

See Section H of this solicitation for more details.

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. For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (Email: olaw@od.nih.gov; Phone: 301-496-7163).

(End of provision)


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):

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

b. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
c. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

d. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

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: 

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: 

7. 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:

a. Compliance Factors

a. 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.

b. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.

c. 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.

d. 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
8. Obtaining and Disseminating Biomedical Research Resources

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guidelines for Recipients of NIH Research Grants and Policy," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website:


a. Sharing Research Data

[Note: This policy applies to all NIH contracts, regardless of dollar value, that are expected to generate research data.]

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:


[If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.]

9. 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
c. BUSINESS PROPOSAL INSTRUCTIONS

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.

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.

3. Certified Cost or Pricing Data

1. General Instructions

   A. You must provide the following information on the first page of your pricing proposal:

      1. Solicitation, contract, and/or modification number;
      2. Name and address of offeror;
      3. Name and telephone number of point of contact;
      4. Name of contract administration office (if available);
5. Type of contract action (that is, new contract, change order, price revision/redetermination, letter contract, unpriced order, or other);

6. Proposed cost; profit or fee; and total;

7. Whether you will require the use of Government property in the performance of the contract, and, if so, what property. See Item 16. Other Administrative Data, subparagraph a.2. Government Property of this Section L.2.c of this solicitation;

8. Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;

9. The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403 5(b)(1) and Table 15 2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;

10. Date of submission; and

11. Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the certified cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, certified cost or pricing data (as defined at FAR 2.101). You must clearly identify on your cover sheet that certified cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including

1. The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and

2. The nature and amount of any contingencies included in the proposed price.

D. You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.

E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.

F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.

H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406 2, submit a Certificate of Current Cost or Pricing Data.

2. Cost Elements

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

A. Materials and services. Provide a consolidated priced summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when certified cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own certified cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor certified cost or pricing data as part of your own certified cost or pricing data as required in paragraph A.2. below. These requirements also apply to all subcontractors if required to submit certified cost or pricing data.

1. Adequate Price Competition. Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205 26(e)).

2. All Other. Obtain certified cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of certified cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either $12.5 million or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. Also submit any information reasonably required to explain your estimating process (including the judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data, and the nature and amount of any contingencies included in the price). The Contracting Officer may require you to submit certified cost or pricing data in support of proposals in lower amounts. Subcontractor certified cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the certified cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective
source's certified cost or pricing data is required as described in this paragraph, it must be included, along with your own certified cost or pricing data submission, as part of your own certified cost or pricing data. You must also submit any other certified cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

B. **Direct Labor.** Provide a time phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.

C. **Indirect Costs.** Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.

D. **Other Costs.** List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.

E. **Royalties.** If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:
   1. Name and address of licensor.
   2. Date of license agreement.
   4. Patent application serial numbers, or other basis on which the royalty is payable.
   5. Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
   6. Percentage or dollar rate of royalty per unit.
   7. Unit price of contract item.
   8. Number of units.
   9. Total dollar amount of royalties.
   10. If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.202 and 31.205-37).

F. **Facilities Capital Cost of Money.** When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB CMF and show the calculation of the proposed amount (see FAR 31.205 10).

3. **Formats for Submission of Line Item Summaries**

   The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

4. **General Information**

   a. There is a clear distinction between submitting certified cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of certified cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by
specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of certified cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.

b. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

4. Requirements for Certified Cost or Pricing Data and Data Other than Certified Cost or Pricing Data, FAR Clause 52.215-20 (October 2010)

(a) Exceptions from certified cost or pricing data.

(1) In lieu of submitting certified cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

   (i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

   (ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include

      (A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

      (B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

      (C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.
(b) Requirements for certified cost or pricing data. If the offeror is not granted an exception from the requirement to submit certified cost or pricing data, the following applies:

1. The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.

2. As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 2010) of FAR Clause 52.215-20, Requirements for Certified Cost or Pricing Data and Data Other than Cost or Pricing Data (October 2010). As prescribed in 15.408(l)(and see 15.403-5(b)(1)), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in the following format:

The format specified in paragraph L.2.c.4. Certified Cost or Pricing Data, subparagraph 3. formats for Submission of Line Item Summaries shall be used for the submission of cost data. Submission of all other certified cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

5. 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:

(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.
6. **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $700,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled “Small Business Subcontracting Plan,” FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation. See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

c. The offeror understands that:

1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:

1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

4. A description of the method used to develop the subcontracting goals.

5. A description of the method used to identify potential sources for solicitation purposes.

6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $700,000 adopt a plan similar to the plan agreed upon by the offeror.

10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government.

11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this RFP are as follows:

33% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

7. **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 [www.esrs.gov](http://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)

8. HUBZone Small Business Concerns

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

9. 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.

10. Other Administrative Data

a. Property

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.
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.

3. Government-Furnished Property

No Government Furnished Property is offered for this acquisition


b. Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (JULY 2013)

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232 34, Payment by Electronic Funds Transfer Other than System for Award Management.

(1) The solicitation number (or other procurement identification number).
(2) The offeror’s name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

(End of Provision)

c. 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.

d. Adequate Accounting System

FAR Part 16 sets forth the requirements and limitations for consideration of contract type. As stated in Section L.1., General Instructions of this solicitation, the resultant contract will not be Firm-Fixed Price. Therefore, the offeror's/contractor's accounting system and practices must be adequate and suitable for accumulating costs under government contracts.

To be considered for an award under this solicitation, the offeror shall include, in the Business Proposal, the following Certification:

"By submission of its signed offer, the Offeror certifies that its accounting system:

- Complies with generally accepted accounting principles (GAAP).
- Provides for:
  - Proper segregation of direct costs from indirect costs.
  - Identification and accumulation of direct costs by contract.
  - A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
  - Accumulation of costs under general ledger control.
  - A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
  - A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
  - Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
  - Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions."
- Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.

- Segregation of preproduction costs from production costs, if applicable.

• Accounting system provides financial information:

  - Required by contract clause concerning limitation of cost (FAR 52.232-20) or limitation on payments (FAR 52.216-16).

  - Required to support requests for progress payments.

• Accounting system was designed, and records are maintained in such a manner that adequate, reliable data are developed for use in pricing follow-on acquisitions.

• Accounting system is currently in full operation.

The Contracting Officer reserves the right to request, with the Final Proposal Revision (FPR), a current (within 18 months) CPA opinion confirming that the Offeror’s accounting system is compliant as certified above.

11. 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.

12. **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.

13. **Proposer's Annual Financial Report**

A copy of the organization's most recent annual report must be submitted as part of the business proposal.

14. **Travel Costs/Travel Policy**

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.

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.
SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

The major evaluation factors for this solicitation include technical (which encompasses experience and past performance factors), and cost/price factors. Although technical factors are of paramount consideration in the award of the contract and cost/price is also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the SOLICITATION. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the SOLICITATION. Offerors must submit information sufficient to evaluate their proposals based on the detailed factors listed below.

2. COST/PRICE EVALUATION

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in FAR 15.404.

Cost Realism: The specific elements of each offeror(s) proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in the offeror(s) technical proposal.

Cost Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal. Cost realism analysis will be conducted in accordance with FAR 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value tradeoff decision.

3. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

a. Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NIAID that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections
against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

b. **Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide [http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm), Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

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

  OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged),

  OR

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

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
• In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
  ◦ the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
  ◦ overriding factors dictate selection of subjects); or
  ◦ gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

• For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
  ◦ inclusion of those groups would be inappropriate with respect to their health; or
  ◦ inclusion of those groups would be inappropriate with respect to the purpose of the research.

• For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research.

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

c. Children

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a
sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance with NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

4. LIVE VERTEBRATE ANIMALS EVALUATION

The offerors proposal must include, as a separate section of the Technical Proposal titled "Vertebrate Animal Section," (VAS) a complete, concise (no more than 1-2 pages) description addressing the following criteria. (See NIH Guide Notice NOT-OD-16-006 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html):

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

b. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).

c. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

d. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

As part of the overall technical evaluation of proposals, the reviewers will consider the acceptability of the offeror's description in the VAS of the technical proposal. The discussion of all criteria will be addressed and evaluated. Based on the evaluation of this Section, the VAS may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the description addressing each of the criteria, or no discussion can be found regarding the VAS), or "acceptable." If the reviewers find that this Section of the technical proposal is "unacceptable" they will provide a narrative supporting their findings.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed description under the VAS is still found to be unacceptable, then your proposal may not be considered further for award.

5. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).
In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

6. EVALUATION OF AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

If the offeror has proposed the use of key biological and/or chemical resources, the offeror's plan for authentication will be reviewed adequacy.

Any concerns associated with key biological and/or chemical resource authentication raised during the review process will need to be resolved prior to award.

7. EVALUATION OF DATA SHARING PLAN

The offeror’s plan for the sharing of final research data, or, if data sharing is not possible, the offeror's documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

8. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

If your proposal does not include a plan or if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

9. TECHNICAL EVALUATION FACTORS

The evaluation factors are used by the technical evaluation committee when reviewing the technical proposals. The factors below are listed in the order of relative importance with weights assigned for evaluation purposes. Subfactors are listed in order of relative importance.

TECHNICAL EVALUATION CRITERIA:
The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO - Additional Technical Proposal Instructions - OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF TECHNICAL PROPOSALS.

CRITERIA WEIGHT

CRITERION 1: TECHNICAL PLAN/APPROACH  45
Appropriateness, feasibility, and adequacy of the proposed technical plan/approach for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.

CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL  20
Appropriateness and adequacy of the education, training, experience, expertise, and proposed levels of effort of the Principal Investigator, Project Manager (if applicable), and scientific and technical staff including subcontractors/consultants for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.
CRITERION 3: PROJECT MANAGEMENT  
Adequacy of the Project Management Plan in terms of staffing, organization, responsibilities, leadership and lines of authority, management of subcontracts/consultants, tracking of project activities, monitoring progress and timelines, and communication with stakeholders.

CRITERION 4: FACILITIES, EQUIPMENT, AND OTHER RESOURCES  
Appropriateness and adequacy of facilities, equipment, space and other resources including those of subcontractors/consultants for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.

TOTAL POSSIBLE WEIGHT: 100

OTHER EVALUATION FACTORS:

COST/PRICE  
PAST PERFORMANCE

SPECIAL CONSIDERATIONS:

HUMAN SUBJECT EVALUATION  
LIVE VERTEBRATE ANIMALS EVALUATION  
EVALUATION OF DATA SHARING PLAN  
EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY SECTION 508

10. EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY - SECTION 508

The offeror’s proposal must demonstrate compliance with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194 for all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order, including EIT deliverables such as electronic documents and reports.

If your proposal does not include a completed HHS “Section 508 Product Assessment Template” (hereafter referred to as the “Template”) which demonstrates that EIT products and services proposed support applicable Section 508 accessibility standards, or, if the completed “Template” included in your proposal is considered “noncompliant,” and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify the “Template” during discussions and in your Final Proposal Revision (FPR). If your “Template” is still considered “noncompliant” by the Government after discussions, your proposal may not be considered further for award.

11. PAST PERFORMANCE FACTOR

Offerors’ past performance information will be evaluated prior to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

OR

Offeror’s past performance information will be evaluated subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.
The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each offeror. Performance risks are those associated with an offeror's likelihood of success in performing the acquisition requirements as indicated by that offeror's record of past performance.

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.
ATTACHMENT 1: PACKAGING AND DELIVERY OF THE PROPOSAL FOR RESEARCH AND DEVELOPMENT AND RESEARCH AND DEVELOPMENT SUPPORT — FOR USE WITH ECPS

NIH TETRAMER CORE FACILITY
RFP-NIAID-DAIT-NIHAI201800017

I. PROPOSAL SUBMISSION

A. eCPS

1. The National Institute of Allergy and Infectious Diseases (NIAID) requires proposals to be submitted via its electronic Proposal Submission System (eCPS).

2. Submission of proposals by facsimile or e-mail is not acceptable.

3. Follow the “How to Submit an Electronic Proposal” instructions provided on the eCPS website at: https://ecps.nih.gov/NIAID/home/howto. Please note that creating an account to submit can take up to three (3) business days. Please register early to allow enough time for the registration process.

4. Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated above by the date and time specified in the solicitation. If your proposal is not received by the date and time specified in the solicitation, it will be considered a “late proposal”, in accordance with FAR Clause 52.215-1 Instructions to Offerors – Competitive Acquisition.

B. Creating and Naming Files:

1. Create one PDF file of your Technical Proposal, including all attachments. The Technical Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned, but must be merged into the Technical Proposal PDF file.

2. The Business Proposal must be comprised of the following files:
   a. The first file must be a PDF of your Business Proposal, with all attachments, including the Solicitation Section J, Attachment entitled “Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet.” The Business Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned and merged into the Business Proposal PDF file.
   b. The remaining file(s) should be the “Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet” in its original Excel format, not PDF. Multiple Excel files may be included, as necessary.

3. Each of the proposals, Technical and Business, must be separate and complete in itself, so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other.
4. File naming convention: It is required that the filenames for both your Technical Proposal, Business Proposal, and Excel Workbook include the name of the offeror, the solicitation number, and the type of proposal (i.e., Technical, Business, or Excel Workbook).

Examples:
Business Proposal: XYZ Company_NIHAI2012001_Business.pdf
Excel Workbook: XYZ Company_NIHAI2012001_Business.xlsx

II. FORMATTING AND PAGE LIMITATIONS:

A. Formatting for proposals

1. Proposals shall not include links to internet web site addresses (URLs) or otherwise direct readers to alternate sources of information.
2. Font size must be 10 to 12 points.
3. Spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
4. Margins must be at least one-inch on all sides.
5. Failure to adhere to the formatting requirements above may impact whether your proposal is reviewed in entirety.

B. Page limitations:

1. Total page count does not include: Title and Back Page; Table of Contents; Section Dividers that do not contain information other than title of Section.
2. Pages in excess of this limitation of 150 pages of the technical proposal will be removed and will not be considered.
ATTACHMENT 2: PROPOSAL INTENT RESPONSE SHEET

RFP No.: RFP-NIAID-DAIT-NIHAI201800017
RFP Title: NIH TETRAMER CORE FACILITY

Please review the attached Request for Proposal (RFP). Furnish the information requested below and return this page by November 19, 2018. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL

[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _______________________________________
Address (print): _________________________________________________________
_______________________________________________________________________
_______________________________________________________________________
_______________________________________________________________________

Project Director's Name (print): __________________________________________
Title (print): _____________________________________________________________
Signature/Date: ___________________________________________________________
Telephone Number and E-mail Address (print clearly):
_______________________________________________________________________
_______________________________________________________________________

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_______________________________________________________________________
_______________________________________________________________________
_______________________________________________________________________

(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
OA, NIAID, NIH
Room 3B59
5601 Fishers Lane, MSC 9821
Rockville, MD 20852
Attn: Maribel Miranda
RFP-NIAID-DAIT-NIHAI201800017
FAX 301-451-5430
Email: Maribel.Miranda@nih.gov
ATTACHMENT 3: BASE CONTRACT STATEMENT OF WORK

NIH TETRAMER CORE FACILITY
RFP-NIAID-DAIT-NIHAI201800017

1) BACKGROUND AND INTRODUCTION

The National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) supports research on the basic understanding of immune responses leading to the development of vaccines and novel therapeutic agents for the prevention and treatment of infectious and immune-mediated diseases, and improvements in public health. This research includes support of various reagent facilities, repositories, and databases that provide resources for biomedical researchers. As a part of the research program to improve our understanding of the progression, prevention, and treatment of infectious and immune-mediated diseases, the NIAID is competing the continuing requirement for the NIH Major Histocompatibility Complex (MHC) Tetramer Core Facility contract (herein referred to as the NIH Tetramer Core Facility). This facility provides synthesis and distribution of soluble MHC tetramer reagents to the global research community.

T lymphocytes (T cells) are a subset of immune cells that play pivotal roles in host immune responses to infectious diseases, immune-mediated diseases, and cancer, including: eliminating infected or aberrant cells; providing help for antibody production; and modulating immune regulation. T cell function can be evaluated by assessing such parameters as cytokine production and production of cytolytic molecules. These parameters generally provide qualitative measurements of T cell activity. Quantitative assessments can offer valuable insights into the magnitude of immune responses during the course of an infection or an immune-mediated disorder, or after vaccination or immune-based therapies. MHC tetramers are valuable tools for the rapid, highly sensitive quantitation of antigen-specific T cells from blood or tissue samples.

MHC tetramers are composed of four identical MHC molecules, each containing an antigen-specific peptide/ligand in the MHC ligand binding groove. The MHC molecules are labeled with biotin, allowing for tetramerization through the addition of a streptavidin-linked fluorophore. Tetramers are produced when the biotinylated MHC molecules attach to the four biotin-binding sites on streptavidin.

In 1999, the NIAID established a tetramer core facility at Emory University, as a two-year subcontract to the NIAID AIDS Reagent Program (awarded to McKesson BioServices). The tetramer program has been continued through a separate contract to Emory University (N01-AI-25456), which has been renewed twice (solicitation: RFP DAIT-02-04 / expiration: 2013; and solicitation: RFP-NIAID-DAIT-NIHAI2011132 / expiration: 2020). The main goal of the NIH Tetramer Core Facility has been and continues to be the provision of custom-made MHC tetramers to researchers and to engage in research and development to improve and expand tetramer technology.

During the past nineteen years of operation, the NIH Tetramer Core Facility expanded its list of available reagents to include: additional mouse, non-human primate, and human MHC class I alleles; pre-made mouse, non-human primate, and human class II tetramers; custom-made mouse, non-human primate, and human class II tetramers; non-classical MHC TL, Qa-1, MR1, and CD1d tetramers, and human CD1a, b and c tetramers; CD1d ligands; and an expanded range of fluorophores for tetramer detection. Since opening in 1999, the NIH Tetramer Core Facility has produced more than 17,000 tetramer reagents, with over 2,000 shipments of reagents annually in the past 5 years. Clients include more than 2,100
investigators in the US and abroad, including at least 45 countries.

The NIAID Division of Allergy, Immunology, and Transplantation (DAIT), Division of Microbiology and Infectious Diseases (DMID), Division of AIDS (DAIDS), and Division of Intramural Research (DIR); and the National Cancer Institute (NCI) support the NIH Tetramer Core Facility. This funding permits tetramer-related technology development, MHC allele gene expression and protein purification, tetramer production and quality control testing, order tracking, and website maintenance. Investigators requesting reagents incur the cost of peptide production, shipping of the peptides to the NIH Tetramer Core Facility, and shipping of the tetramer reagents to their institution.

The Contracting Officer Representative (COR) oversees NIH Tetramer Core Facility operations and serves as chairperson of the NIAID Tetramer Resource Committee (TRC). The NIAID TRC is composed of NIAID and NCI scientific staff, chosen by the COR. The TRC reviews and prioritizes tetramer requests (submitted through the NIH Tetramer Core Facility website); as well as provides guidance to the COR regarding research priorities and novel advances in tetramer related technology development, production and usage.

One Indefinite Delivery, Indefinite Quantity (ID/IQ) type contract will be awarded to an organization to provide a comprehensive suite of MHC tetramers and related products; and R&D efforts to improve and expand tetramer technology. The work to be performed under this contract will be initiated by NIAID and will be directed and funded using Task Orders.

2) SCOPE

The scope of activities to be carried out by the NIH Tetramer Core Facility Contractor are synthesis and distribution of soluble MHC-peptide tetramer and related reagents to the global research community, and performance of research and development to improve tetramer technologies and increase the types of products available to the biomedical research community.

I. GENERAL TASK ORDER REQUIREMENTS

The following requirements shall apply to each Task Order:

a. Project management to support all Task Orders awarded under the base contract. Specifically, the contractor shall have the capability to manage the various activities, including subcontractors, required for the execution of work performed under this contract. This includes Task Order and financial management, general administration, quality assurance and quality control, communications, management of data, documents.

II. DESCRIPTION FOR INDIVIDUAL TASK AREAS

A. TASK AREA A: Operation and Management of the NIH Tetramer Core Facility

1. Scope of Task Area A: Operate and maintain a centralized tetramer reagent facility to produce and ship quality-controlled, custom synthesized or pre-made antigenic peptide/ligand-MHC monomeric or tetrameric molecules for use by TRC-approved investigators; operate a distribution, tracking, and reporting system for all requested and approved reagents; provide and maintain a NIH Tetramer Core Facility public website.
2. **Requirements for Task Area A:** The contractor shall have the capabilities to do the following:

   a) Produce recombinant MHC molecules and related reagents; purify recombinant proteins; fold or exchange peptides or other ligands into MHC monomeric or oligomeric proteins; biotinylate or label MHC-ligand complexes; complex biotinylated MHC-ligand to specific fluorophores to produce tetrameric or oligomeric reagents; perform quality control; and produce and ship reagents for approved requests.

   b) Operate a multi-level access system for: public online submission and tracking of tetramer/reagent requests through the NIH Tetramer Core Facility website, and completion and submission of the Materials Transfer Agreement (MTAs) developed by NIAID; TRC-only access to the reagent requests through the website and compiled tetramer request information, and for COR submission of TRC meeting results; and Tetramer Core Facility staff tracking of pending and approved tetramer requests and completed MTAs. This system also will be able to send the submitted requests directly from the website to the NIH TRC staff via email.

   c) Provide a publicly accessible website that contains information regarding reagent availability, technical specifications, and use protocols; standard operating procedures for tetramer production; additional information of interest to the user community, such as tetramer applications; descriptions of the request, review, and ordering process; online order submission and tracking capabilities for users; online help for technical and administrative issues; and include an online customer feedback form. Additionally, the contractor shall provide regular maintenance and updates to the website as needed.

B. **TASK AREA B: Tetramer Technology Research and Development**

   1. **Scope of Task Area B:** Identify, develop, and incorporate new processes, approaches, and technologies to ensure a state-of-the-art tetramer reagent production facility, including, but not limited to, development of MHC tetramers for non-traditional animal models (e.g., ferret, guinea pig, swine, marmoset and other NHPs, etc.), and development of MHC-related tetramers/oligomers (e.g., Killer-cell immunoglobulin-like receptors (KIRs), B cell receptor, T cell receptor, etc.).

   2. **Requirements for Task Area B:** The contractor shall optimize current manufacturing methods; evaluate and implement new technologies; and develop new reagents related to tetramer usage.
ATTACHMENT 4: TASK ORDER

NIH TETRAMER CORE FACILITY
RFP-NIAID-DAIT-NIHAI201800017

TASK ORDER A-1
OPERATION AND MANAGEMENT OF THE NIH TETRAMER CORE FACILITY

[Associated with Task Area A]

NOTE: The NIAID anticipates issuing Task Order A-1 on the effective date of the contract. Offerors are to include in their proposals a response that specifies the methods by which this Task Order will be accomplished and the project management plan, with associated costs. Offerors should refer to the Additional Technical Proposal Instructions and Additional Business Proposal Instructions for guidance regarding preparation of their proposals.

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

a. The estimated cost of the Base Period of this Task Order is $TBD.
b. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the total estimated cost of the Task Order will be increased as follows:

<table>
<thead>
<tr>
<th></th>
<th>Estimated Cost ($)</th>
<th>Estimated Cost ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Base Period</td>
<td>$TBD</td>
<td>$TBD</td>
</tr>
<tr>
<td>Option Period(s):</td>
<td>$TBD</td>
<td>$TBD</td>
</tr>
<tr>
<td>Total [Base Period and Option(s)]</td>
<td>$TBD</td>
<td>$TBD</td>
</tr>
</tbody>
</table>

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

STATEMENT OF WORK

I. SCOPE
Operate and maintain a centralized tetramer reagent facility to produce and ship quality-controlled, custom synthesized or pre-made antigenic peptide/MHC monomeric or tetrameric molecules for use by TRC-approved investigators; operate a distribution, tracking, and reporting system for all requested and approved reagents; provide a NIH Tetramer Core Facility public website.

II. TECHNICAL REQUIREMENTS
Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below.

The requirements for Task Area A defined in the base Statement of Work apply to all work performed under this Task Order.

In addition to the requirements laid out in the base Statement of Work, the Contractor shall provide the following:

1. SYNTHESIS AND DISTRIBUTION OF SOLUBLE MHC-PEPTIDE TETRAMER AND RELATED REAGENTS
   
   a. Produce recombinant MHC molecules: Clone and express genes for human, rodent, non-human primate or other mammalian species’ class I, class II, and non-classical MHC molecules; as well as the appropriate beta-2 microglobulin. Genetic cloning procedures may include the introduction of structural modifications to the genes encoding the MHC molecules to improve MHC-ligand monomer and tetramer production. The Contractor shall express the proteins in the appropriate systems for the MHC gene expression vectors used and the desired form of the MHC molecules.

   b. Purify recombinant MHC proteins: Isolate the expressed MHC proteins from bacterial inclusion bodies, cell lysates, cell supernatants, or other fractions suitable to the proposed technologies for MHC molecule production. Purification methods shall be optimized for efficient extraction, isolation, and concentration of the product for high yield renaturation, as required for final monomer or tetramer production.

   c. Fold or exchange peptides or other ligands into MHC monomeric or oligomeric proteins: MHC ligand exchange reactions shall depend on the methods proposed by the Contractor. MHC-ligand complexes shall be folded (renatured) in a manner that yields the most efficient incorporation of ligands into the antigen-binding groove of the purified MHC proteins, resulting in production of fully-refolded, stable complexes of ligand, MHC chain(s), and beta-2 microglobulin. Peptides and other ligands may either be obtained from the requesting investigators (clients), for custom synthesis, or be provided by the Contractor for synthesis of stock tetramer reagents.

   d. Biotinylate or label MHC-ligand complexes: Biotin or other suitable label for oligomer formation shall be conjugated using appropriate methodologies.

   e. Complex biotinylated MHC-ligand to specific fluorophores to produce tetrameric or oligomeric reagents: Renatured, labeled MHC-ligand monomers shall be reacted with appropriate fluorophore conjugates, as required for a requestor’s use specified in an approved request. Fluorophores shall be purchased from commercial sources, when available, or be produced by the Contractor. All fluorophores shall be tested for their ability to produce labeled tetramers or higher degree oligomers, high fluorescence specific activity, and sensitivity for T cell detection.

   f. Perform Quality Control: Establish quality control standards for all reagents produced including MHC class I, MHC class II, and non-classical MHC monomers and tetramers; novel MHC ligands; and non-commercial fluorophores. Quality control methods should be stringent, but are NOT required to meet Good Laboratory Practices (GLP) or Good
Manufacturing Practices (GMP) requirements.

i. Quality Control of stock batches: The quality control procedures shall ensure purity, product functionality, and reliability of reagents provided to requesting investigators. Control measures shall include appropriate tests to characterize the product’s molecular size as an indicator of proper folding and complex formation and shall include biochemical analyses to demonstrate appropriate chemical composition, product purity, and biological activity.

ii. Quality Control of final custom-made reagents: Production of customer orders of MHC class I, non-classical class I, and class II, shall include quality control measures that ensure proper MHC-ligand folding, ligand binding to the requested MHC molecules, and tetramerization or other requested oligomerization of the product. In addition, the Contractor shall contact users, in addition to those users that provide customer feedback, to obtain reagent functionality information on tetramers and other reagents provided by the NIH Tetramer Core Facility. This information shall be used to improve overall customer service and the quality of distributed reagents.

g. Produce and ship reagents for approved requests:

i. Produce and ship all final products shall occur within a timeframe determined by the Contractor and COR. Quality control procedures for all reagents shall follow the procedures outlined in Section 1.f of the Technical Requirements.

ii. Distribute reagents to TRC-approved investigators within a time period determined by the Contractor and COR, following completion of quality control testing and tetramer production. The Contractor shall provide appropriate shipping materials and ship the reagent(s) by appropriate methods to the approved requestor to ensure high quality performance of the reagents. The shipping procedure shall include providing the proper package handling and customs documentation for domestic and foreign destinations. A package insert shall be included describing the enclosed reagent(s), including identification of the MHC molecule; peptide or other ligand; beta-2 microglobulin species (for MHC class I reagents); fluorophore label; protein concentration; buffer composition; suggested use protocol; proper reagent storage methods; and results of quality control testing. In cases where monomers are shipped instead of tetramers, the packing insert shall include detailed instructions for tetramerization with appropriate fluorophores.

iii. Retain and store excess ligand or specific MHC-peptide monomeric complexes from custom tetramer/reagent task orders, to be used for production of refill requests for the same client that provided the original ligand stock. Peptide/ligand stocks shall not be used to fill requests from other clients unless permission is given by the original client, since the original client incurred a cost for ligand production and shipping of the ligand to the NIH Tetramer Core Facility.

2. DISTRIBUTION, TRACKING, AND REPORTING SYSTEM OF REAGENTS PRODUCED

a. Provide an online accessible form for requestors to submit tetramer/reagent requests at
the NIH Tetramer Core Facility website: The form shall include minimally the following fields: Requesting Investigator name; Institution; MHC allele or other reagent requested; beta-2 microglobulin; fluorophore requested; peptide or other ligand sequence, antigen source, and pathogen (if applicable); data or journal reference supporting peptide-MHC restriction of requested reagent(s); abstract describing project goals and reagent usage. The completed requests and any attachments should be sent directly from the website to the NIH Tetramer Resource Committee (TRC) staff electronically, and also should be made accessible to the TRC through the website. The website access should enable the TRC to review all information related to the request, including attachments, and to download the requests as individual files or in bulk. This task shall be conducted in a manner that protects the scientific confidentiality of the requestors’ proposed research by ensuring that the requestors’ research interests are not made directly available to the NIH Tetramer Core Facility staff. Requestor contact information and other pertinent reagent request information required to fulfill the order shall be made available to the NIH Tetramer Core Facility staff.

b. Compile all of the tetramer request information, which shall include: Requesting Investigator name; Institution; MHC allele or other reagent requested; beta-2 microglobulin; fluorophore requested; and peptide or other ligand sequence, antigen source, and pathogen (if applicable), into an online downloadable spreadsheet format and make accessible to the TRC through restricted access on the website and distribution via email, by 5pm EST three days prior to the TRC meeting. The COR will serve as the chairperson of the TRC and will provide the NIH Tetramer Core Facility staff with a schedule of the TRC meetings to be posted on the website so that the scientific community is informed of deadlines for a given review cycle and the Tetramer Core Facility staff can manage upcoming workloads. During the review meeting, the TRC will look for completedness of the request, which includes supportive data confirming MHC restriction of the requested peptide-MHC complexes and a detailed abstract outlining the scope of work and intended usage of the requested reagent(s). The COR will enter a summary of the TRC review meeting on the online spreadsheet, including any follow-up needed by the Tetramer Core Facility staff and additional information required from the requestor. The Tetramer Core Facility staff (e.g., Facility manager) will send the TRC inquires to the relevant requestors, and will include the COR on these correspondence.

c. Track pending and approved tetramer requests:

i. Obtain and store a completed Material Transfer Agreement (MTA) from each approved requestor and their institution, which will serve as a registration form and be signed by the principal investigator (i.e., primary senior scientist responsible for the research project) and the Institution’s business official. The MTAs will be provided by the COR, after approval from the NIAID Technology Transfer and Intellectual Property Office. The signed MTAs will be valid for a period designated by NIAID, unless the investigator changes institutions. In this case, the Contractor shall obtain a new MTA from the investigator and their new institution prior to final approval of reagent requests.

ii. Within three (3) business days of the TRC meeting send the task order number(s) to approved requestors with product information and instructions for shipping the appropriate amount and quality of peptide ligands to the NIH Tetramer Core Facility.
iii. Contact approved requestors regarding fulfillment of orders, as needed. This task includes verifying the peptides or other ligands that the requestor will supply and, for refill requests, indicating whether ligands or biotinylated monomers are available from previous orders; identifying genetic plasmids containing MHC genes not currently available through the NIH Tetramer Core Facility that the requestor must supply; and confirming the availability of specific fluorophores, as needed.

iv. Address any queries from investigators regarding the status of their approved, pending (TRC reviewed, but not yet approved), or new orders.

v. Maintain a computerized database (or other appropriate computer-based method/system) to track all tetramer reagent requests received, pending completion, and filled; and to maintain an inventory of available reagents and materials, including excess peptides and monomeric MHC-peptide complexes stored from previous orders.

3. NIH TETRAMER CORE FACILITY WEBSITE DESIGN AND MAINTENANCE

   a. Ensure that the contractor provided website contains the following:

      i. Complete information on reagent availability
      ii. Technical specifications
      iii. Use protocols
      iv. Tetramer applications
      v. Standard operating procedures for tetramer production;
      vi. Detailed descriptions of the reagent request, review, and order completion process;
      vii. Multi-level access for public, TRC, and Tetramer Core Facility usage and reagent/order tracking, which includes reagent order forms to be used by the broader scientific community, compilation of reagent requests in spreadsheet format for access and review by the TRC, and online entry system of TRC review summary by the COR;
      viii. Online help for technical and administrative issues; and
      ix. An online customer feedback form.

   b. Provide routine website maintenance, as needed, to ensure continuous operation.

Website content shall require approval by the COR prior to public posting, and shall be updated regularly as new reagents, methodologies, or information becomes available.

Options

In addition to the services/quantities outlined above to be provided for the base requirement, Options(s) for additional services/quantities under the Task Order may be exercised at the discretion of the Government and are defined as follows:

Option 1 through 6: Extend the Term of the Task Order: The Government may include options to extend the period of the performance. The total period of performance resulting from
the base period plus all potential Term Options is 7 years. If Option(s) 1 through 6 are exercised, the services required will be the same as provided during the base year.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional D. clauses applicable to this Task Order beyond those in the base contract.

SECTION E – INSPECTION AND ACCEPTANCE

There are no additional E. clauses applicable to this Task Order beyond those in the base contract.

SECTION F – DELIVERIES OR PERFORMANCE

a. The period of performance of this contract shall be from TBD through TBD (not to exceed 1 year from task order award date).

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

<table>
<thead>
<tr>
<th>Option</th>
<th>Option Period</th>
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<tbody>
<tr>
<td>Option 1</td>
<td>TBD (not to exceed 1 year)</td>
</tr>
<tr>
<td>Option 2</td>
<td>TBD (not to exceed 1 year)</td>
</tr>
<tr>
<td>Option 3</td>
<td>TBD (not to exceed 1 year)</td>
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<tr>
<td>Option 4</td>
<td>TBD (not to exceed 1 year)</td>
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<tr>
<td>Option 5</td>
<td>TBD (not to exceed 1 year)</td>
</tr>
<tr>
<td>Option 6</td>
<td>TBD (not to exceed 1 year)</td>
</tr>
</tbody>
</table>

c. In performance of this Task Order, the Contractor shall provide TBD direct labor hours annually during the base period and Options 1 through 6 if exercised by the Government.

TASK ORDER REPORTING REQUIREMENTS AND DELIVERABLES

All reports required herein shall be submitted in electronic format.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

Technical Reports

In addition to those reports required by the other terms of this task order, the Contractor shall prepare and submit the following reports during the period of performance of this task order:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing]
publications that arise from its NIH funded research.]

1. Quarterly Progress Report
This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

2. Annual Progress Report
This report shall include a summation of the results of the entire task order work for the period covered. An annual report will not be required for the period when the Final Report is due. A Quarterly Report shall not be submitted when an Annual Report is due.

3. Final Report
This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this task order. A quarterly/annual report will not be required for the period when the Final Report is due.

The Contractor shall provide the COR with the Final Report in draft form, in accordance with the DELIVERIES Article in SECTION F of this task order, 90 working days prior to the expiration date of this task order. The COR will review the draft report and provide the Contractor with comments within 30 working days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

4. Summary of Salient Results
The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the task order.

TASK ORDER DELIVERABLES

<table>
<thead>
<tr>
<th>Item</th>
<th>Reports</th>
<th>Recipients</th>
<th>Delivery Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Quarterly Progress Report</td>
<td>1 electronic copy to COR and CO</td>
<td>Each report is due on/before the 30th of each month following each reporting period.</td>
</tr>
<tr>
<td>b.</td>
<td>Annual Progress Report</td>
<td>1 electronic copy to COR and CO</td>
<td>Each report is due on/before the 30th of the month following each reporting period.</td>
</tr>
</tbody>
</table>
| c.   | Draft Final and Final Report and Summary of Salient Results | 1 electronic copy to COR and CO | Draft Final Report is due 90 calendar days prior to the final period of performance date of task order.  

Final Report is due on/before the final period of performance date of the task order. |
### 2. Other Reports and Deliverables (Delivery Schedule)

<table>
<thead>
<tr>
<th>Item</th>
<th>Deliverables</th>
<th>SOW Reference</th>
<th>Recipient</th>
<th>Delivery Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>All MHC gene expression vectors, cell lines, peptide and ligand stocks, MHC monomer stocks, stored tetramers (where applicable) and production protocols for all reagents produced by and for the NIH Tetramer Core Facility.</td>
<td>II-1</td>
<td>CO and COR</td>
<td>Due on/before the final period of performance date of the task order.</td>
</tr>
<tr>
<td>2.</td>
<td>All Standard Operating Procedures for reagent production, protocols for novel technologies developed under this contract, and all novel and existing reagents developed or used under this contract for reagent production and not specified in item 1 above.</td>
<td>II-1</td>
<td>CO and COR</td>
<td>Due on/before the final period of performance date of the task order.</td>
</tr>
<tr>
<td>3.</td>
<td>All laboratory equipment (e.g., freezers, tissue culture hoods, incubators, protein purification equipment) purchased and used solely for tasks required by the contract.</td>
<td>II-1</td>
<td>CO and COR</td>
<td>Due on/before the final period of performance date of the task order.</td>
</tr>
<tr>
<td>Item</td>
<td>Deliverables</td>
<td>SOW Reference</td>
<td>Recipient</td>
<td>Delivery Schedule</td>
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<tr>
<td>4.</td>
<td>All data management platforms, data models, computational tools/algorithms, source codes and written documentation used for the NIH Tetramer Core Facility internal database (Tracking client orders) or website.</td>
<td>II-2 and II-3</td>
<td>CO and COR</td>
<td>Due on/before the final period of performance date of the task order.</td>
</tr>
<tr>
<td>5.</td>
<td>Completed reagent requests sent directly to the TRC.</td>
<td>II-2a</td>
<td>TRC</td>
<td>Automatic delivery via the website; on-going.</td>
</tr>
<tr>
<td>6.</td>
<td>Compile all of the tetramer request information to be distributed to the TRC for the bi-weekly review.</td>
<td>II-2a-b</td>
<td>TRC</td>
<td>By 5pm EST three days prior to the TRC meeting. Schedule to be provided by the COR.</td>
</tr>
</tbody>
</table>
SECTION G – TASK ORDER ADMINISTRATION DATA

There are no additional G. clauses applicable to this Task Order beyond those in the base contract.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

There are no additional H. clauses applicable to this Task Order beyond those in the base contract.
NOTE: The following Sample Task Order indicated in this Attachment is provided to assess the Offeror’s capabilities to conduct and fulfill the requirements of the Statement of Work for projects of similar scope and size to be issued under contracts awarded in response to this solicitation. Although the Sample Task Order will NOT be executed nor will awards be made for the Sample Task Order, Offerors are to include in their proposals a response that specifies the methods by which each Sample Task Order will be accomplished and the project management plan, with associated costs. Offerors should refer to the Additional Technical Proposal Instructions and Additional Business Proposal Instructions for guidance regarding preparation of their proposals.

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

The estimated cost of this task order is $ TBD.

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

STATEMENT OF WORK

I. SCOPE
   To conduct research and development that would enhance the quality, functionality (e.g., sensitivity), and breadth of available reagents and decrease production time.

II. TECHNICAL REQUIREMENTS
   Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below.

   The requirements for Task Area B defined in the base Statement of Work apply to all work performed under this Task Order.

   In addition to the requirements laid out in the base Statement of Work, the Contractor shall:

   1. Optimize current manufacturing methods to improve production, quality control, reliability and functionality of tetramer and other Facility-generated reagents.

   2. Evaluate and implement new technologies to improve upon or replace current tetramer/oligomer production methods.

   3. Develop new reagents related to tetramer usage, for example novel fluorophores; expansion of
available MHC alleles; expanded pre-made reagents including CD1d ligands, CD1 tetramers, and pre-made class I tetramers; novel MHC - ligand complex oligomers to improve T cell detection methods for detection of rare or low avidity T cells, especially CD4 T cells; development of MHC tetramers for non-traditional animal models (e.g., ferret, guinea pig, swine, marmoset and other NHPs, etc.), and non-MHC tetramers, such as NK cell receptor (KIR) or other immune cell receptor molecule tetramers/oligomers. All novel reagents that will become part of the product list available to the biomedical research community shall undergo quality control measures, as described in Task Order A-1.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional D. clauses applicable to this Task Order beyond those in the base contract.

SECTION E – INSPECTION AND ACCEPTANCE

There are no additional E. clauses applicable to this Task Order beyond those in the base contract.

SECTION F – DELIVERIES OR PERFORMANCE

The period of performance of this contract shall be from TBD through TBD (estimated completion date).

TASK ORDER REPORTING REQUIREMENTS AND DELIVERABLES

All reports required herein shall be submitted in electronic format.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

Technical Reports
In addition to those reports required by the other terms of this task order, the Contractor shall prepare and submit the following reports during the period of performance of this task order:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

1. Final Report
This report is to include a summation of the work performed and results obtained for the entire Task Order period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this task order. A quarterly report will not be required for the period when the Final Report is due.

The Contractor shall provide the COR with the Final Report in draft form (in accordance with the DELIVERIES Article in SECTION F of this task order 90 working days prior to the completion date of this task order. The COR will review the draft report and provide the Contractor with comments within 30 working days after receipt. The Final Report shall be
corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

2. Summary of Salient Results
The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the task order.

*Complete the following Tables with the Reports and Deliverables relevant to the requirement. Sample language is provided as guidance only.*

**TASK ORDER DELIVERABLES**

### 1. Technical Progress Reports

<table>
<thead>
<tr>
<th>Item</th>
<th>Reports</th>
<th>Recipients</th>
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</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Draft Final and Final Report and Summary of Salient Results</td>
<td>1 electronic copy to COR and CO</td>
<td>Draft Final Report is due 90 calendar days prior to the completion date of task order. Final Report is due on/before the completion date of the task order.</td>
</tr>
</tbody>
</table>

### 2. Other Reports and Deliverables (Delivery Schedule)

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<tbody>
<tr>
<td>1.</td>
<td>All MHC gene expression vectors, cell lines, peptide and ligand stocks, MHC monomer stocks, stored tetramers (where applicable) and production protocols for all reagents produced by and for the NIH Tetramer Core Facility.</td>
<td>II-1, II-2, II-3</td>
<td>CO and COR</td>
<td>On or before the completion date of the task order.</td>
</tr>
<tr>
<td>Item</td>
<td>Deliverables</td>
<td>SOW Reference</td>
<td>Recipient</td>
<td>Delivery Schedule</td>
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</tr>
<tr>
<td>2.</td>
<td>All Standard Operating Procedures for reagent production, protocols for novel technologies developed under this contract, and all novel or standard reagents developed under this contract and not specified in item 1 above.</td>
<td>II-1, II-2, II-3</td>
<td>CO and COR</td>
<td>On or before the completion date of the task order.</td>
</tr>
<tr>
<td>3.</td>
<td>All licensing agreements entered into by the Contractor for completion of any or all of the research listed in this contract and proposed by the Contractor in its Statement of Work shall be transferable to the government upon completion of the contract.</td>
<td>II-1, II-2, II-3</td>
<td>CO and COR</td>
<td>On or before the completion date of the task order.</td>
</tr>
</tbody>
</table>
SECTION G – TASK ORDER ADMINISTRATION DATA

There are no additional G. clauses applicable to this Task Order beyond those in the base contract.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

There are no additional H. clauses applicable to this Task Order beyond those in the base contract.
ATTACHMENT 6: ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS, FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS

NIH TETRAMER CORE FACILITY
RFP-NIAID-DAIT-NIHAI201800017

It is strongly recommended that offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

These additional Technical Proposal instructions reflect the requirements of the solicitation and provide specific instructions and formatting for the Technical Proposal. While Section L of the solicitation provides a generic set of Technical Proposal instructions applicable to all NIH R&D solicitations, these instructions are tailored to the specific requirements of the RFP. The information requested in these instructions should be used to format and prepare the Technical Proposal, and should be used as a Table of Contents for your Technical Proposal. Offerors should follow the instructions in Section L of the solicitation, and include the information requested here.

Offerors are advised to give careful consideration to the Statement of Work, all reference materials, and attachments, the Technical Evaluation Criteria in Section M, and the solicitation as a whole in the development of their Technical Proposals.

Offerors proposing subcontracts to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration/coordination between the prime Contractor and all proposed subcontractors, and the expected advantages of such an approach.

Offerors must refer to the solicitation Attachment entitled “Packaging and Delivery of the Proposal,” which details strict guidelines, including page limitations, formatting and layout of proposals, and prohibits the offerors use of links to internet web site addresses (URLs) to direct readers to alternate sources of information.

Include the Attachment “Packaging and Delivery of the Proposal”, with the SP.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1:

1) PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, and identify if the proposal is an original or a copy. 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 also include the legend regarding Restriction on Disclosure and Use of Data prescribed by FAR 52.215-1 (c)]

2) TABLE OF CONTENTS
SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested 3-page maximum)

Provide a brief overview of the Technical Proposal, including:

1) A brief description of the activities proposed by the offeror and those that shall be provided by any proposed subcontractor, which includes the scope of MHC tetramer reagents and related resources that the offeror is proposing to provide.
2) A list of all key personnel and subcontractors, with degrees, titles and role in the project.
3) By area of expertise, provide the total number of staff, the number available to be assigned to the contract for the offeror and all proposed subcontractors, and total number of additional staff to be hired and trained.
4) A brief description of the facilities and equipment to be made available by the offeror and all proposed subcontractors.

SECTION 3: TECHNICAL PLAN/APPROACH FOR EACH TASK AREA

Offerors shall provide the information outlined below as part of their technical proposal. For each proposed subcontract, the technical proposal must provide a detailed description of the subcontract research plan and contribution to the overall proposal, a complete description of the facilities, and the professional backgrounds of proposed personnel, within the appropriate sections of the research proposal.

1. TASK AREA A: Operation and Management of the NIH Tetramer Core Facility (Task Order A-1; SOW Section C II for each):

   a. DESCRIBE THE SYNTHESIS AND DISTRIBUTION OF SOLUBLE MHC-PEPTIDE TETRAMERS AND RELATED REAGENTS (Task Order A-1, SOW Section C II-1), including:
      i. The types of reagents to be provided by the Tetramer Facility, including: MHC class I, class II, and non-classical MHC alleles; any pre-made tetramers; CD1d or other MHC ligands and peptides; fluorophores; etc.
      ii. The scientific basis for the proposed experimental approaches for production of tetramers and related reagents and quality control methods.
      iii. The experimental approaches for production and quality control of all tetramers and related reagents, including a detailed description of the source of human, mouse, or non-human primate T cells that will be used for testing MHC class II tetramers.
      iv. Alternative approaches to be employed, or methods for problem solving, if the proposed experimental approaches and quality control methods do not achieve the defined goals.
      v. Subcontract activities needed to address the specific tasks (if any), and methods to identify and add new subcontracts as needed to perform any of the contract duties.

   b. DESCRIBE THE DISTRIBUTION, TRACKING, AND REPORTING SYSTEM OF REAGENTS PRODUCED (Task Order A-1, SOW Section C II-2), including:
      i. Methods and procedures for tracking tetramers and other reagents.
      ii. Proposed activities needed to address the specific tasks associated with providing consolidated reagent request information to the TRC for review and approval,
including how requestor research confidentiality will be maintained, how the 
TRC will be permitted access to the website; how the requests and review 
information will be sent directly to the TRC; and how the COR will have access 
to enter the review meeting summary on the online spreadsheet.

iii. Procedures for administration, production, quality control, and shipping of 
approved tetramer/reagent requests.

iv. Methods for obtaining client feedback on provided reagents.

v. Plans for client interactions, including providing technical support/advice, that 
minimize costs to the client and the NIH Tetramer Core Facility, but maximize 
customer service.

c. DESCRIBE PLANS FOR THE NIH TETRAMER CORE FACILITY WEBSITE 
DESIGN AND MAINTENANCE (Task Order A-1, SOW Section C II-3), including:

i. The types of information to be included on the public NIH Tetramer Core 
Facility website.

ii. Plans to incorporate the following required elements:
   a. Complete information on reagent availability
   b. Technical specifications
   c. Use protocols
   d. Tetramer applications
   e. Standard operating procedures for tetramer production;
   f. Detailed descriptions of the reagent request, review, and order 
      completion process;
   g. Multi-level access for public, TRC, and Tetramer Core Facility usage 
      and reagent/order tracking, which includes reagent order forms to be 
      used by the broader scientific community, compilation of reagent 
      requests in spreadsheet format for access and review by the TRC, and 
      online entry system of TRC review summary by the COR;
   h. Online help for technical and administrative issues;
   i. An online customer feedback form

iii. Procedures for maintaining and updating website information, including 
technical support for issues related to online submission of reagent requests and 
the process for NIAID COR approval of website content.

iv. Sample screen shots of the proposed NIH Tetramer Core Facility website and key 
features of the website to improve usability and information dissemination.

v. Subcontract activities needed to address any of the required tasks, and methods to 
identify and add new subcontracts as needed to perform the contract duties (if 
necessary).

d. OPTION 1 through 6: EXTEND THE TERM OF THE TASK ORDER- Discuss 
plans and procedures for continuing and providing the same services indicated in the 
Statement of Work beyond the Task Order base period. To address this option, offerors 
should describe the methods and procedures to maintain the operations specified in the 
Statement of Work beyond the base period, including retaining or recruiting necessary 
staff, and maintaining and/or acquiring required equipment and facility space.

2. TASK AREA B: Tetramer Technology Research and Development (Sample Task Order B-1, 
SOW Section C II)
a. Provide a detailed description of:
   i. Procedures to identify, develop, and incorporate new processes and methodologies for optimized production, quality control, and reliability of tetramers and related reagents manufactured at the NIH Tetramer Core Facility.
   ii. Methods for developing and optimizing new tetramer-related reagents, including any proposed MHC tetramers for non-traditional animal models and non-MHC tetramers, for public distribution, including alternative approaches to be employed, or methods for problem solving, if the proposed experimental approaches do not achieve the defined goals.
   iii. Subcontract activities needed to address any of the specific tasks, and methods to identify and add new subcontracts as needed to perform the contract duties (if necessary).

SECTION 4: SCIENTIFIC AND TECHNICAL PERSONNEL

Provide information relevant to document individual training, experience, qualifications and expertise necessary for the successful completion of all Task Order requirements. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the Task Order.

1) Principal Investigator (PI): Describe the experience, training, expertise, and qualifications, and level of effort of the proposed Principal Investigator to lead and direct the activities to be carried out under this Task Order. In particular, include experience and qualifications of the PI to plan, manage, and direct the activities to be carried out under this contract:
   a. Plan, manage, and direct projects of similar scope and size;
   b. Provide research resources to the scientific community;
   c. Knowledge of MHC tetramer technology and application of MHC tetramer technology to various areas of immunology research; and
   d. Knowledge of protein expression and purification methods.

2) Other Key Scientific and Technical Personnel: Describe the experience, training, expertise and qualifications, as well as the level of effort, for all proposed key scientific and technical personnel.

   Facility Manager:
   a. Include experience and qualifications of the Facility Manager to conduct the activities to be carried out under this contract, including communicating with approved requestors; tracking pending and approved tetramer requests; updating website content (in conjunction with the Technical Director and Principal Investigator, and after approval by the COR); monitoring the budget; and preparing progress reports and other deliverable documentation to be submitted to the COR and CO.
   b. Include experience and qualifications of the proposed scientific and technical staff to conduct the activities to be carried out under this contract: MHC tetramer technology, basic immunology, protein expression and purification, quality control procedures, and information technology (website design and maintenance, etc.).

   Technical Director:
   a. Include experience and qualifications of the Technical Director to conduct the activities to be carried out under this contract, including addressing technical questions from the scientific community; directing tetramer production and technology development/implementation; monitoring spending; and preparing progress reports and
other deliverable documentation, in conjunction with the Facility Manager and Principal Investigator.

b. Include experience and qualifications of the proposed scientific and technical staff to conduct the activities to be carried out under this contract: MHC tetramer technology, basic immunology, protein expression and purification, quality control procedures, and information technology (website design and maintenance, etc.).

SECTION 5: FACILITIES, EQUIPMENT, AND OTHER RESOURCES

The Technical Proposal should document availability and adequacy of facilities, equipment, space and other resources necessary to carry out the Statement of Work, including:

1) Location and features of facilities including a floor plan and a list of equipment and resources dedicated to the project for the prime contractor and any proposed subcontractors (lease or ownership information should be provided).

2) Identification and description of ALL support resources (including Information Technology systems) that will be required to effectively complete the SOW.

SECTION 6: PROJECT MANAGEMENT

1) Provide a Project Management Plan for the overall organization that addresses the planning, initiation, implementation, conduct, monitoring and completion of tasks identified in the Statement of Work.
   a. If consultants and/or subcontractors are proposed, include the following:
      i. A plan for soliciting, evaluating, negotiating, awarding and managing any proposed subcontracts in accordance with Federal regulations.
      ii. A plan to identify and remediate problems in subcontractor performance.
   b. The plan shall also include organization of the following meetings:
      i. Task Order Initiation Meeting: Assume that this meeting will occur in Bethesda, Maryland within 60 days after the effective date of the Task Order to discuss contract initiation. Assume that this meeting shall be attended by all of the Contractor’s key personnel.
      ii. Site Visits: Assume that this meeting shall be attended by all of the Contractor’s key personnel, and assume one site visit in the base year and one in option year 4 if it is exercised.

2) Provide a Staffing Plan that describes roles, responsibilities, and level of effort for all scientific and technical personnel, including all proposed subcontractors and consultants. Provide an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel. Include a chart of the proposed organizational/management structure for the project.

3) Describe the project management systems that will be used to track activities and to keep multiple activities on time and budget. The plan must include a description of the systems proposed for tracking project activities and monitoring progress, timelines and budgets, including plans for managing and coordinating the reagent resource tasks, quality control procedures, reporting requirements, and research and development aspects of the project as a whole; and proposed operating procedures, particularly with regard to timeliness, and decision making processes, including prioritization of important project elements and troubleshooting technical issues in reagent production or technology development efforts.
4) Outline how the PI (or Project Manager) will communicate with the COR and CO and how the PI (or Project Manager) will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

SECTION 7: OTHER CONSIDERATIONS

Other than those detailed in the Government Furnished Property clause or otherwise publicly available, the offeror shall not propose government furnished resources, to include government employees, facilities, intellectual property or biological materials. If you propose government furnished resources your proposal will not be considered further for award.
In addition to the format requirements for the Business Proposal that are contained in Section L of the solicitation, the information presented in this section of the RFP is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as attachments, the Technical Evaluation Criteria, and, the RFP as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your Business Proposal. Offerors should consider and include the information requested here, as well as any other information which will benefit the proposal.

BUSINESS PROPOSAL – TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVER SHEET (use form NIH 2043 identified in Section J of the solicitation)

SECTION 2 – COST OR PRICE SUPPORT

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in a clearly marked section of the proposal.

SECTION 3 – UNIFORM COST ASSUMPTIONS

1) Technical Cost Assumptions

A. Ongoing activities: Tetramer production costs shall include a workload estimate of 450 requests per month, with approximately one third of requests each for innate-like T cell monomers and tetramers (e.g. CD1 and MR1 reagents), custom MHC class I, and class II tetramers, for the first year of the contract.
B. The Contractor shall provide each client with at least 0.2 milligrams of each final tetramer product.
C. Reagent production times for the current NIH Tetramer Core Facility contractor are provided in the table below. These numbers are generalizations and may not reflect recent advances in tetramer production that increase efficiency.

<table>
<thead>
<tr>
<th>Type of Reagent</th>
<th>Average Production Time (“ready for shipment”)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td>Pre-made monomer and tetramers</td>
<td>5-10 days</td>
</tr>
<tr>
<td>----------------------------------------</td>
<td>-----------</td>
</tr>
<tr>
<td>Custom-made class I monomers and tetramers made via traditional refolding</td>
<td>2 months</td>
</tr>
<tr>
<td>Custom-made monomers and tetramers made via peptide exchange</td>
<td>2 months</td>
</tr>
<tr>
<td>Custom-made monomers and tetramers requiring new cloning</td>
<td>6 months</td>
</tr>
</tbody>
</table>

2) **Travel**

**General Scientific Meetings:** Offerors may propose travel to 1-2 general scientific meetings per year for the Principal Investigator and selected Contractor staff, up to 2 (two) additional staff per year, for presentations of work conducted under this contract or to expand their knowledge of scientific areas directly related to contract duties.

3) **Special Shipping and Packaging**

Offerors should include a uniform assumption of two thousand (2000) domestic shipments per year. Offerors should include a uniform assumption of four hundred (400) international shipments per year.

Note: The offeror will provide the packaging, but the approved requestors (domestic and international investigators) will pay all shipping charges.

4) **Storage**

Offerors should include a uniform assumption of a total of one thousand (1000) new peptide stocks, other MHC ligands, and MHC monomers to be stored at the NIH Tetramer Core Facility site each year.

5) **Government Furnished Property**

*Check the appropriate box.*

- [ ] Government Furnished Property is offered for this acquisition.

_The Contract Specialist will provide a listing of all Government Furnished Property that is offered for this acquisition, including property available to be transferred from incumbent contractor. The Contract Specialist will include this listing as an attachment to the solicitation and potential offerors will be advised that this property is available to be transferred to the successful offeror._

- [x] No Government Furnished Property is offered for this acquisition.

- [ ] The purchase of Government Furnished Property will not be authorized as a direct charge under the resultant Task Order.

**SECTION 4 – OPTIONS**

OPTION 1 through 6 – Provide a detailed budget for each option year (6 total option years).

**SECTION 5 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION**
Refer to Section L of the solicitation for documentation requirements. All relevant documentation should be included in a clearly marked section of the proposal.

1) Small Business Subcontracting Plan

Section L of the RFP specifies the minimum documentation requirements for completing a subcontracting plan. This plan should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

2) Extent of Small Disadvantaged Business Participation

Section L of the RFP specifies the minimum documentation requirements for small disadvantaged business utilization. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

3) Past Performance Data, including references

Section L of the RFP specifies the minimum documentation requirements for providing past performance information. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.