**SOLICITATION**

**SECTION A - SOLICITATION/CONTRACT FORM**

1. **Requisition or other Purchase Authority:** Requisition

2. **Request for Proposal (RFP) Number:** NIH-NICHD-OPPTB-2018-2

3. **Issue Date:** 01/05/2018

4. **Set Aside:**
   - [X] No
   - [ ] Yes See Part IV Section L

5. **Title:** Best Pharmaceuticals for Children Act Pediatric Trials Network

6. **ISSUED BY:**
   - Office of Acquisitions
   - Eunice Kennedy Shriver National Institute
   - of Child Health and Human Development (NICHD)
   - National Institutes of Health
   - 6710B Rockledge Drive
   - Room 1107, MSC 7000
   - Bethesda, MD 20892

7. **SUBMIT OFFERS TO:**
   - See Part III, Section J, "Packaging and Delivery of the Proposal,
     ATTACHMENT 1 of this Solicitation.

8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 4:00 p.m. local time on 02/21/2018. 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:** Primary Point of Contact: Angela Wish
    - PHONE: 301-435-6947
    - E-MAIL: angela.wish@nih.gov
    - COLLECT CALLS WILL NOT BE ACCEPTED.

12. Technical Proposal Page Limitation: See "Packaging and Delivery of the Proposal" - Attachment 1

13. Deadline for receipt of questions is: January 31, 2018

Secondary Point of Contact:
- Alice Pagán
- PHONE: 301-435-6959
- E-MAIL: alice.pagan@nih.gov
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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 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 Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) will establish an Indefinite-Delivery, Indefinite-Quantity (IDIQ) contract to support clinical activities for the Best Pharmaceuticals for Children Act - Pediatric Trials Network (BPCA-PTN). The purpose of this contract is to establish a Network of clinical research sites collaborating to conduct safe and effective BPCA clinical trials and to perform ancillary activities in support of these trials.

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 $5,000 (minimum) nor more than a total of $96,000,000 (maximum) for successful performance of this contract.

b. 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.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.
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 IDIQ contract Statement of Work, dated January 5, 2018, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

Note: Please be advised that the Contractor shall perform work under this contract only as directed in Task Order(s) issued by the Contracting Officer.

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

ARTICLE C.2. REPORTING REQUIREMENTS AS SPECIFIED BY TASK ORDERS

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."

If paper/hardcopy documents/reports are required to be submitted under any of the Task Orders issued under this contract, those reports shall be printed or copied, double-sided, on at least 30 percent post consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

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 Task Order 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 Task Order award. The Contractor shall include the applicable PubMed Central or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.

Only electronic versions of the below reports will be required:

<table>
<thead>
<tr>
<th>No.</th>
<th>Deliverable</th>
<th>Due Date</th>
<th>Recipients</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Draft Work Plan</td>
<td>As required by the TO</td>
<td>Electronic copy to COR</td>
</tr>
<tr>
<td>2</td>
<td>Final Work Plan</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>3</td>
<td>Final Work Plan Posted to Collaborative Website</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS &amp; posted to collaborative website</td>
</tr>
<tr>
<td>No.</td>
<td>Deliverable</td>
<td>Due Date</td>
<td>Recipients</td>
</tr>
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</tr>
<tr>
<td>4</td>
<td>Progress Reports</td>
<td>As required by the TO</td>
<td>Electronic copy to COR, CO/CS &amp; BPCA-DCC</td>
</tr>
<tr>
<td>5</td>
<td>Draft Manual Operating Procedures (MOP)</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>6</td>
<td>Final Report</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>7</td>
<td>Roster of Employees Requiring Suitability Investigations</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>8</td>
<td>IT Security Plan (IT-SP)</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>9</td>
<td>Draft Final Report</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>10</td>
<td>Reporting of New and Departed Employees</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>11</td>
<td>Contractor-Employee Non-Disclosure Agrmnts.</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>12</td>
<td>Vulnerability Scanning Reports</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>13</td>
<td>Section 508 Annual Report</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>14</td>
<td>Financial Conflict of Interest Report</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>15</td>
<td>List of Employees Requiring NIH IT Security Awareness Training</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>16</td>
<td>Minutes from Meetings, Teleconferences, and/or Webcasts</td>
<td>As required by the TO</td>
<td>Electronic copy to COR</td>
</tr>
<tr>
<td>17</td>
<td>General plans for communication, staffing plan, &amp; process for pilot</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>18</td>
<td>IRB Application</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>19</td>
<td>Summaries of Literature Searches</td>
<td>As required by the TO</td>
<td>Electronic copy to COR</td>
</tr>
<tr>
<td>20</td>
<td>Draft Protocol</td>
<td>As required by the TO</td>
<td>Electronic copy to COR</td>
</tr>
<tr>
<td>21</td>
<td>Final Protocol</td>
<td>As required by the TO</td>
<td>Electronic copy to COR</td>
</tr>
<tr>
<td>22</td>
<td>Draft Statistical Analysis Plans</td>
<td>As required by the TO</td>
<td>Electronic copy to COR</td>
</tr>
<tr>
<td>23</td>
<td>Draft Informed Consent and Assent Forms</td>
<td>As required by the TO</td>
<td>Electronic copy to COR</td>
</tr>
<tr>
<td>No.</td>
<td>Deliverable</td>
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<td>Recipients</td>
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</tr>
<tr>
<td>28</td>
<td>Standard Operating Procedures (SOPs)</td>
<td>As required by the TO</td>
<td>Electronic copy to COR</td>
</tr>
<tr>
<td>29</td>
<td>Final Informed Consent and Assent Forms</td>
<td>As required by the TO</td>
<td>Electronic copy to COR</td>
</tr>
<tr>
<td>30</td>
<td>Draft and Final Manual of Operating Procedures (MOP)</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>31</td>
<td>Subcontractor Performance Evaluation</td>
<td>As required by the TO</td>
<td>Electronic copy to COR &amp; CO/CS</td>
</tr>
<tr>
<td>32</td>
<td>Annual Service Contract Act Reporting</td>
<td>As required by the TO</td>
<td>Electronic copy to CO/CS</td>
</tr>
</tbody>
</table>

2. **Summary of Salient Results**

The Contractor will be required to prepare and submit, with the final report, as required by Task Order, 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.

3. **Annual Technical Progress Report for Clinical Research Study Populations**

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations (when appropriate) for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Cumulative Inclusion Enrollment Report," which is set forth in SECTION J of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report. If the clinical study(s) involves US and non-US sites, the US sites and non-US sites should be reported on separate Cumulative Inclusion Enrollment Reports.

The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract.

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies. If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website: [http://grants.nih.gov/grants/funding/women_min/women_min.htm](http://grants.nih.gov/grants/funding/women_min/women_min.htm).

For NIH-defined Phase III Clinical Trials: Include a description of the plans for valid analysis in the study design and outcomes. This includes designing the study in a manner that potential differences, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol could be conducted. Also, provide a description of any analyses by sex/gender, race, and/or ethnicity, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender, race and/or ethnicity.
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. Information Security and Physical Access Reporting Requirements

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

a. Roster of Employees Requiring Suitability Investigations

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

b. IT Security Plan (IT-SP)

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

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

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

c. IT Risk Assessment (IT-RA)

The contractor shall submit the IT-RA within thirty (30) days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management
Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy.

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

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

d. **FIPS 199 Assessment**

The Contractor shall submit a FIPS 199 Assessment within thirty (30) days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard.

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

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

The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed within three (3) months after contract award.

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

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

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

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

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

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

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

g. **Contractor - Employee Non-Disclosure Agreement(s)** The contractor shall complete and submit a signed and witnessed "Commitment to Protect Non-Public Information - Contractor Agreement" form for each contractor and subcontractor employee who may have access to non-public Department information under this contract. This form is located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf.
(Reference subparagraph E.3.d. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

h. **Vulnerability Scanning Reports**

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

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

3. **Section 508 Annual Report**

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

**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 annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. All reports shall be sent to the following address:

- **Contracting Officer**
- National Institutes of Health
- Eunice Kennedy Shriver NICHD
- National Institute of Child Health & Human Development
- Office of Acquisitions
- 6710B Rockledge Drive, Room 1107
- Bethesda, Maryland 20892-7510

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](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.

Note: Additional packaging and marking instructions may be specified in individual Task Order(s).
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, [he Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:
   Obstetric and Pediatric Pharmacology and Therapeutics Branch
   Eunice Kennedy Shriver
   National Institute of Child Health and Human Development
   National Institutes of Health
   6710B Rockledge Drive, Room 2327
   Bethesda, MD 20892

   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 IDIQ contract ordering period shall be from April 16, 2018 through April 15, 2026.

ARTICLE F.2. DELIVERIES

a. Satisfactory performance of this 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 in accordance with the stated delivery schedule: Refer to individual Task Orders for specific delivery schedules.

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 after award
NICHD/OPPTB
6710B Rockledge Drive, MSC 7002
Bethesda, MD 20892

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>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>To be determined at time of award</td>
<td>Principal Investigator</td>
</tr>
</tbody>
</table>

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.

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

c. **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, and any other factor specifically identified in the TORFP will be used for evaluation of each proposal.

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

a. Invoice Submission/Contract Financing Request, NIH(RC)-1 for NIH Cost-Reimbursement Type Contracts are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a “proper invoice” pursuant to FAR Subpart 32.9, Prompt Payment.
1. Payment requests shall be submitted to the offices identified below. **The Contractor will be required to submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with payment requests to the approving official named in subparagraph b. below.**

   a. The original invoice only (excluding supporting documentation) shall be mailed 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 electronic copy of the invoice (including supporting documentation) shall be submitted to the following **approving official:**
      
      Contract Specialist  
      NICHD, Office of Acquisitions  

      E-mail: To Be Determined  

      The Contractor shall submit an electronic copy of the payment request/invoice to the approving official instead of a paper copy. The invoice 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). The invoice must include all supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.). 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.

      Central Point of Distribution: nichdbranchainvoices@mail.gov  

      The Contractor shall submit an electronic copy of the payment request to the Central Point of Distribution mailbox. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. **Note: The original invoice 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 Eunice Kennedy Shriver National Institute of Child Health and Human Development.

   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. 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. 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 Task Order Title is: To be specified for each individual task order.

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, including 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 as follows on the contract anniversary date.

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.

(End of clause)

ARTICLE H.2. HUMAN SUBJECTS

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

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.
ARTICLE H.3. 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.4. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

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


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

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

The Data and Safety Monitoring Board shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H.5. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS IN CLINICALTRIALS.GOV

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

- the registration of certain “applicable clinical trials” (see Definitions at: http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.
In addition, the Contractor shall notify the Contracting Officer’s Representative (COR), with the trial registration number (NCT number), once the registration is accomplished. This notification may be included in the Technical Progress Report covering the period in which registration occurred, or as a stand alone notification.

The Contractor is the Sponsor, therefore the “Responsible Party” for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (http://www.ClinicalTrials.gov).

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

ARTICLE H.6. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS CLINICALTRIALS.GOV

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

- the registration of certain "applicable clinical trials" (see Definitions http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and

- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

NICHD is the “Responsible Party” for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of the applicable clinical trial(s) performed under this contract in the Government database, ClinicalTrials.gov (http://www.ClinicalTrials.gov).

The contractor shall provide the “Responsible Party” with all essential data for timely compliance with ClinicalTrials.gov reporting requirements.

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

ARTICLE H.7. 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.8. 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.9. 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.10. 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.11. 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.12. 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.13. 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.14. LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES

The Contractor shall not use contract funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act, except for normal and recognized executive-congressional communications. This limitation shall not apply when the Government determines that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

ARTICLE H.15. 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.16. PRIVACY ACT, HHSAR 352.224-70 (December 2015)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct in CFR 45 part 5b and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement: (a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and (b) specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html.
ARTICLE H.17. 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.18. GUN CONTROL

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

ARTICLE H.19. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I, the Task Order will consist only of the Base Period of the Statement of Work, as defined in Sections C and F of the Task Order. Pursuant to FAR Clause 52.217-9, Option to Extend the Term of the Task Order, set forth in SECTION I, and also defined in Sections C and F of this Task Order, the Government may, by unilateral Task Order modification, require the Contractor to perform additional options set forth in the Statement of Work. If the Government exercises this option, notice must be given at least 30 days prior to the expiration date of the Task Order, and the estimated cost plus fixed fee of the Task Order will be increased as set forth in the ESTIMATED COST PLUS FIXED FEE Article in SECTION B of the Task Order.

This provision applies to Task Order(s) that contain Options. Options to Extend the Term may be included in some individual Task Orders.

ARTICLE H.20. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

1. The Small Business Subcontracting Plan, dated (to be determined) is attached hereto and made a part of this contract.

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

b. Subcontracting Reports

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

1. Individual Subcontract Reports (ISR)

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

   April 30th
   October 30th
   Expiration Date of Contract

2. Summary Subcontract Report (SSR)

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

- 25 -
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:

To be determined
Contracting Officer

ARTICLE H.21. INFORMATION AND PHYSICAL ACCESS SECURITY

A. HHS-Controlled Facilities and Information Systems Security

a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:


c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

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

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

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

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

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

Upon receipt of the Government's notification of applicable Suitability Investigations required, the
Contractor shall complete and submit the required forms within 30 days of the notification.

The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to
a background check/investigation, will work under the contract and if they have previously been the subject
of national agency checks or background investigations.

All contractor and subcontractor employees shall comply with the conditions established for their
designated position sensitivity level prior to performing any work under this contract.

Contractors may begin work after the fingerprint check has been completed.

e. Investigations are expensive and may delay performance, regardless of the outcome of the
investigation. Delays associated with rejections and consequent re-investigations may not be excusable
in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor
shall ensure that any additional employees whose names it submits for work under this contract have a
reasonable chance for approval.

f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple
investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the
contract price of no more that the cost of the additional investigation(s).

g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems
Security" language in all subcontracts that require subcontractor personnel to have the same frequency
and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled
information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled
information system or in hard copy; or (4) any combination of circumstances (1) through (3).

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

i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon
termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or
designee.

B. Standard for Security Configurations

1. The Contractor shall configure its computers that contain HHS data with the latest applicable United States
Government Configuration Baseline (USGCB) and/or other approved HHS IT Security Configurations.
(See: https://usgcb.nist.gov/)

Note: Approved security configurations include, but are not limited to, those published by the Department,
the OpDiv/StaffDiv, and the National Institute of Standards and Technology (NIST). OpDiv/StaffDivs 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 OpDiv CISO and/or Information System Security Officer (ISSO) shall be consulted to determine the
appropriate configuration reference for a particular system or services acquisition.)
2. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS and must adhere to all NIH configuration standards and policies (See: https://ocio.nih.gov/InfoSecurity/Policy/Pages/CM.aspx). The following security configuration requirements apply:
Federal Desk Core Configuration (FDCC)

3. 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). 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.

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

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


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

C. Standard for Encryption language

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

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

c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.
d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).

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

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

D. Security Requirements For Federal Information Technology Resources

a. Applicability. This clause applies whether the entire contract or order (hereafter “contract”), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS’ mission. The term “information technology (IT)”, as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources. This clause does not apply to national security systems as defined in FISMA.

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

1. Protecting Federal information and Federal information systems in order to ensure their -
   a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;
   b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and
   c. Availability, which means ensuring timely and reliable access to and use of information.

2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.

3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer’s (OCIO) Web site.

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

1. **IT Security Plan (IT-SP)** - due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.
   a. The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-
Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:


ii. National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of Federal Information Processing Standard (FIPS) 200, Recommendation Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.

iii. HHS-OCIO Information Systems Security and Privacy Policy.

2. **IT Risk Assessment (IT-RA)** - due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor’s final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.

3. **FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment)** - due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor’s final version into the contract.

4. **IT Security Certification and Accreditation (IT-SC&A)** - due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems - see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer’s Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security, Certification and Accreditation of Federal Information Systems; and NIST 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provided it to the Contracting Officer for review, comment, and acceptance.

   a. After resolution of any comments provided by the Government on the draft IT-SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor’s final version into the contract as a compliance requirement.

   b. The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:

   i. Annual testing of the system contingency plan; and

   ii. The performance of security control testing and evaluation.

   d. **Personal identity verification.** The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer’s Representative (COR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in “HHS-Controlled Facilities and Information Systems Security” requirements specified in the SOW/PWS of this contract.
e. Contractor and subcontractor employee training. The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COR evidencing that Contractor employees have completed the required training.

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

g. Subcontracts. The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -

  a. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or
  b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.

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

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

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

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

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

E. Additional NIH Requirements

1. SECURITY CATEGORIZATION OF FEDERAL INFORMATION AND INFORMATION SYSTEMS (FIPS 199 Assessment)

   a. Information Type:

      [X] Administrative, Management and Support Information:

      [ ] Mission Based Information:

   b. Security Categories and Levels:

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

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

2. INFORMATION SECURITY TRAINING

The contractor shall comply with the below training:

a. Mandatory Training

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

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

b. Role-based Training

   HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance about "NIH Information Security Awareness and Training Policy," at: [https://ocio.nih.gov/InfoSecurity/Policy/Documents/Final-InfoSecAwarenessTrainPol.doc](https://ocio.nih.gov/InfoSecurity/Policy/Documents/Final-InfoSecAwarenessTrainPol.doc).

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

c. Rules of Behavior


3. PERSONNEL SECURITY RESPONSIBILITIES

The contractor shall comply with the below personnel security responsibilities:

a. The Contractor shall notify the Contracting officer and the COR within five working days before a new employee assumes a position that requires access to HHS information systems or data, or when an employee with such access stops working on this contract. The Government will initiate a background investigation on new employees assuming a position that requires access to HHS information systems or data, and will stop pending background investigations for employees that no longer work under the contract or no longer have such access.
b. **New contractor employees who have or will have access to HHS information systems or data:** The Contractor shall provide the COR with the name, position title, e-mail address, and phone number of all new contract employees working under the contract and provide the name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.

c. **Departing contractor employees:** The Contractor shall provide the COR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COR upon request.

d. **Commitment to Protect Non-Public Departmental Information and Data.**

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

   - 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
   - Public Law 96-511 (Paperwork Reduction Act)

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

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

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


5. **VULNERABILITY SCANNING REQUIREMENTS**

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

ARTICLE H.22. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45

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

a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request.

A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

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

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

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

Significant financial interests do not include the following:

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

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

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

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

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

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

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

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

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

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

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

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.
If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

**ARTICLE H.23. 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 Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, Department of Health and Human Services, under Contract No. To Be Determined"

**ARTICLE H.24. TASK ORDER/DELIVERY ORDER CONTRACT OMBUDSMAN**

In accordance with FAR 16.505(b)(5), the following individual has been designated as the NIH Ombudsman for task order and delivery order contracts.

The appropriate individual will be included in the resultant contract as follows:

<table>
<thead>
<tr>
<th>For R&amp;D Contracts:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr. Sherry Mills</td>
</tr>
<tr>
<td>NIH Competition Advocate</td>
</tr>
<tr>
<td>6705 Rockledge Drive, Suite 305</td>
</tr>
<tr>
<td>Bethesda, MD 20892</td>
</tr>
<tr>
<td>Phone: (301) 435-2687</td>
</tr>
<tr>
<td>E-mail: <a href="mailto:sherry.mills@nih.gov">sherry.mills@nih.gov</a></td>
</tr>
</tbody>
</table>

**ARTICLE H.25. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES**

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at: [http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf](http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf) is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

Note: For the purposes of this Article, the terms, "research tools", "research materials", and "research resources" are used interchangeably and have the same meaning.

**ARTICLE H.26. SHARING RESEARCH DATA**

The data sharing plan submitted by the Contractor is [acceptable]. The Contractor's data sharing plan, dated TBD is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.
The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:


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.27. 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.28. 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.

ARTICLE H.29. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD

The Contractor shall not use contract funds (direct or indirect) to conduct meetings or conferences in performance of this contract without prior written Contracting Officer approval.

In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.

ARTICLE H.30. GUIDELINES FOR INCLUSION OF WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES IN NIH-SUPPORTED CONFERENCES

Pursuant to the NIH Revitalization Act (P.L. 103-43, Section 206), which adds Section 402(b) to the Public Health Service Act, it is required that NIH, "in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research." In addition, Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990 require reasonable accommodations to be provided to individuals with disabilities.

It is NIH policy that organizers of scientific meetings should make a concerted effort to achieve appropriate representation of women, racial/ethnic minorities, and persons with disabilities, and other individuals who have been traditionally underrepresented in science, in all NIH sponsored and/or supported scientific meetings.

Therefore, it is the contractor's responsibility to ensure the inclusion of women, minorities, and persons with disabilities in all events when recruiting speakers and/or participants for meetings or conferences funded by this contract.

See the policy announcement for additional details and definitions at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html
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: https://oamp.od.nih.gov/DGS/reference-material-prospective-offerors-and-contractors

The resultant IDIQ contract will allow for the issuance of Cost Reimbursement Completion or Term Form and Firm Fixed Price Task Orders. Therefore, clauses affecting both Cost Reimbursement and Firm Fixed Price Orders have been included in this RFP.

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

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

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

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE 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 Clauses 52.215-15, Pension Adjustments and Asset Reversions (October 2010); 52.215-18, Reversion or Adjustment of Plans for Post Retirement Benefits (PRB) Other Than Pensions (July 2005); and, 52.215-19, Notification of Ownership Changes (October 1997), are deleted in their entirety.

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

d. **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.

e. **Alternate II** (October 2001) of FAR Clause 52.219-9, Small Business Subcontracting Plan (November 2016) is added.

f. 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 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (October 2016).

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

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


7. FAR Clause 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (October 2014).

   "(c) Waiver of evaluation preference.....

   [ ] Offeror elects to waive the evaluation preference."

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

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

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

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

12. Alternate V (December 2007), FAR Clause 52.227-14, Rights in Data--General (May 2014).
Specific data items that are not subject to paragraph (j) include:

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

14. FAR Clause 52.229-8, Taxes-Foreign Cost-Reimbursement Contracts (March 1990).

15. FAR Clause 52.230-2, Cost Accounting Standards (October 2015).


17. FAR Clause 52.230-5, Cost Accounting Standards - Educational Institution (August 2016).

18. FAR Clause 52.230-6, Administration of Cost Accounting Standards (June 2010).


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


22. FAR Clause 52.246-23, Limitation of Liability (February 1997).

23. FAR Clause 52.247-63, Preference for U.S. Flag Air Carriers (June 2003).

24. FAR Clause 52.251-1, Government Supply Sources (April 2012).

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

1. HHSAR Clause 352.208-70, Printing and Duplication (December 2015)

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

3. HHSAR Clause 352.219-71, Mentor-Protégé Program Reporting Requirements (December 2015).

4. HHSAR Clause 352.223-70, Safety and Health (December 2015)

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

Note: The Salary Rate Limitation is at the Executive Level II Rate.
See the following website for Executive Schedule rates of pay: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/. (For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

c. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

1. NIH(RC)-11, Research Patient Care Costs (4/1/84).
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.

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

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

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

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

(End of clause)

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 03/15/2018 through 03/14/2026.

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 $5,000, 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 $20,000,000.

2. Any order for a combination of items in excess of $50,000,000; 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 10 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."

b. Exception 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 March 15, 2031.

(End of clause)

5. FAR Clause 52.217-9, Option to Extend the Term of the Contract (March 2000). This clause applies only to Task Orders issued and not to the IDIQ parent contract.

a. The Government may extend the term of this contract by written notice to the Contractor within 7 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

b. If the Government exercises this option, the extended contract shall be considered to include this option clause.

c. The total duration of this contract, including the exercise of any options under this clause, shall not exceed (to be specified in task orders where inclusion of an options(s) is necessary).

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

b. THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.
# 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 Proposals for Use with the NIH electronic Contract Proposal Submission (eCPS) Website</td>
<td>See attached documents at the end of this RFP</td>
</tr>
<tr>
<td>Attachment 2:</td>
<td>Proposal Intent Response Sheet</td>
<td>See attached documents at the end of this RFP</td>
</tr>
<tr>
<td>Attachment 3:</td>
<td>Statements of Work: Attachment 3a-IDIQ Contract; Attachment 3b-Task Order 1; Attachment 3c-Sample Task Order 2</td>
<td>See attached documents at the end of this RFP</td>
</tr>
<tr>
<td>Attachment 4:</td>
<td>Reporting Requirements and Deliverables: Attachment 4a-Task Order 1; Attachment 4b-Sample Task Order 2</td>
<td>See attached documents at the end of this RFP</td>
</tr>
<tr>
<td>Attachment 5:</td>
<td>Section K - Representations, Certifications, and Other Statements of Offerors</td>
<td>See attached documents at the end of this RFP</td>
</tr>
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</table>

### TECHNICAL PROPOSAL ATTACHMENTS

<table>
<thead>
<tr>
<th>Attachment No.</th>
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<tbody>
<tr>
<td>Attachment 9:</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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<tr>
<td>Attachment 13:</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/buscntrctprpslsprdsht08-2014_508.xlsx">https://oamp.od.nih.gov/sites/default/files/DFASDocs/buscntrctprpslsprdsht08-2014_508.xlsx</a></td>
</tr>
<tr>
<td>Attachment 16:</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>
</tr>
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</table>

**INFORMATIONAL ATTACHMENTS**

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<tr>
<th>Attachment No.</th>
<th>Title</th>
<th>Location</th>
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<tbody>
<tr>
<td>Attachment 22:</td>
<td>Government Property Schedule</td>
<td>To be determined during negotiations.</td>
</tr>
</tbody>
</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 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 2006)]

   a. Definitions. As used in this provision--

   "Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal. "In writing", "writing", or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information. "Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award. "Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations. "Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

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

   c. Submission, modification, revision, and withdrawal of proposals.

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

      2. The first page of the proposal must show--

         i. The solicitation number;

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

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

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

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

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

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

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

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

   (3) It is the only proposal received.

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

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

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

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

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

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

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

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

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

(e) **Restriction on disclosure and use of data.**

(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 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 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.

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

(10) 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.

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

(12) 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.

(13) 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.
Alternate II (October 1997). As prescribed in 15.209(a)(2), add a paragraph (c)(9) substantially the same as the following to the basic clause:

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

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 541715 (formerly 541712 and updated in 2017).
2. The small business size standard is 1000.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

c. TYPE OF CONTRACT AND NUMBER OF AWARDS

1. It is anticipated that one (1) IDIQ base contract and the first Task Order (TO No. 1) will be awarded from this solicitation and the award will be made on or about April 16, 2018.
2. It is anticipated that the award made from this solicitation will be an IDIQ contract for the issuance of cost reimbursement and fixed price task orders with an ordering period of eight (8) years. In addition, Task Order 1 will be awarded from this solicitation and will be a cost reimbursement type task order.
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. TASK ORDERS UNDER INDEFINITE DELIVERY CONTRACTS

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

One or more task orders may be issued during the performance period of the resultant contract. The government has no obligation to issue any task orders, beyond the minimum identified in SECTION B of the contract. In the event of any inconsistency between any task order and the contract, the contract shall control.

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

3. 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 the proposal.

d. ESTIMATE OF EFFORT
It is expected that an IDIQ contract will be awarded as a result of this SOLICITATION. The Task Orders listed below will be included in the solicitation. To assist you in the preparation of your proposal the Government estimates the effort required for Task Order 1 as follows:

Task Order 1:
The Government considers the effort to be approximately 3,640 labor hours per year.

The above information is provided for guidance only and is not to be considered restrictive (see Attachment 3 "Additional Proposal Instructions for more details).

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:

Alice Pagán
Contracting Officer
Office of Acquisitions
6710B Rockledge Drive Room 1107
Bethesda, MD 20892 MSC 7000

(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. USE OF NON-GOVERNMENT PERSONNEL FOR TECHNICAL PROPOSAL EVALUATION

In accordance with 42 C.F.R. 52h, Non-Government personnel will be utilized as reviewers in the evaluation of Technical Proposals submitted in response to this solicitation. While NIH requires competent, objective, and expeditious evaluation of proposals submitted in response to R&D solicitations, the use of Non-Government reviewers will be strictly controlled. Non-Government reviewers will be utilized in the evaluation of Technical Proposals only and will not have access to Business proposals submitted in response to this solicitation. All proposed Non-Government reviewers will be required to identify any conflicts of interest held with relation to offeror’s organizations and/or investigators submitting proposals in response to this solicitation and will be required to ensure the confidentiality of review documents and proceedings.

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 IDIQ contract for the issuance of cost-reimbursement and fixed price task orders 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 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 technically 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 NICHD’s policy to conduct discussions with all offerors in the competitive range, NICHD 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 NICHD 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 NICHD 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](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. **52.203-98 Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements--Representation (DEVIATION)**

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

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

c. Representation. By submission of its offer, the Offeror represents that it does not require employees or subcontractors of such entity seeking to report fraud, waste or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information. (End of provision)

15. Past Performance Information

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

A list of the last 3 contracts completed during the past One year and THE LAST 5 CONTRACTS AWARDED and 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 who 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 $750,000.

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. Information and Physical Access Security is applicable to this solicitation and the following information is provided to assist in proposal preparation.
IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Business Proposal entitled "Information Security."

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

A. HHS-Controlled Facilities and Information Systems Security

a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:


c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

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

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

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

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

As part of its proposal, and if the anticipated position sensitivity levels are specified in paragraph (d) above, the Offeror shall notify the Contracting Officer of (1) its proposed personnel who will be subject to a background check/investigation and (2) whether any of its proposed personnel who will work under the contract have previously been the subject of national agency checks or background investigations.

Upon award, the Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access and/or maintain a Federal Information System(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days after the effective date of the contract. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

The Contractor shall notify the Contracting Officer in advance when any new personnel, who are subject to a background check/investigation, will work under the contract and if they have previously been the subject of national agency checks or background investigations.

All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract.

Contractors may begin work after the fingerprint check has been completed.

e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.

f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the additional investigation(s). Accordingly, if position sensitivity levels are specified in paragraph (d) above, the Offeror shall ensure that the employees it proposes for work under this contract/order have a reasonable chance for approval.

g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer.

i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

B. Standard for Security Configurations

1. The Contractor shall configure its computers that contain HHS data with the latest applicable United States Government Configuration Baseline (USGCB) and/or other approved HHS IT Security Configurations. (See: https://usgcb.nist.gov/)

   Note: Approved security configurations include, but are not limited to, those published by the Department, the OpDiv/StaffDiv, and the National Institute of Standards and Technology (NIST). OpDiv/StaffDivs 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 OpDiv CISO and/or Information System Security Officer (ISSO) shall be consulted to determine the appropriate configuration reference for a particular system or services acquisition.)

2. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS and must adhere to all NIH configuration standards and policies (See: https://ocio.nih.gov/InfoSecurity/Policy/Pages/CM.aspx). The following security configuration requirements apply: Federal COR Configuration (FDCC)

3. 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). 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.

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

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

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

C. **Standard for Encryption language**

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

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

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

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

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

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

D. **Security Requirements For Federal Information Technology Resources**

a. **Applicability.** This clause applies whether the entire contract or order (hereafter "contract"), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS' mission. The term "information technology (IT)", as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and
related resources. This clause does not apply to national security systems as defined in FISMA.

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

1. Protecting Federal information and Federal information systems in order to ensure their -
   a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;
   b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and
   c. Availability, which means ensuring timely and reliable access to and use of information.

2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.

3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.

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

1. IT Security Plan (IT-SP) - due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.

   a. The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:


      ii. National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the
information and the requirements of Federal Information Processing Standard (FIPS) 200. Recommend Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.

iii. HHS-OCIO Information Systems Security and Privacy Policy.

2. IT Risk Assessment (IT-RA) - due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor’s final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.

3. FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment) - due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor’s final version into the contract.

4. IT Security Certification and Accreditation (IT-SC&A) - due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems - see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer’s Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security, Certification and Accreditation of Federal Information Systems; and NIST 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provided it to the Contracting Officer for review, comment, and acceptance.

a. After resolution of any comments provided by the Government on the draft IT-SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor’s final version into the contract as a compliance requirement.

b. The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:
   i. Annual testing of the system contingency plan; and
   ii. The performance of security control testing and evaluation.

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

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

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

g. **Subcontracts.** The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -

   a. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or

   b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.

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

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

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

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

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

**E. Additional NIH Requirements**

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

[X] Administrative, Management and Support Information:

[ ] Mission Based Information:

b. Security Categories and Levels:

<table>
<thead>
<tr>
<th>Confidentiality Level:</th>
<th>[ ] Low</th>
<th>[X] Moderate</th>
<th>[ ] High</th>
</tr>
</thead>
<tbody>
<tr>
<td>Integrity Level:</td>
<td>[X] Low</td>
<td>[ ] Moderate</td>
<td>[ ] High</td>
</tr>
<tr>
<td>Availability Level:</td>
<td>[X] Low</td>
<td>[ ] Moderate</td>
<td>[ ] High</td>
</tr>
</tbody>
</table>

Overall Level: [ ] Low [X] Moderate [ ] High

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

2. INFORMATION SECURITY TRAINING

The contractor shall comply with the below training:

a. Mandatory Training

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

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

b. Role-based Training

HHS requires role-based training when responsibilities associated with a given role or position, could, upon execution, have the potential to adversely impact the security posture of one or more HHS systems. Read further guidance about "NIH Information Security Awareness and Training Policy," at: https://ocio.nih.gov/InfoSecurity/Policy/Documents/Final-InfoSecAwarenessTrainPol.doc.

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

c. Rules of Behavior

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

3. PERSONNEL SECURITY RESPONSIBILITIES

The contractor shall comply with the below personnel security responsibilities:

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

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

c. **Departing contractor employees:** The Contractor shall provide the COR with the name, position title, and position sensitivity level held by or pending for departing employees. The Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COR upon request.

d. **Commitment to Protect Non-Public Departmental Information and Data.**

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

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- Public Law 96-511 (Paperwork Reduction Act)
Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

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

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


5. VULNERABILITY SCANNING REQUIREMENTS

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

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.

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

(End of provision)

The "HHS Section 508 Product Assessment Template" is included in SECTIONS 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.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. Unique Entity Identifier, FAR Provision 52.204-6 (October 2016).


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


e. Single or Multiple Awards, FAR Clause 52.216-27, (October 1995).
f. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

g. Certification Regarding Trafficking in Persons Compliance Plan, FAR Provision 52.222-56 (March 2015)

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. These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of human subjects participating in research activities supported or conducted by HHS.

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

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

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

e. In accordance with 45 CFR part 46, offerors considered for award shall file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board shall ensure that: The risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111 for additional requirements regarding initial and continuing review. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP Web site (at http://www.hhs.gov/ohrp/assurances/index.html).

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

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

(End of provision)

Alternate I (DEC 2015).

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

(g) The offeror’s proposal shall document that it has an approved or active FWA from OHRP, related to the designated IRB reviewing and overseeing the research. When possible the offeror shall also certify the IRB has reviewed and approved the research. If the offeror cannot make this certification at the time of proposal submission, its proposal must include an explanation. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the

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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 and Characteristics:
  - Describe the proposed involvement of human subjects in response to the solicitation.
  - Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
  - Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

- Sources of Materials:
  - Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

- Potential Risks:
  - Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
  - Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

b. Adequacy of Protection Against Risks

- Recruitment and Informed Consent:
  - Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document
for the Contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the Contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

• Protection Against Risk:
  
  ◦ Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
  
  ◦ Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
  
  ◦ In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

c. Potential Benefits of the Proposed Research to the Subjects and Others

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

d. Importance of the Knowledge to be Gained

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

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

Collaborating Site(s)

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

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/
Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

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

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

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

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

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

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), and applies to research subjects of all ages. All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:


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 "Planned Enrollment Report" (see Section J, Attachments)

**NOTE 1:** For all proposals, use the ethnic and racial categories and complete the "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](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, "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, "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.
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

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- 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 7) and determined and documented that:

a. the research presents no more than minimal risk, and
b. no more than inconvenience to the prisoner subjects, and
c. prisoners are not a particular focus of the research.

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

f. Research Involving Human Fetal Tissue

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

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

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

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

g. 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 . 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 .
h. Data and Safety Monitoring in Clinical Trials

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


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

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

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

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

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

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan you should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. The NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual /Safety Officer
- Designated medical monitor
• Internal Committee or Board with explicit guidelines
• Data and Safety Monitoring Board (DSMB - required for multisite trials)
• Institutional Review Board (IRB - required)

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

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

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

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

a. The registration of certain "applicable clinical trials" in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and

b. The reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

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

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

• Where the Contractor is the IND/IDE holder, the Contractor will be considered the Sponsor, therefore the "Responsible Party."

• Where there is no IND/IDE holder or where the Government is the IND/IDE holder, the Government will generally be considered the "Sponsor" and may designate the contractor's Principal Investigator (PI) as the "Responsible Party."

• For Multi-Center trials where there is no IND/IDE holder or where the Government is the IND/IDE holder, the "Responsible Party" will be designated at one site (generally the lead clinical site) and all other sites will be responsible for providing necessary data to the "Responsible Party" for reporting in the database.

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

5. 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. 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.

6. Section 508 accessibility standards for HHS Web Site Content and Communications Materials

Regardless of format, all Web content or communications materials specifically produced for publication on, or delivery via, HHS Web sites, including text, audio, or video, under this contract shall conform to applicable Section 508 accessibility standards. Remediation of any materials that do not comply with the applicable accessibility standards of 36 CFR Part 1194 as set forth herein shall be the responsibility of the Contractor.

The following Section 508 accessibility standards apply to the content or communications material identified in this Statement of Work Performance Work Statement:

1194.21 Software applications and operating systems
1194.22 Web-based intranet and internet information and applications
1194.24 Video and multimedia products
1194.25 Self-contained, closed products
1194.26 Desktop and portable computers
1194.41 Information, documentation, and support

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.

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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. **Data Other than Certified Cost or Pricing Data**

   a. Data submitted shall be sufficient to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., data to support an analysis of material costs (when sufficient data on labor and overhead rates is already available), or data on prices and quantities at which the offeror has previously sold the same or similar items.

   Data submitted must support the price proposed. The offeror shall include sufficient detail or cross references to clearly establish the relationship of the data provided to the price proposed. The offeror shall support any data provided with explanations or supporting rationale, as needed, to permit the Contracting Officer and authorized representative to evaluate the documentation.

   [Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

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)

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 Service Disabled Veteran-Owned Small Businesses.

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. 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. 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
4. The management and control of any Government property shall be in accordance with FAR Part 45.

b. **Royalties**

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

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

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

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

(End of Provision)

d. **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e. **Adequate Accounting System**

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

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

"By submission of its signed offer, the Offeror certifies that its accounting system:
• Complies with generally accepted accounting principles (GAAP).

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

• Accounting system provides financial information:
  
  ◦ Required by contract 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.

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

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)
If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] Fac Cap Cost of Money (Has) The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] Fac Cap Cost of Money (Has Not) The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

10. 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.

11. 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.


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

13. 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

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The tradeoff process described in FAR 15.101-1 may be used. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated offeror. The Government intends to make an award 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 NICHD 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
The 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. 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).

5. 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.

6. 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.

7. 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.

The score will be based on a combined evaluation of the technical proposal comprised of three sections, the IDIQ Contract, Task Order 1, and Sample Task Order 2. Therefore, the three sections will not be scored individually.
1. QUALIFICATIONS OF ORGANIZATIONAL EXPERIENCE AND STAFF (Points: 40)

Offerors shall provide evidence of their experience in conducting and managing pediatric clinical trial activities that may lead to changes in labeling for medications used in pediatric patients, including evidence of the following:

a. Ability to objectively recruit study appropriate high-quality study sites;
b. Ability to manage patient screening, recruitment, enrollment and retention;
c. Ability to perform activities relating to informed patient assent/consent;
d. Ability to develop protocols with the requisite components;
e. Ability to assess and report adverse events to the BPCA-DCC; collect patient specimens; collect and assess quality of study data; and create, maintains and store research records;
f. Ability to provide qualified scientific, technical and administrative staff for specific duties and responsibilities as required in the Statements of Work, including:

1) A Principal Investigator (PI) to lead and direct the activities required under the SOW either directly or indirectly trough subcontracts, or in collaboration with BPCA DCC other key third parties. The PI shall possess experience in managing similar projects.

2) Staff who will oversee, support, and collaborate with other BPCA partners and Government staff to perform required task areas. Experience, at a minimum, should include work in one or more of the following areas: pediatric pharmacology; the design and conduct of pediatric clinical trials; activities in pre-clinical research or product (drug/device) development; and/or data analysis of pharmacokinetic and pharmacodynamic (PK/PD), safety and efficacy of pediatric clinical trials.

3) Administrative and/or contract management staff to oversee a complex task order contract, including the acquisition, award and administration of subcontracts; financial management and reporting; creation, performance and implementation of corrective actions to ensure quality control of individual tasks and/or subcontracts.

4) A mix of various personnel to perform task requirements, including:

i. Ability to support researchers and/or experts who may require support for statistical analysis, literature reviews, protocol management, medical writing or other ancillary support.

ii. Ability to implement and manage information technology to enhance operations; and ensure quality control of data resulting from the contract;

iii. Ability to establish and/or follow policies and procedures to ensure timely reporting of trial results, including bio-specimen samples to a laboratory or the BPCA repository;

iv. Ability to work together with the BPCA DCC in compiling requisite FDA regulatory documents for submission.

2. SOUNDNESS OF TECHNICAL APPROACH (Points: 30)

Feasibility of the offeror's proposed technical approach for the conduct of individual tasks, including:

a. Ability to identify and establish partnerships with various researchers that have experience designing and conducting pediatric clinical and/or device trials (both domestically and internationally) by creating feasible protocols; understanding pre-clinical drug development; successfully recruiting patients in specific therapeutic areas; collecting and analyzing PK/PD, safety and efficacy data; and translating resultant findings into relevant publications.

b. Adequacy of statistical analysis plan including PK modeling to determine correct dosing for protocol purposes.

c. Evidence to ensure quality control, including policies and procedures to ensure timely and accurate implementation and completion of clinical trial activities, in addition to resolving potential impediments and obstacles.

d. Ability to collaborate with project personnel including Government staff, BPCA DCC, and key third parties while utilizing mutually agreed upon lines of responsibility.
e. The adequacy of proposed methods for collecting and managing source documentation from the clinical sites and/or laboratories. f. Realistic approach to collaborating with the BPCA-DCC to ensure quality control of study data and data security.
g. Adequacy, thoroughness and feasibility of the approaches and plans proposed for soliciting, evaluating, executing and post-award administration of subcontracts, including:

1). Plans and procedures for developing solicitations, assembling qualified technical evaluation panels, conducting peer review of proposals received, and negotiating and awarding subcontracts in an objective and efficient manner;
2). Address principles for managing conflicts of interest with subcontract proposals;
3). Plans for closely monitoring and assessing technical, administrative and operational performance of subcontractors and implementing remedial actions to correct performance problems.

3. UNDERSTANDING THE PROJECT REQUIREMENTS *(Points: 20)*

Adequacy of the offeror's proposal to perform the following:

a. Participate as a collaborator in the BPCA consortium in order to ensure the successful conduct and completion of pediatric clinical trial activities;
b. Identify and access personnel, including researchers, consultants and/or subcontractors with expertise in various pediatric therapeutic areas or drug development to perform various task areas;
c. Possess the requisite expertise and resources to support pediatric drug development activities, as required in the SOW;
d. Oversee a complex network operation, while maintaining quality control of multiple on-going tasks;
e. Ability to audit, oversee, and evaluate facilities, personnel and equipment for compliance with Regulations: current Good Clinical Practices (cGCP), Good Laboratory Practices (cGLP), and Good Manufacturing Practices (cGMP).

4. FACILITIES *(Points: 10)*

a. Adequacy of the infrastructure including; clinical and pharmaceutical facilities and equipment for the collecting, processing, storing, analyzing, and shipping protocol-related patient samples in accordance with protocol specifications and requirements;
b. Provide evidence of the organizations approach for the following:

1) Utilizing information technology to communicate/share data with the BPCA-DCC other partners, subcontractors, clinical sites etc.
2) Proposed laboratory(s) are in compliance with:
   i. FDA's Good Laboratory Practice (GLP) regulations (i.e., US CFR Title 21 Part 58) (when applicable)
   ii. FDA's Guidance for Industry on Bioanalytical Method Validation.

8. 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.

9. **PAST PERFORMANCE FACTOR**

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.
PACKAGING AND DELIVERY OF PROPOSAL FOR USE WITH THE NIH ELECTRONIC CONTRACT PROPOSAL SUBMISSION (eCPS) WEBSITE

I. PROPOSAL SUBMISSION

A. eCPS:

2. Proposals submitted by facsimile or e-mail will not be accepted.
3. Follow the “How to Submit an Electronic Proposal” instructions provided on the eCPS website at: https://ecps.nih.gov/home/howto. Please note that creating an account to submit may take up to three (3) business days. Please apply for a new account early to allow enough time for the registration process.
4. Offerors are solely 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 HHSAR 352.215-070, Late Proposals and Revisions (December 18, 2015).

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. Create one PDF file of your Business Proposal, including all attachments: 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, but must be merged into the Business Proposal PDF file. Additionally, the “Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet” (http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx) must be included in the Business Proposal.
3. Create your Business Document Excel. The Excel file should be the “Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet” (http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx) included in the Business Proposal in its original Excel format, not PDF. Multiple Excel files may be included, as necessary.
4. File naming convention: It is requested that the filenames for 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:
Excel Workbook: XYZ Company_ NIH-NICHD-OPPTB-2018-2_Business.xlsx
II. FORMATTING AND PAGE LIMITATIONS

A. Proposal Formatting:

1. The PDF files should be created in a format that enables word searches to the maximum extent practicable.
2. Each of the proposals, Technical and Business, must be separate and complete, so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other.
3. Proposals shall not include links to internet website addresses (URLs) or otherwise direct readers to alternate sources of information.
4. Font size must be 10 to 12 points.
5. Spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
6. Print margins must be at least one-inch on each edge of the paper.
7. Signatures may be electronic, or scanned, but must be merged into the respective file.

Failure to adhere to the formatting requirements above may impact whether your proposal is reviewed in its entirety.

B. Page Limitations

<table>
<thead>
<tr>
<th>TECHNICAL PROPOSAL</th>
<th>BUSINESS PROPOSAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>The offeror must submit one (1) electronic PDF file for the Technical Proposal with three (3) sections:</td>
<td>The offeror must submit one (1) electronic PDF file for the Business Proposal with three (3) sections:</td>
</tr>
<tr>
<td>1. IDIQ – Not to exceed 50 pages</td>
<td>1. IDIQ Contract</td>
</tr>
<tr>
<td>2. Task Order 1 – Not to exceed 25 pages</td>
<td>2. Task Order 1</td>
</tr>
<tr>
<td>The proposal should not exceed 100 pages, including all sections</td>
<td>NO PAGE LIMITS ON BUSINESS PROPOSALS. In addition, the Offerors must include the Excel Spreadsheet with the Breakdowns of the Proposed Estimated Costs.</td>
</tr>
</tbody>
</table>

The page limitation is inclusive of all attachments, but does not include: bio sketches/resumes, references, Summary of Related Activities, NIST 800 53 Self-Assessment, Proposal Cover Sheet, Section Dividers that do not contain information other than title of Section, Technical Proposal Direct Cost Summary Sheets, Title and Back Page and Table of Contents. (Please note that the Draft Information Security Plan should be included in the business proposal). Pages in excess of this limitation will be removed from the proposal and will not be considered.
III. ORGANIZATION OF TECHNICAL PROPOSAL

Offerors are requested to write their Technical Proposal in three (3) parts:
First Part - shall address the IDIQ Contract Statement of Work and shall not exceed 50 single spaced pages. Part 2 - shall address the Task Order 1 Statement of Work and shall not exceed 25 single spaced pages. Part 3 - shall address the Sample Task Order 2 Statement of Work and shall not exceed 25 single spaced pages. Issues to be presented and/or addressed in Task Order 1, and Sample Task 2, that were previously addressed within the IDIQ Contract Statement of Work, should be referenced only, as opposed to repeating passages.
PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NICHD-OPPTB-2018-2
RFP Title: Best Pharmaceuticals for Children Act – Pediatric Trials Network

Please review the attached Request for Proposal. Furnish the information requested below and return this page by January 25, 2018. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

Company/Institute Name (print):

Address (print):

Principal Investigator’s Name (print):

Title (print):

Signature/Date:

Telephone Number and E-mail Address (print):

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

(Continue list on a separate page if necessary)

RETURN VIA E-MAIL TO:

Angela Wish, Contract Specialist
Email: angela.wish@nih.gov
AND
Alice Pagan Pereira, Contracting Officer
Email: alice.pagan@nih.gov
I. BACKGROUND AND INTRODUCTION

Several practical problems have discouraged drug testing in children. These include the lack of a suitable infrastructure to conduct pediatric pharmacology research; the unforeseeable nature of some clinical responses in immature individuals; the possibility of unanticipated adverse reactions; the threat of effects on growth, development or health, long after the drug's administration, and difficulties predicting dose or concentration-response relationships by extrapolating data obtained in adults or experimental animals. Researchers and clinicians involved in pediatric drug development face daily challenges that include, but are not limited to the following: the need to obtain parental permission and/or the child's assent; ethical issues related to the conduct of non-therapeutic research in children; the lack of technology applicable to children; and the lack of incentives that would encourage pharmaceutical companies to study drugs in neonates, infants, children and adolescents.

There is a significant unmet need for pediatric therapeutic and diagnostic device development. Despite these challenges, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) is aware of the critical need to establish and maintain an environment in which safe and effective pediatric clinical and device trial activities can quickly be initiated and managed.

A. Best Pharmaceuticals for Children Act of 2012

On October 25, 2002, the Director of the National Institutes of Health (NIH) delegated to the Director of the NICHD the authority and responsibility for establishing and conducting the pediatric drug development activity as set forth under Part B, Title IV, Section 409 I (a) and (b) of the Public Health Service Act (PHS Act). This led to the development of the Best Pharmaceutical for Children Act (BPCA) 2002, which in addition to renewing the provision for six (6) months of additional marketing exclusivity in return for pediatric testing of on-patent drugs, provided NIH the additional mechanisms for studying on- and off-patent drugs. Since the inception of BPCA 2002, NICHD had awarded 13 individual projects to various academic organizations to gather information that may inform pediatric labeling. Further information relating to BPCA can be found at this website: http://bpca.nichd.nih.gov/.

BPCA was reauthorized as part of the Food and Drug Administration (FDA) Amendments Act (FDAAA) in September 2007, again in 2012 as part of the FDA Safety and Innovation Act (FDASIA), and recently in August of this year as part of the FDA Reauthorization Act of 2017 (FDARA). This 2007 legislation streamlined the process by which NICHD can initiate drug studies that are of critical importance for specific pediatric therapeutic areas. The focus of this newer legislation allows research on biomarkers, and improved the process of disseminating study results to the general public. By implementing this new legislation, NICHD seeks to accomplish the following:
redirect the prioritization process by focusing on needs in pediatric therapeutics and identifying diseases and conditions bringing children into contact with the health care system;
• identify gaps in knowledge of drugs, biologics and/or devices utilized in pediatric care in the respective therapeutic area;
• and prioritizing studies (and/or therapeutic approaches) that will recognize and provide a public health benefit.

Since BPCA was initiated, NICHD has collaborated with NIH colleagues in other Institutes and Centers, the FDA, and many experts in pediatrics, public health and pharmacology. Because of these collaborations, and from input gathered during previous years, NICHD has prioritized and studied multiple therapeutic areas. (Refer to II, Objectives).

B. BPCA Collaborations

To accomplish the objectives of the BPCA, NICHD awards a series of Contracts that will operate as a Consortium to support a variety of BPCA activities. To ensure a successful collaboration, all Contractors or Consortium Partners who support BPCA activities will communicate and work together on a regular basis, to achieve the mission of NICHD and the goals of BPCA as described below:

1) **BPCA-Pediatric Trials Network (PTN)** – (this Contract) establishes a Network, with the award of this Indefinite Delivery, Indefinite Quantity (IDIQ) Contract, of clinical research sites collaborating to conduct safe and effective BPCA pediatric clinical trials.

2) **BPCA-Data Coordinating Center (DCC)** – provides regulatory and statistical support for BPCA clinical trial activities including data collection, data analyses, data monitoring, auditing, and data submission to the FDA.

3) **Biological Specimen Repository** – stores residual specimens under this Contract.

4) **Data and Specimen Hub (DASH)** will be utilized for completed trials data. It is a centralized resource for researchers to store and access de-identified data from NICHD funded research studies for the purposes of secondary research use.

C. NICHD Activities

The NICHD provides direct support for clinical research and clinical research networks that focus on specific diseases or public health issues. One of the goals of NICHD is to conduct research to better understand the effects and effectiveness of pharmaceuticals on maternal and child health. This Contract will ensure that NICHD is able to contract quickly and efficiently to acquire experts with the ability to support studies relating to pediatric drug and device development.

II. SCOPE AND OBJECTIVES

The main objective of this Contract is to create, operate and maintain an effective infrastructure for conducting safe and effective pediatric clinical trials and for performing ancillary activities in support of these trials.
BPCA has authorized NICHD to identify therapeutic gaps in pediatrics, which are pediatric diseases, disorders or conditions and now biomarkers where more complete knowledge and testing of therapeutics (including drugs, devices and biologics) can be beneficial to the pediatric population. Under this legislation, the NICHD can foster additional research specifically related to children, which addresses issues such as developmental pharmacology, pharmacokinetics (PK), pharmacogenomics, biomarkers of disease and unique aspects of pharmacodynamic (PD) responses to treatments. In addition to gathering clinical trial data to improve labeling, NICHD seeks to gather epidemiology data on drugs already being used in routine clinical care; the results of this type of assessment could help direct future NIH studies.

Therefore, this Contract will maintain the requisite staff for managing a complex and dynamic “Network” operation for the work outlined below, in addition to creating a collaborative relationship with other Consortium partners to accomplish this work.

NICHD anticipates the need to initiate activities in approximately five (5) to ten (10) therapeutic areas with multiple therapeutic approaches for each therapeutic area. These activities will require multiple scientific and clinical investigators with expertise in various disease areas such as:

- Cardiovascular diseases
- Infectious disease
- Respiratory diseases
- Hematology
- Renal diseases
- Gastroenterology
- Acute Care
- Neonatal therapeutic areas
- Obesity related pharmacology
- Biodefense
- Neuro/Psych

Note: Although the activities will primarily occur in the United States (US), NICHD anticipates that approximately 10% of activities may occur in non-U.S. sites such as the European Union (EU).

### III. TECHNICAL REQUIREMENTS

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary resources, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government under the terms of this Contract, as needed to perform the technical requirements outlined below through the individual Task Orders (TOs). In each task order, the Contractor shall include an educational component with the purpose of encouraging the development of pediatric pharmacology researchers.
A. PTN Start-Up Activities,

1) The Contractor shall conduct an Initial Kick-off Meeting to include the Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB) staff, the COR, and other Government officials in the Rockville area. The purpose of the meeting will be to introduce the PTN and BPCA DCC key staff, to orient the Contractor about the mission of the OPPTB and BPCA, to discuss plans for developing a work plan, utilizing the “Collaborative Web-Based Workspace” (described below under III.3.a.), and determine a schedule of activities for the BPCA-PTN.

2) Immediately after the Initial Kick-Off meeting, the Contractor shall establish a “Program Management Team (PMT)”. The PMT will be responsible for the following:

   Efficiently plan, implement, and manage all Task Orders (TOs) as they are awarded. The PMT follows NICHD established standard policies and procedures for ensuring effective and consistent communication with the Contractor, other Consortium partners, the Contracting Officer’s Representative (COR), and the Contracting Officer (CO).

   The PMT will be led by a Principal Investigator (PI) or another senior staff person who will serve as the point of contact to the COR and the BPCA Data Coordinating Center (DCC) PI to ensure effective management and quality control of all staff administering the Task Order. The PI (or key staff) shall ensure quality control of all task activities, and ensure progress of projects undertaken by subcontractors.

   This team shall include administrative staff capable of managing a complex operation that at a minimum includes: collaborating with multiple personnel; awarding and overseeing multiple subcontracts; managing financial activities of the contract and individual tasks; creating technical/finance reports of all activities conducted by the Contractor and its subcontractors, and providing overall quality assurance of network operations.

   Provide access to medical writers, research analysts, statisticians, protocol managers, quality control, and information technology (IT) staff capable of collaborating and supporting partners in the Government, the BPCA Consortium, and key staff working on individual Task Orders. The Contractor shall ensure consistency when overseeing the conduct of recurring clinical trial activities awarded via issuance of individual Task Orders.

   1. The Contractor shall develop a Draft Work Plan and provide a copy to the COR, for review and comment, a draft work plan and timelines for activities.
      a. The Draft Work Plan shall be provided for comments to the COR after the Kick-Off meeting.
b. The Contractor shall revise the Draft Work Plan based on comments by the COR, finalize and return to the COR.

c. At a minimum, the Draft Work Plan shall address the following:
   i. Key staff roles and responsibilities for financial management; subcontracting; managing conflicts of interest; and satisfying reporting requirements.
   ii. Criteria, measures and methods to objectively evaluate the effectiveness, productivity, and overall performance of the BPCA-PTN and subcontractors.
   iii. Processes to maintain weekly contact with the COR with respect to all activities performed.
   iv. Processes to manage collaborations with other Consortium partners (described below).
   v. A tentative schedule of regular meetings and conference calls/webcasts with the COR.
   vi. A plan to communicate revised procedures and problems.
   vii. A summary of reporting requirements and deliverables.

d. The Final Work Plan shall be dated and posted on the Collaborative Web-Based Workspace’s website for reference.

e. The Final Work Plan shall be modified and updated as needed to reflect newly adapted processes or activities.

B. Specific Focus Areas

1) Core Function Activities

Provide oversight and administrative support to ensure the efficient planning, collaboration with Consortium partners, implementation and management of all TOs awarded under this Contract. The Contractor will provide core staffing to ensure continuity of operations and ensure overall quality management of the Contract by: ensuring effective and consistent communication with the COR, the Contracting Officer (CO), and Principal Investigators (PIs) of individual TOs and the Consortium partners; overseeing TOs administration and ensuring quality control in individual TOs; managing subcontractors; providing regular technical and financial status reports including all ongoing projects (TOs).

a. The Contractor shall ensure coherency with the Network operations including, but not limited to the following: planning, overseeing, and managing all individual TOs; and defining activities to ensure collaboration among the Consortium partners, Government staff, and individual staff responsible for the success of each TO.

b. Provide the requisite staffing, equipment and resources to develop and maintain a technical and administrative infrastructure to efficiently plan, implement and manage all TOs. The Contractor shall establish a standard process to ensure effective and consistent communication with the Contractor, Consortium partners, COR and the CO.
c. This technical and administrative infrastructure shall include a PI (or other key staff) who will be the point of contact and ensure effective communications and management of all staff who will administer the Contract, support individual TOs, and collaborate with the Consortium partners. The PI (or senior staff) will ensure quality control of all task activities, and oversee the status and progress of projects undertaken by subcontractors.

d. This infrastructure shall manage and oversee a large and complex operation that includes administering complex contractual and TO activities; overseeing multiple subcontractors and consultants; ensuring quality control of the projects, and producing financial and technical status reports on all activities conducted through the individual TOs.

e. The Contractor shall provide the requisite personnel including medical writers, research analysts, statisticians, protocol managers, quality assurance personnel, and Information Technology (IT) staff to efficiently collaborate with partners in the Government and the Consortium Partners. The Contractor shall ensure consistency when overseeing the conduct of clinical trial activities awarded via individual TOs.

f. As required by the COR, the Contractor shall interact with researchers who will be performing pre-clinical and clinical trial activities with researchers engaged in other NIH trials, e.g., the National Cancer Institute (NCI), the National Institute of Mental Health (NIMH), the National Heart Lung and Blood Institute (NHLBI) and the National Institute of Neurological Diseases and Stroke (NINDS).

2) Establish and Maintain a Network Steering Committee (NSC):

This committee shall be comprised of approximately seven (7) to twelve (12) members as needed. Steering Committee membership shall change and shall include experts and leaders in pediatrics, clinical pharmacology, drug safety, toxicology, public health, and ethics, etc. The COR and other representatives from the Government and Consortium Partners will participate as needed.

a. The Contractor shall conduct the following, as required:

1. Assemble an NSC comprised of clinicians and researchers who will create a document for guidance in overall project planning, including prioritization of activities; determining study feasibility; considering design issues; reviewing data analysis and discussing proposed approaches for publishing findings of studies conducted.

2. Assemble a nomination package of potential experts for each NSC that will include the following:
   a) a Curriculum Vitae;
   b) training and/or experience;
   c) international recognition of the individual, and;
   d) willingness to serve for a specified period and participate in face-to-face meetings, conference calls and/or webcasts.

3. Arrange and support webcasts, teleconferences and in-person meetings.
4. Assist and support the NSC in creating a guide document, including the provision of logistics staff to arrange activities; research analysts to provide background info; and medical writers to help summarize discussions, meetings, and calls.

5. Oversee the review, editing and formatting of the draft “guide” document.

6. Provide the draft to the COR for comment and editing.

7. Incorporate COR’s comments/edits and finalize the document.

8. A copy of the final guide shall be sent to the COR and CO and posted to the collaborative website for reference.

3) Protocol Development

a. Immediately after the Initial Kick-Off meeting, the Contractor shall begin working on identifying researchers and clinicians to establish Protocol Development Teams (PDT). The PDT shall provide expertise in selected therapeutic areas to design clinical trial study protocols. The PDT shall be comprised of, but not limited to, the Principal Investigators, Co-Investigators, Project Leaders, Medical Writers, Protocol Chairs, Research Analysts and Clinical Pharmacologists/Toxicologists.

b. The PDT will be responsible for developing the clinical protocols and informed consent forms prior to the initiation of any study including primary and secondary endpoints, and determining specific safety measures. The finalization of the protocol will be completed under the study task order. These collaborations will result in a draft protocol that will be used for the conduct of subsequent studies. In most instances, the PDTs will be physicians who practice medicine in the relevant therapeutic area, can recruit and retain the patient population for a particular drug study, and who may be available to participate as a PI in the resultant clinical study.

c. The PDT shall provide expertise in areas including: pharmacokinetic/pharmacodynamic/pharmacogenetic (PK/PD/PG), dose-response data, designing a sparse PK sampling strategy, and/or a dense sampling strategy if no prior information is available, identifying an assay for the drug substance and relevant metabolites, identifying potential PD measures; and identifying potential PG markers that may be correlated with drug disposition and/or response.

d. Work together with the BPCA-DCC in the protocol development process.

e. Provide logistic support and/or medical writers for the PDTs and arrange, prepare and support communications for:
   1. kick-off meetings;
   2. weekly conference calls or webcasts;
   3. minutes, summaries, action items.

f. Provide statistical support for analysis of study design and results, for secondary analyses as requested by the COR.

g. Oversee creation of deliverables, e.g., Protocols - After deliberations, the group shall prepare and submit to the COR a Project Plan (i.e., protocol) detailing how a particular study will be accomplished, including safety and efficacy endpoints, as well as PK/PD/PG or dose-response data collection. Protocols in general shall include the following:
1. A brief introduction to the study, proposed methods for addressing the disease area, anticipated problems and their possible resolution, and a description of the patient population.

2. An estimate for the number of sites needed by the nature of the protocol and number of participants needed for timely completion of the proposed studies (in most instances these sites will be academic health centers and/or community based pediatric practice sites that provide medical care for children).

h. Identification of potential suitable vendors such as central laboratories, drug formulation and distribution companies, etc.

i. After comment and approval by the COR and BPCA-DCC, the Contractor shall post the final draft protocol to the collaborative website.

4) Conduct Pediatric Clinical Studies

The Contractor shall provide experts and support collaborations with the following groups: researchers capable of designing clinical pharmacology studies and analyzing data groups; clinicians capable of recruiting and retaining the patient population and conducting the trial; and DCC staff who will assist in finalizing the protocol and facilitating data transfer from pediatric clinical trials of the prioritized drugs to characterize PK/PD, safety and efficacy in infants, children and adolescents.

a. Establish a Pediatric Therapeutic Area Group (PTAG)

The PTAG is comprised of researchers and/or clinicians with knowledge and expertise of the specific therapeutic area as required. These experts shall be identified and selected by a competitive process based on their knowledge of the therapeutic area and ability to provide the patient population. They shall collaborate with select members of the BPCA-DCC (e.g., statisticians and medical writers) to finalize the protocol to guide the clinical study.

The PTAG will be responsible for:

1. finalizing the protocol.
2. may subsequently perform as PI(s).
3. selecting study sites for trial purposes will be based on a critical screening process.
4. overseeing recruitment and retention of the patient population for study performance.
5. overseeing data collection and transfer of data to the BPCA-DCC according to the protocol (including processing, storage and shipping of all biological fluids, entering data into eCRFs).
6. responding to data queries and participation in monitoring visits and audits by the BPCA-DCC as needed; patient safety follow-up as indicated in the protocol, participating in the creation of a clinical report, and publishing study results.
7. participate in the analysis and publication of data generated from the studies.
b. Perform Core Clinical Pharmacology Activities

The Contractor shall perform routine, non-research, regulatorily compliant pharmacology study design and analyses in support of clinical trial activities that may include but not be limited to the following:

1. Evaluate literature for PK/PD/PG relationships based on existing data.
2. Incorporate pertinent (PK/PD/PG) measures into clinical trial design.
3. Design the PK/PD/PG portion of the clinical studies, including population PK and/or dense sampling designs, for incorporation into protocol in collaboration with study PI(s) on inclusion of pertinent clinical PD, safety and efficacy endpoints.
4. Develop sensitive and specific chemical assays of study drugs and metabolites in small volumes of biological fluids.
5. Perform the drug assays on all collected biologic fluids, including blood, urine, sputum and others.
6. Provide PK/PD/PG data analysis expertise, perform analyses of clinical data.
7. Ensure available data is transferred to the BPCA-DCC.
8. During the course of the study, perform interim analyses of data as indicated to inform the study design.
9. Provide residual samples to the NICHD Repository, unless the COR requests otherwise.
10. Provide PK/PD/PG report that will form the basis for the FDA submission and future publications.

c. Planning, Oversight and Conduct of Clinical Studies

The Contractor shall ensure the effective planning and oversight of clinical activities including, but not limited to the following:

1. Overall Compliance
   a) Operate in compliance with all Federal Regulations and NIH policies applying to the conduct of all research involving human subjects including Title 21 CFR 50, 56, and 312, and HHS Title 45 CFR 46.
   b) Ensure compliance with Good Clinical Practice (GCP) standards as described by the FDA and the International Committee on Harmonization (ICH).
   c) Participate in the development of the core safety monitoring plan.
   d) Ensure that each site conducting clinical trials has a current, approved Federal-Wide Assurance Number on file with the Office for Human Research Protection.
   e) Operate in compliance with the Europe, the Middle East and Africa (EMEA) and the European Commission (EC), and ICH guidance, as required.
f) Laboratory Requirements - All methods shall be validated according to the laboratory’s Standard Operating Procedures on the conduct of bioanalytical method validations and in compliance with:
   i. FDA’s Good Laboratory Practice (GLP) regulations (i.e., US CFR Title 21 Part 58) (when applicable).
   ii. FDA’s Guidance for Industry on Bioanalytical Method Validation.
   iii. FDA’s Electronic Records and Signatures Regulations (i.e. US CFR Title 21 Part 1).
   iv. Laboratory Written Protocol under the direction of a qualified Study Director’s Management.

2. Collaborative Activities

The Contractor shall ensure an effective and efficient collaboration with the BPCA-DCC and NICHD Repository, which at a minimum will require the following:

a) Work with the BPCA-DCC to develop and implement Manual of Procedures (MOP) for each study which details the relationships and responsibilities amongst the PTGs, PTN, BPCA-DCC and NICHD Repository.

b) Work with the BPCA-DCC in providing the requisite education and training.

c) The Contractor shall collaborate with the BPCA-DCC to ensure that all necessary documentation is FDA compliant, and in some cases, EMEA compliant.

d) Review, coordinate and adapt the BPCA-DCC randomization process.

e) Follow the quality assurance procedures and implement the protocol-specific monitoring plans developed by the BPCA-DCC.

f) Contractor and sub-contractors shall be accessible for periodic site visits by personnel from the BPCA-DCC and the NICHD to discuss progress and problems and to review data.

g) Present a continuous laboratory monitoring plan, acceptable to the COR and BPCA-DCC that will conform with the FDAs “Guidance for Industry Bioanalytical Method Validation”.

h) Provide the BPCA-DCC with all the required data elements included in the BPCA-DCC’s information system.

i) Ensure that data is correctly transmitted to the BPCA-DCC.

j) Ensure that information requested by the BPCA-DCC and/or COR or the FDA is provided to assure regulatory compliance for research activities of the clinical sites.

k) Provide residual samples to the NICHD repository, unless the COR requests otherwise.
3. Conduct Clinical Studies

a) Manage the design, performance and analysis of pediatric clinical trials needed to characterize PK/PD/PG, safety and efficacy of the study drugs.
b) Identify potential clinical sites and ensure that they have the necessary specialized equipment (hardware and software) and training for sites to electronically communicate with the prime Contractor, and the BPCA-DCC, when applicable.
c) Ensure the biological specimens are properly collected, processed, stored and transferred as necessary for further analysis.
d) Ensure that all sites, under the guidance of the COR and with the technical support of the BPCA-DCC, when needed, properly use the randomization process and relevant operational procedures developed by the BPCA-DCC.
e) Oversee the timely recruitment and retention of patients; monitor progress and activities of the sites, changing or adding sites as needed to ensure adequate and timely completion of studies.
f) Ensure that data is appropriately entered into the electronic Case Report Forms (eCRFs) in accordance with BPCA-DCC’s policies and procedures.
g) Respond to data queries and participate in monitoring visits and audits by the BPCA-DCC, as needed.
h) Ensure patient safety follow-up as indicated in the protocol.
i) Respond to all queries from the BPCA-DCC regarding problems with the entered data and achieve resolution of these problems.
j) The site PI and pertinent site personnel shall prepare for and be accessible for periodic Site Visits and audits by personnel from the BPCA-DCC and the COR to discuss progress and problems and to review data. These visits and audits may occur at site initiation, interim/study mid-point and closeout.

4. Post Clinical Requirements

a) Collaborate with the BPCA-DCC to ensure transfer of data from the clinical sites to the BPCA-DCC. (Primary data analyses as specified in the protocol will be performed by the BPCA-DCC.)
b) Obtain standardized format de-identified public use data sets (i.e., user friendly) from the BPCA-DCC for utilization by studies PIs and other investigators for potential meta-analysis or reanalysis of the data, for ancillary research in conjunction with preparation of manuscripts for publication or meeting presentations.
c) Provide residual samples as required for storage at the NICHD Repository, unless the COR requests otherwise.

5. Meetings and Travel:

a) Contractor shall participate in regular/progress meetings related to the conduct of clinical trial activities.
5) Develop Formulations for Pediatric Use

Produce a liquid, “flexible dosing” solid dose or other easily swallowed formulation of a readily available and FDA approved drug substance. The Contractor will not be required to produce novel molecules in the conduct of these activities.

As requested, the Contractor will manufacture pediatric friendly formulations of candidate drugs that may be used in clinical trials.

a. The PTN shall perform the following, as required by Task Order:

1. Perform pre-formulation studies to determine physical/chemical properties of drug substances targeted for formulation development as required. These determinations may include the following:
   a) Identification of Biopharmaceutical Classification System (BCS) classification, partition coefficients, solubility in various solvents, pH-solubility profiles, pH-rate profiles, expected taste problems (bitterness) identification of drug-excipient interactions and estimates of short term stability.
   b) Drug concentration, identity, integrity, purity, potency, and contamination required for release for clinical use.
   c) Assessment of post-production stability, and Bioavailability and bioequivalence studies and food-effects studies of research formulations (a formulation that is not commercially available).

2. Develop New Dosage Forms

Develop an oral pediatric dosage form, which is designed to achieve progress toward one or more of the following goals:

   a) enhanced drug solubility in any clinically-relevant vehicle, but especially hydrophilic vehicles with clinical potential.
   b) enhanced drug stability to protect the drug from degradation during shipment or storage.
   c) improved bioavailability to deliver greater amounts of drug to the blood after oral administration.
   d) acceptability (taste) for specialized (e.g., pediatric) use.
   e) consideration “Flexible Dosing” Solid Dose Forms.

3. Conduct Pilot-Scale Manufacturing

   a) Manufacture pilot batches of pharmaceutical dosage forms designed to be administered to children, to evaluate the feasibility of manufacturing the dosage form for use in clinical trials.
4. Conduct Good Pharmacovigilance Practice (GVP)-Compliant Manufacturing of Clinical Supplies

a) Manufacture, process, package, and label production batches of pediatric dosage forms in full compliance with current 21 CFR sections 210 and 211, Good Manufacturing Practice (GMP) the and ICH regulations for use in NICHD sponsored or other clinical trials.
b) Final batch size and label design will be designated by the COR and will depend on the specific drug and its intended use.

5. Perform Quality Control Testing

a) Conduct quality control testing on bulk drug substances, and on pilot batches, and on production batches of dosage forms manufactured in compliance with current GMP requirements.
b) Tests shall depend on the type of dosage form and will be designated by the COR after consultation with the Contractor.
c) Tests shall include determinations of drug identity and purity, content uniformity, weight variation, particulate matter, pH, residual moisture and dissolution/disintegration characteristics.

6. Conduct Shelf Life Stability Studies

Conduct shelf life stability studies on production batches of dosage forms manufactured in compliance with current GMP requirements, under both ambient and accelerated conditions for a period of no less than two years with standard interim sampling.

7. Document the Characteristics of Drug Substances and Drug Products

a) As appropriate for particular investigations covered by an Investigational New Drug (IND) application, provide written hard copy documentation (e.g., Certificate of Analysis or equivalent) pertaining to the composition, manufacture and quality control of the drug substance and the manufactured drug product in sufficient detail such that it can be submitted to the FDA as part of an IND application.
b) This documentation shall include information contained in master production and control records, batch production and control records and/or laboratory records.

8. Ship Clinical Batches

a) Ship the manufactured, packaged and labeled clinical dosage forms to the sites.
b) Clinical dosage forms shall be labeled appropriately and packaged in a form suitable for the specified clinical trial.
c) The Contractor shall utilize shipping procedures and materials that maximize product stability. Destination sites and any special shipping requirements will be designated by the COR.

9. The Contractor shall ensure the following:

a) Provision of documentation in formats that meet FDA submission requirements.
b) Oversight and audit of facilities and studies to ensure personnel, equipment and facilities are compliant with FDA regulatory requirements.
c) Evaluation of production and laboratory reports, or oversight and/or audit manufacturing and test facilities to ensure that personnel, equipment and facilities are compliant with the requirements of the relevant health authorities in the countries in which the proposed clinical trial study sites are located.

10. Collaborative activities

a) Oversee collaborations with the BPCA-DCC to ensure receipt of FDA-compliant reporting regarding drug manufacturing.

6) Establish and Maintain a Drug Distribution Center

Purchase, dispense and provide quality control of study products for clinical trials (PRN). The Contractor shall provide the following support during pre-clinical and clinical drug studies:

a. Purchase, receive, store, label, package, ship and distribute study products.
b. Provide Inventory control and quality assurance of study supplies for each protocol.
c. Provide written reviews, reports, transfers, packaging, storage, dosage, labeling, usage and returns of products in conjunction with the COR’s approval while establishing a secure clinical web site for clinical site pharmacists that supplies protocol-specific information and requirements.
d. Provide security/safety measures and procedures.
e. Process and dispose of returned and unused drug product.
f. Provide record maintenance; and services to facilitate an orderly transfer of all or part of the projects, as required by the COR and CO.

7) Oversee Clinical Trials in Pediatric Device Development or Validation

Ensure the effective planning and timely integration of multiple contributions from different disciplines (including medical and engineering expertise) in the conduct of device development activities.
8) Ancillary Requirements

Provide Analysis of Previous Studies – analyze data or findings; conduct literature reviews; develop publications of studies.

The Contractor shall support the following activities as requested:

a. Provide statistical leadership or clinical trial design expertise for the development of protocols and analysis of study data.

b. Provide consultants across the course of study for independent advice to NICHD/NIH who may have expertise in chemistry, medicinal chemistry, ethics, pharmacokinetics for input in pre-clinical and clinical studies.

c. Provide expertise in epidemiology, and medical subspecialty expertise in various areas such as mental health, obstetrics, and infectious disease, among others.

d. Submit data to NICHD that is consistent with FDA requirements for labeling.

e. Provide support services for literature and information gathering (including labels), review, summary, publication.

f. Provide analysis of conditions and medication use in pediatric populations (health services, feasibility, cost, number of sites, etc.).

g. Collaborate with the BPCA-DCC on Publications and Communications

i. Develop and implement policies and procedures for authorship, preparation, review, and final approval of manuscripts resulting from studies, and for submission of manuscripts for publication in peer reviewed journals. The Contractor/Sites must submit manuscripts to the COR for NICHD approval before submission to journals.

j. Design and maintain a publicly-accessible, Americans with Disabilities Act Section 508-compliant, internet-based website to provide information regarding PTN activities for study sites as well as lay and scientific audiences. Information about Section 508 can be found at http://www.section508.gov.

9) Initiate Pediatric Device Development

The Contractor shall effectively support and oversee device development activities that generally will include the following subtasks:

a. Stakeholder Input

1. Assemble experts that may include clinicians, engineers, community and/or advocacy groups to obtain input regarding prioritization and feasibility of pediatric device development activities.

2. Provide reports outlining the group’s findings and suggestions for device development.
b. Product Development

1. Integrate a multi-disciplinary team of engineers, statisticians, clinicians, laboratory personnel and others to develop, design and evaluate device development plans and needed clinical studies.
2. NICHD anticipates that work in device development will involve outcome measure, and clinical validation of devices that can be used in children.

c. Collaborative activities

1. Ensure that there is compliance with the regulatory aspects of the device development process.
2. Ensure the data sets will be submitted to the BPCA-DCC for submission to the FDA.
3. Work collaboratively with subject matter experts to improve efficacy of research management and to develop best practices, policies and procedures.

10) Oversee Contract Transition

Develop a Final Transition Plan

The Contractor shall develop a Final Transition Plan prior to the expiration date of the IDIQ Contract. At a minimum, the transition plan shall include the following items and any additional information the Contractor deems necessary for an orderly transition:

a. Schedule for delivery of data, datasets, databases, and/or systems developed under this Contract to the COR or designated entity, including study files, call center, and websites.

b. List of open trials and actions needed to ensure their continuation or completion during the transition period.

c. List of INDs and any actions or reports due during the transition period and plan for the submission of new INDs.

d. List of incomplete remedial site actions or open safety issues and plan for their resolution.

e. List of facilities and equipment support provided and any scheduled support to be provided during the transition period.

f. Provide a list of subcontracts with a transition plan.

g. At a minimum, the final transition plans shall include an estimate of cost, time frame to complete transition, and the staff required to execute a successful and timely transition.

h. Should the responsibilities of this Contract be transferred to a successor Contractor or to the Government, the Contractor shall provide the following deliverables not later than the expiration date of the IDIQ Contract:
1. A cleaned and edited data set, on media and in a format determined by the COR and copies of all data management tools, including data documentation,
data dictionaries, and data entry software and editing programs to allow reading and analysis of the data.

2. All computer programs used for reading, cleaning, manipulating, graphing, and analyzing data and programs used for generating new datasets.

3. An audit trail of all raw data corrections, hard copies of the original data collected from study participants from all studies conducted under this Contract, and all logs and other records related to data collection, entry, editing, analysis, and transfer.

4. Final Report with summaries of analyses performed by the Contractor through all TOs issued under this IDIQ Contract.
STATEMENT OF WORK
Task Order 1

IDIQ Contract Title: Best Pharmaceuticals for Children Act (BPCA) Pediatric Trials Network (PTN)

Task Order 1 Title: Core Function Activities

Period of Performance: Base Year and Four (4) 12-Month Option Periods

I. BACKGROUND AND INTRODUCTION:

Throughout the years, several practical problems have discouraged drug testing in children. These include the lack of a suitable infrastructure to conduct pediatric pharmacology research; the unforeseeable nature of some clinical responses in immature individuals; the possibility of unanticipated adverse reactions; the threat of effects on growth, development or health, long after the drug's administration, and difficulties predicting dose or concentration-response relationships by extrapolating data obtained in adults or experimental animals. Researchers and clinicians involved in pediatric drug development face daily challenges that include, but are not limited to the following: the need to obtain parental permission and/or the child's assent; ethical issues related to the conduct of non-therapeutic research in children; the lack of technology applicable to children; and the lack of incentives that would encourage pharmaceutical companies to study drugs in neonates, infants, children and adolescents.

There is a significant unmet need for pediatric therapeutic and diagnostic device development. Despite these challenges, the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) is aware of the critical need to establish and maintain an environment in which safe and effective pediatric clinical and device trial activities can quickly be initiated and managed.

II. SCOPE:

The purpose of this Task Order is to establish and maintain centralized teams of experts who will develop protocols and informed consent forms and oversee, monitor and support all scientific and clinical aspects of research activities under the BPCA-PTN IDIQ contract.

III. TECHNICAL REQUIREMENTS:

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary resources, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government under the terms of this task order, as needed to perform the Statement of Work (SOW) as defined below.

A. PTN Start-Up Activities – As directed by COR and CO:

1. The Contractor shall conduct one (1) Initial Kick-off Meeting within seven (7) days of this Task Order award, arrange a one-day meeting with the Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB) staff, the COR, and other Government officials in the Rockville
area. The purpose of the meeting will be to introduce the PTN and BPCA DCC key staff, to
orient the Contractor about the mission of the OPPTB and BPCA, to discuss plans for developing
a work plan, utilizing the “Collaborative Web-Based Workspace” (described below under
III.3.a.), and determine a schedule of activities for the BPCA-PTN.

2. The Contractor shall establish a “Program Management Team (PMT)” no later than seven (7)
days after Task Order award. The PMT will be responsible for the following:

   a. Efficiently plan, implement, and manage all Task Orders (TOs) as they are awarded. The
      PMT follows NICHD established standard policies and procedures for ensuring effective and
      consistent communication with the Contractor, other Consortium partners, the Contracting
      Officer’s Representative (COR), and the Contracting Officer (CO).
   b. The PMT will be led by a Principal Investigator (PI) or another senior staff person who will
      serve as the point of contact to the COR and the BPCA Data Coordinating Center (DCC) PI
to ensure effective management and quality control of all staff administering the Task Order.
The PI (or key staff) shall ensure quality control of all task activities, and ensure progress of
projects undertaken by subcontractors.
   c. This team shall include administrative staff capable of managing a complex operation that at
   a minimum includes: collaborating with multiple personnel; awarding and overseeing
   multiple subcontracts; managing financial activities of the contract and individual tasks;
   creating technical/finance reports of all activities conducted by the Contractor and its
   subcontractors, and providing overall quality assurance of network operations.
   d. Provide access to medical writers, research analysts, statisticians, protocol managers, quality
   control, and information technology (IT) staff capable of collaborating and supporting
   partners in the Government, the BPCA Consortium, and key staff working on individual
   Task Orders. The Contractor shall ensure consistency when overseeing the conduct of
   recurring clinical trial activities awarded via issuance of individual Task Orders.

3. The Contractor shall develop a Draft Work Plan and provide a copy to the COR and the CO, for
review and comment, a draft work plan and timelines for activities.

   a. The Draft Work Plan shall be provided for comments to the COR within ten (10) business
days of the Initial Kick-off meeting.
   b. The Contractor shall revise the Draft Work Plan based on comments by the COR, finalize
and return to the COR within ten (10) business days of receipt.
   c. At a minimum, the Draft Work Plan shall address the following:
      i. Key staff roles and responsibilities for financial management; subcontracting;
         managing conflicts of interest; and satisfying reporting requirements.
      ii. Criteria, measures and methods to objectively evaluate the effectiveness, productivity,
         and overall performance of the BPCA-PTN and subcontractors.
      iii. Processes to maintain weekly contact with the COR with respect to all activities
         performed.
      iv. Processes to manage collaborations with other Consortium partners (described below);
      v. A tentative schedule of regular meetings and conference calls/webcasts with the COR;
      vi. A plan to communicate revised procedures and problems.
      vii. A summary of reporting requirements and deliverables.
d. The Final Work Plan shall be dated and posted on the Collaborative Web-Based Workspace’s website for reference.

e. The Final Work Plan shall be modified and updated as needed to reflect newly adapted processes or activities.

4. Establish and Maintain a Network Steering Committee (NSC):

This committee shall be comprised of approximately seven (7) to twelve (12) members as needed. Steering Committee membership shall change and shall include experts and leaders in pediatrics, clinical trialists, clinical pharmacology, drug safety, toxicology, public health, and ethics, etc. The COR and other representatives from the Government and Consortium Partners will participate as needed.

a. The Contractor shall conduct the following, as required:

i. Assemble an NSC comprised of clinicians and researchers who will create a document for guidance in overall project planning, including prioritization of activities; determining study feasibility; considering design issues; reviewing data analysis and discussing proposed approaches for publishing findings of studies conducted.

ii. Assemble a nomination package of potential experts for each NSC that will include the following:
   a) a Curriculum Vitae
   b) training and/or experience
   c) international recognition of the individual
   d) willingness to serve for a specified period and participate in face-to-face meetings, conference calls and/or webcasts

iii. Arrange and support webcasts, teleconferences and in-person meetings.

iv. Assist and support the NSC in creating a guide document, including the provision of logistics staff to arrange activities; research analysts to provide background info; and medical writers to help summarize discussions, meetings, and calls.

v. Oversee the review, editing and formatting of the draft “guide” document.

vi. Provide the draft to the COR for comment and editing.

vii. Incorporate COR’s comments/edits and finalize the document.

viii. A copy of the final guide shall be sent to the COR and CO and posted to the collaborative website for reference.

B. Protocol Development

1. Immediately after the Initial Kick-Off meeting, the Contractor shall begin working on identifying researchers and clinicians to establish Protocol Development Teams (PDT). The PDT shall provide expertise in selected therapeutic areas to design clinical trial study protocols. The PDT shall be comprised of, but not limited to, the Principal Investigators, Co-Investigators, Project Leaders, Medical Writers, Protocol Chairs, Research Analysts, Research Coordinators, and Clinical Pharmacologists/Toxicologists.

2. The PDT will be responsible for developing the draft clinical protocols and informed consent forms prior to the initiation of any study including primary and secondary endpoints, and
determining specific safety measures. The finalization and implementation of the protocol will be completed under the study task order. These collaborations will result in a draft protocol that will be used for the conduct of subsequent studies. In most instances, the PDTs will be physicians who practice medicine in the relevant therapeutic area, can recruit and retain the patient population for a particular drug study, and who may be available to participate as a PI in the resultant clinical study.

3. The PDT shall provide expertise in areas including: pharmacokinetic/pharmacodynamic/pharmacogenetic (PK/PD/PG), dose-response data, designing a sparse PK sampling strategy, and/or a dense sampling strategy if no prior information is available, identifying an assay for the drug substance and relevant metabolites, identifying potential PD measures; and identifying potential PG markers that may be correlated with drug disposition and/or response.

4. Work together with the BPCA-DCC in the protocol development process, specifically in the areas of finalizing protocol endpoints, regulatory requirements for the clinical sites, and in the development of statistical analyses plans.

5. Provide logistic support and/or medical writers for the PDTs and arrange, prepare and support communications for:
   a. kick-off meetings
   b. weekly conference calls or webcasts
   c. minutes, summaries, action items

6. Provide statistical support for analysis of study design and results, for secondary analyses as requested by the COR.

7. Provide deliverables, e.g., Final Draft Protocols (submitted under task order 1—see Deliverables section). After deliberations, the group shall prepare and submit to the COR a Project Plan (i.e., protocol) detailing how a particular study will be accomplished, including safety and efficacy endpoints, as well as PK/PD/PG or dose-response data collection. Protocols in general shall include the following:
   a. A brief introduction to the study, proposed methods for addressing the disease area, anticipated problems and their possible resolution, and a description of the patient population.
   b. An estimate for the number of sites needed by the nature of the protocol and number of participants needed for timely completion of the proposed studies (in most instances these sites will be academic health centers and/or community based pediatric practice sites that provide medical care for children).

8. Identification of potential suitable vendors such as central laboratories, drug formulation and distribution companies, etc.

9. After comment and approval by the COR and BPCA-DCC, the Contractor shall post the final draft protocol to the collaborative website.

C. Task Order Management

The Contractor shall perform the following:

1. Provide overall management and support to staff, subcontractors, consultants, and Consortium partners responsible for overseeing and conducting the individual Task Orders, including development of Standard Operating Procedures (SOPs) for the Network.

2. At a minimum, it will include providing the following personnel: management staff, administrative support, budget personnel, medical writers, logistics staff, research analyst, protocol writers, etc.
3. Track task-specific costs when submitting monthly invoices against the Task Orders.
4. Provide a biannual report (see below “Reports”) that provides the overall status of the IDIQ contract, including a summary of individual Task Orders. The Contractor shall provide a summary for all task activities that will include at a minimum the following:
   a. Ongoing tasks and their periods of performance
   b. Level of funding of individual Task Orders and modifications
   c. Technical successes and challenges
   d. Detailed fiscal reporting for each Task Order will be required monthly. This information generally shall include: total direct labor; accountable personal property; supplies; travel; clinical trials; subcontracts; service agreements for laboratories and laboratory facilities; vendor agreements; prime contract and subcontract indirect rates and costs; and total obligated and expended amounts.

D. Information Technology

Management Portal - the Contractor shall utilize the Collaborative Web-Based Workspace (or portal) developed by the BPCA-DCC to store and access current and relevant information including:

2. Minutes from teleconferences, meetings and webcasts.
3. Current and past technical reports.
4. Contractor shall also adopt and utilize the BPCA-DCC web-based Data Collection and Management System for data generated under BPCA trials.

E. Consortium Activities

This Task Order shall provide the requisite staffing and oversight to establish and maintain a collaborative environment that will use the BPCA DCC Standard Operating Procedures (SOP) to streamline recurring activities among BPCA Consortium partners. At a minimum, these activities will include interaction with the following partners:

1. The BPCA-DCC - is responsible for overseeing data quality of the BPCA clinical trials, for preparing and submitting all regulatory documents to FDA, and managing the Data and Safety Monitoring Board (DSMB) which has been established for BPCA trials.¹
   a. Specifically, the BPCA-PTN shall contact the BPCA-DCC to establish a time to meet with the PI and other key staff within two (2) weeks after the Effective Date of the Task Order (EDOTO) to begin discussing various roles and responsibilities of the BPCA-PTN and the BPCA-DCC.
   b. The goal of the first meeting will be to discuss plans for developing a MOP that shall be submitted to the COR within six (6) weeks of Task Order award.
   c. Specifically, the BPCA-PTN staff shall work with the BPCA-DCC to develop procedures that guide the operations of the BPCA-PTN and the BPCA-DCC, including a table outlining the BPCA-PTN and the BPCA-DCC staff responsibilities for data transfer, publication policy,

¹ The DCC is responsible for arranging meetings and calls that directly relate to Consortium activities, e.g., scheduling, providing note takers, maintaining records of the meetings, and creating a Consortium web space.

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training for protocol implementation and data entry, site monitoring visits, and tertiary statistical analysis that will occur and be billed to relevant Task Orders as needed.

d. Other topics for discussion will include details of the BPCA-DCC’s Electronic Data System, their responsibilities for ensuring and housing proper forms, an understanding of site monitoring, and all activities to ensure compliance with all regulatory guidelines for efficient data transfer to the BPCA DCC, when needed for BPCA.

e. Ensure an understanding by key staff that all appropriate regulatory documents generated under through the individual Task Orders are provided to the BPCA DCC in an efficient cost-effective manner.

- During the first quarter of Task Order award anticipate a minimum of one weekly (one-hour) face-to-face meetings at NICHD facilities in Rockville, MD with approximately eight key staff.

- Following the first quarter after the EDOTO, anticipate quarterly Consortium meetings during the life of the Task Order in Rockville, MD with approximately eight key staff.

2. The NICHD Repository - The Contractor shall meet with the NICHD Repository Contractor to create a streamlined process to ensure an effective and efficient collaboration for providing and receiving samples from the NICHD Repository that, at a minimum, will require the Contractor to:

a. Schedule a meeting with the NICHD Repository within eight (8) weeks of the EDOTO to review procedures which will be submitted to the COR within two (2) months after the EDOTO.

b. Generate audit trails and reports from the system at any point in the process to determine the status of a specific sample or batch of samples and to identify problems in the processing pipeline.

c. Ensure the quality and integrity of the data generated throughout this process.

d. Ensure that the type, number and volume of participant samples required are available.

e. Consult clinical sites on the appropriate collection, testing, storage, and shipping of participant samples.

f. The Contractor shall work with individual clinical sites as needed to understand these procedures.

3. Data and Specimen Hub (DASH) - shall be utilized for completed trials data. It is a centralized resource for researchers to store and access de-identified data from NICHD-funded research studies for the purposes of secondary research use. It serves as a mechanism for NICHD-funded extramural and intramural investigators to share research data from studies in accordance with the NIH Data Sharing Policy and the NIH Genomic Data Sharing Policy.

F. Logistic Activities

The PTN activities will require an extensive level of communication with the NICHD COR and CO, subcontractors, and Consortium partners both at the contractual level, and during individual Task Orders performance. This Task Order relates to the overall management structure of the BPCA-PTN. Costs relating to meetings, calls, webcasts or travel for individual Task Orders activities should be applied to those Task Orders. At a minimum, the anticipated logistic activities under this Task Order include the following:
1. Consortium meetings - Preparation of agenda items; a list of participants; and meeting materials that relate specifically to BPCA-PTN activities, as stated above. A list of the BPCA-PTN action items resulting from the meetings shall be provided.

2. Progress meetings in general shall include the COR, BPCA-PTN PI and/or BPCA-PTN key staff, to be held at NICHD offices to discuss overall program management, including discussions of staffing, quality control, etc.
   a. At a minimum, during the first six (6) months of the Task Order the Contractor shall coordinate with the COR to arrange monthly meetings to discuss overall project/program progress.
   b. After six (6) months, these face-to face meetings shall occur, and be arranged, quarterly for the duration of the Task Order.

3. Conference calls or webcasts – at a minimum the Contractor shall schedule weekly conference calls between the COR and the BPCA-PTN PI and/or senior staff, to discuss overall planning, quality management, contractor performance, challenges, determining priorities for implementing new studies; staffing levels to accomplish the TO; deliverables and timelines. The Contractor shall:
   a. Provide a writer to prepare a conference call summary of approximately 2 pages. Summaries shall include a list of participants, issues presented, and a list of action items.
   b. Prepared summaries shall be sent to the COR within three (3) business days for comments and a final summary sent electronically to the COR and CO within three (3) business days.
   c. The final approved minutes shall be stored on the BPCA-DCC management portal as discussed below.

G. Reports

The Contractor will provide regular reporting as defined below that summarizes all activities at the program/project level. These “Reports” relate to the overall status of the program/project both technically and financially. There will also be monthly reports submitted for individual tasks that will provide specific details of task-related activities, deliverables, and costs.

1. Biannual Progress Report:
   This technical report shall include a summation of the results of the work performed and a financial status report covering the six-month reporting period. This report shall be submitted as required in the “Deliverables and Technical Reporting Requirements.” A Bi-annual Report is not required for the period when the Final Report is due.

2. Annual Progress Report:
   This technical report shall include a summation of the results of the work performed and a financial status report covering the twelve-month reporting period. This report shall be submitted as required in the “Deliverables and Technical Reporting Requirements.” An Annual Report is not required for the period when the Final Report is due.

3. Financial Reports:
   Overall financial status including all Task Orders obligations, modifications, and overall expenditures and remaining balances. The contractor shall provide this information in both narrative format, and in a spreadsheet, that contains Task Orders details.

4. The technical reports shall include:
a. Face page to include the contract number, contract title, performance period covered, Contractor’s name and address, telephone number, fax number, email address and submission date.

b. Include a brief “Executive Summary” that includes: a brief overview of the work completed, collaborative activities, and major accomplishments.
   i. Provide a description of the work performed, collaborative activities, and accomplishments achieved under each active task for that year.
   ii. Technical, logistical, or financial problems encountered and how they were resolved.
   iii. A list, description and status of Final Study Reports for trials completed during the reporting period.
   iv. A list, description and justification of laboratory facilities established and current measures of quality assurance and quality control measures.
   v. A list and justification of all subcontracts established or terminated.
   vi. Key personnel changes.
   vii. A list and brief description of all substantive partnerships involving industry, or government-funded clinical research programs. The description must outline the goals of the partnership, obligations of the individual partners, and progress in meeting the major objectives.
   viii. List of Final Study Reports for the entire reporting period and as well as manuscripts and abstracts published or submitted for publication.
   ix. A status report on all clinical trials summarizing adherence to, and deviations from, projected timelines for protocol development, implementation, and completion. The report must outline steps taken, or to be taken, in the next quarterly reporting period to address significant deviations.
   x. A financial status report summarizing invoiced expenditures and the Contractor’s best estimates of actual costs incurred (invoiced plus those to be invoiced). The report must detail the relevant and projected expenditures for each Task Order, considering deviations from projected timelines for completion of studies.
   xi. Full disclosure of any inventions, and patent or copyright applications submitted or in development.
   xii. A report summarizing the Network’s reporting and management of Conflict of Interest. At a minimum, the report must provide anonymous summary data regarding real and potential conflicts of interest and the steps taken to address these issues.

H. Final Report

1. The Contractor shall submit a “draft” Final Report to the COR for comments within forty-five (45) days prior to Task Order completion. This report, at a minimum, shall include a summation of the results of the entire project/program and activities performed for the period of performance.
2. The Contractor shall revise the draft based on comments by the COR, finalize and return to the COR and the CO within ten (10) days prior the completion of the Task Order.
3. The Report at a minimum shall include the following:
   a. Face page to include the Task Order number, Task Order title, performance period covered, Contractor’s name and address, telephone number, fax number, email address, and submission date.
b. Include a brief “Executive Summary” that includes: a brief overview of the work completed, collaborative activities, and major accomplishments of the Task Order.
c. Include a timeline of the Task Orders as they were awarded and completed.
d. Address any legislative changes that may have impacted work performed.
e. Provide a general description of the work performed, collaborative activities, and accomplishments achieved, under each Task Order completed.
STATEMENT OF WORK

Sample Task Order 2 Title: Pharmacokinetics and Safety of Ciprofloxacin in Obese Children

Period of Performance: 2 years

NOTE: The following Sample Task Order is provided to assess the Offerors’ 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 Sample Task Order 2 will NOT be executed nor will an award be made, Offerors are to include in their proposals a response that specifies the methods by which the Sample Task Order 2 will be accomplished. Offerors should refer to the Additional Proposal Instructions for guidance.

For evaluation purposes, offerors are required to develop a protocol for the Sample Task Order 2 study and submit it with their proposal. This requirement includes the following:

1. The Offeror must provide a summary of literature of successful and failed pediatric PK/Safety clinical trials (as well as FDA label review) for ciprofloxacin involving obese children and relevant comparator studies.

2. A draft protocol shall be developed including the following:
   a. Assume that the number of patients 1–18 years of age needed to achieve statistical significance is 50. To ensure adequate representation across the pediatric age spectrum, the study population will contain a minimum of 6 children in each of the following age cohorts: 1<-6 years, 6<-12 years, and 12<-18 years.
   b. Determine the number of sites required for adequate recruitment.
   c. Develop a screening process for site recruitment.
   d. Develop inclusion/exclusion criteria for the study.
   e. Develop a drug specific PK study design, employing a timed sampling scheme in order to determine the PK.
   f. Present draft statistical analysis plan including PK modeling to determine correct dosing for protocol purposes.
   g. The impact of all covariates on ciprofloxacin systemic exposure and apparent plasma clearance (e.g., demographic determinants of extent of obesity such as the waist: hip ratio, genotype, body mass index (BMI), and resting energy expenditure (REE) shall be explored using validated population-based PK methods (NONMEM).
   h. As part of the protocol describe what steps will be taken to ensure clinical and laboratory Quality Control.
   i. Develop clinical and laboratory criteria for safety and tolerability.
   j. Draft/revise the informed consent and assent forms (ICF).

I. BACKGROUND AND INTRODUCTION

Approximately one out of every five children in the United States is obese and the prevalence of childhood obesity has tripled since 1980. Thirty three percent of adults in the United States are obese. Obesity results in changes in body composition, physiology, and plasma protein binding, all of which can have important implications for pharmacokinetics and drug dosing. The PK changes observed may include altered absorption and decreased bioavailability for drugs which undergo significant first pass
metabolism due to increased cardiac output leading to increased liver perfusion); increased volume of
distribution secondary to increased perfusion of lean tissues and, for lipophilic compounds, increased fat
tissue mass; altered metabolism due to fatty infiltration of the liver which could impact metabolic
capacity; and altered renal elimination\(^4\) due to increased kidney size, renal blood flow, and glomerular
filtration and changes in protein binding due to alpha-1 acid glycoprotein. It is reasonable to hypothesize
that drug distribution patterns in obese patients can be anticipated by considering the physicochemical
properties of the drug. Evidence suggests that hydrophilic drugs with small volumes of distribution in
non-obese individuals should be dosed according to ideal body weight. However, highly lipophilic agents
display much greater pharmacokinetic variability in obese subjects highlighting the need for additional
research.

Utilizing the “wrong” dose of a drug has the potential of limiting the efficacy of the therapeutic agent as
well as placing the patient at increasing risk of drug related toxicity. For example, obese children who
suffer cardiac arrest are 25% more likely to die than their non-obese counterparts. While the effects of
obesity in cardiac arrest outcomes are multifaceted, the utilization of the Broselow Tape (which is based
on a child’s weight that is in the 50 percentile) in emergency departments may result in the under dosing
of select cardiac resuscitation drugs (e.g., amiodarone). For other drugs, dosing obese children based on
actual weight in cardiac arrest situations may result in significant overdoses (e.g., epinephrine).

Evidence demonstrates that excess weight affects the disposition of antibiotics and this can result in
antibiotic treatment failure (ATF). Consenting patients (N = 18,014), randomly sampled from Santé
Québec Health Surveys (1992, 1998), were linked with administrative health databases. Patients were
within the normal, overweight, and obese weight categories aged 20-79 years old, receiving at least one
course of antibiotic therapy from the survey date until December 2005. ATF was defined as any
additional antibiotic prescriptions or hospitalizations for infections within the 30 days after initial therapy.
Sixty four percent of the ATFs were either overweight or obese. Obesity is a significant risk factor for
ATF, and this association may be due to the current "one size fits all" dosing strategy, which warrants
further investigation.

The pharmacokinetics of commonly used drugs in obese adults and children can be markedly different
than their lean peers and specific dosing recommendations for this population are needed.

The Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD) plans
to conduct studies obtaining relevant data such that ciprofloxacin can be accurately dosed and safely
utilized by obese children. Currently ciprofloxacin has the FDA label indication for the treatment of
pyelonephritis, complicated urinary tract infection (UTI,) and post exposure anthrax prophylaxis.

**II. SCOPE:**

This Task Order is an open label pharmacokinetic (PK)/safety study. This study will help provide the
requisite information to adequately and safely dose obese children with ciprofloxacin for the above
indications.

**III. TECHNICAL REQUIREMENTS:**

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary
resources, qualified personnel, material, equipment, and facilities, not otherwise provided by the
Government under the terms of this Task Order, as needed to perform the technical requirements outlined
below.
A. Technical Requirements

1. Phase 1A - Preparation for Implementation (2 Months)
   a. Review, coordinate, and adopt the BPCA-DCC’s Data Management System.
   b. The Contractor shall identify and sub-contract with selected study sites.

2. Phase 1B - Preparation for Implementation (2 Months)
   a. Develop and implement the Manual Operating Procedures (MOP) for the Study which details the relationships and responsibilities among the DCC, the PTN and all subcontractors (if applicable). Review and finalize all forms necessary for protocol implementation including Informed Consent and Assent Forms, case report forms, standards of operating procedures, etc.
   b. Demonstrate that the MOP includes a means to measure and follow the quality assurance procedures for the centers and/or labs, and implement the protocol-specific monitoring plans developed by the BPCA-DCC.
   c. Obtain Internal Review Board (IRB(s)) approvals for the final Food and Drug Administration (FDA) approved protocol, demonstrate Health Insurance Portability and Accountability Act (HIPPA) compliance, and any other requirements as specified by the Contractor's agency, department, and/or State.
   d. Develop a problem-resolution policy and process for the study related activities that includes policies for under performance.
   e. Contractor shall be accessible for periodic site visits by personnel from the BPCA-DCC and the COR to discuss progress, problems and to review data.

3. Phase 2 - Implementation (14 Months)
   a. Conduct an Investigators’ meeting to include members of the Contractor’s (subcontractors, if applicable) staff, the COR, and appropriate representatives from the BPCA-DCC. This meeting will be conducted prior to patient enrollment.
   b. Obtain written parental or legal guardian permission to participate in a clinical trial.
   c. Prior to transmission of data with data identifiers to the BPCA-DCC, written authorization from parents or legal guardians must be obtained.
   d. Recruit and retain 50 patients to complete the requirements of the statement of work.
   e. Provide the COR with biannual and annual reports of the activities of the clinical trial. Copies of the information shall also be provided to the BPCA-DCC.
   f. Comply with NIH and FDA policies and regulations concerning clinical trials. Follow the quality assurance procedures and implement the protocol-specific monitoring plans developed by the BPCA-DCC.
   g. Provide the BPCA-DCC with all the required data elements included in the information system and standardized computer based data collection system, i.e., the NIH Clinical Database. The Contractor shall provide information requested by the BPCA-DCC and/or the COR to assure regulatory compliance for research activities.
   h. Respond to all inquiries from the BPCA-DCC regarding problems with the data and achieve resolution of these problems.
   i. The Contractor shall meet with the COR and CO a minimum of once a year to review progress of the study. This meeting may be included in one of the mandatory meetings listed previously; however, additional meetings may be added at the discretion of the COR and/or CO.
   j. The Contractor shall conduct biannual performance evaluations of all subcontractor(s) sites, if applicable, and submit the results to the BPCA-DCC and to the COR and CO. This information...
may be included in the Contractor’s biannual report to the COR. Monitoring of the subcontract sites shall be done using a graded plan that will be developed by the BPCA-DCC in cooperation with the Contractor, COR and CO.

k. The Contractor shall report all adverse drug events to the BPCA-DCC. The BPCA-DCC shall be notified of all serious adverse events within 24 hours in accordance with the FDA (Code of Federal Regulations). The PIs shall be available for questions regarding serious adverse events.

l. The Contractor shall monitor progress of research studies at the study site(s) and resolve any issues.

m. The Contractor shall recommend, as necessary, additional study sites.

n. With the approval of the COR and CO, establish a publications policy among all sites involved (if subcontractors are utilized).

o. The Contractor’s performance will be monitored by the COR and CO on a continuous basis through periodic meetings, site visits, and review of financial and technical reports.

4. Phase 3 - Close Down (6 Months)

a. Finalize the database and all supporting documentation and forward (i.e., cleaned and edited) to the COR upon completion of the study.

b. Provide the NICHD COR and CO with a final report of the activities of the clinical trial.

c. Submit data to the FDA, request label change (if requested by the COR).

d. Ensure that study participants' privacy and the confidentiality of their personal information are maintained throughout the conduct of the study and afterwards consistent with the Contractor's IRB protocol.

e. Maintain all study documents per the requirements of the Contractor's IRB(s).

f. Participate in data analysis and preparation of scientific papers with the BPCA-DCC and COR.
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The items specified below as will be required to be delivered F.O.B. Destination as set forth in FAR Clause 52.247-35, F.O.B. Destination, Within Consignees Premises (April 1984), and in accordance with and by the date(s) specified below and any specifications stated in the task order.

a. Technical Reports Delivery and Distribution Schedule:

<table>
<thead>
<tr>
<th>TYPE OF DELIVERABLE</th>
<th>DUE DATE</th>
<th>RECIPIENTS &amp; NUMBER OF COPIES</th>
<th>SUBSEQUENT REPORTS DUE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Draft Work Plan</td>
<td>Within ten (10) business days of the Kick-Off Meeting</td>
<td>Electronic copies to COR</td>
<td>As required</td>
</tr>
<tr>
<td>Final Work Plan</td>
<td>Within ten (10) business days of receipt of COR and CO comments</td>
<td>Electronic copies to COR and CO/CS</td>
<td>As required</td>
</tr>
<tr>
<td>Final Work Plan Posted on the Collaborative Website</td>
<td>Within ten (10) business days of receipt of COR and CO comments</td>
<td>Electronic copy to COR and CO/CS and posted to: link to collaborative website</td>
<td>As required</td>
</tr>
<tr>
<td>Draft Protocol</td>
<td>As required by the COR and CO</td>
<td>Electronic copies to COR</td>
<td>As required</td>
</tr>
<tr>
<td>Bi-Annual Progress Report</td>
<td>Due fifteen (15) days following each six- month period of the Task Order.</td>
<td>Electronic copies to COR, CS and BPCA-DCC</td>
<td>As required</td>
</tr>
<tr>
<td>Standard Operating Procedures (SOPs)</td>
<td>Within ninety (90) days of Task Order Award</td>
<td>Electronic copies to COR and CO/CS</td>
<td>As required</td>
</tr>
<tr>
<td>Draft Manual of Operating Procedures (MOP)</td>
<td>Within six (6) weeks of Task Order Award</td>
<td>Electronic copies to COR and CO/CS</td>
<td>As required</td>
</tr>
<tr>
<td>Draft Final Report</td>
<td>Forty-five (45) days prior to Task Order completion.</td>
<td>Electronic copy to COR and CO/CS</td>
<td>As required</td>
</tr>
<tr>
<td>Final Report</td>
<td>Within ten (10) days prior to completion of the Task Order</td>
<td>Electronic copy to COR and CO/CS</td>
<td>Task Order completion</td>
</tr>
</tbody>
</table>

Copies of reports shall be sent to the following:

- Contracting Officer’s Representative (COR) - To Be Determined
- Contracting Officer (CO) - To Be Determined
- Contract Specialist (CS) - To Be Determined
TECHNICAL REPORTING REQUIREMENTS AND DELIVERABLES –
Best Pharmaceuticals for Children Act (BPCA)-Pediatric Trials Network (PTN)
Sample Task Order 2 - Safety of Ciprofloxacin in Obese Children

The items specified below as will be required to be delivered F.O.B. Destination as set forth in FAR Clause 52.247-35, F.O.B. Destination, Within Consignees Premises (April 1984), and in accordance with and by the date(s) specified below and any specifications stated in the task order.

a. Technical Reports Delivery and Distribution Schedule:

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</tr>
</thead>
<tbody>
<tr>
<td>Agenda for PDT and other Meetings</td>
<td>24 hours in advance of meeting date.</td>
<td>Electronic copies to COR</td>
<td>As required</td>
</tr>
<tr>
<td>Minutes from Meetings/ conf. calls and/or webcasts</td>
<td>48 hours after the meeting</td>
<td>Electronic copies to COR</td>
<td>As required</td>
</tr>
<tr>
<td>Draft Informed Consent and Assent Forms (ICF)</td>
<td>Within two months of Task Order award date</td>
<td>Electronic copies to COR</td>
<td>As required</td>
</tr>
<tr>
<td>Final Informed Consent and Assent Forms (ICF)</td>
<td>Within two months of Task Order award date</td>
<td>Electronic copies to COR</td>
<td>As required</td>
</tr>
<tr>
<td>Manual of Operating Procedures (MOP)</td>
<td>Within two months of Task Order award date</td>
<td>Electronic copies to COR, and CO/CS</td>
<td>Submit within 15 days after the first six months of each reporting year. A biannual report is not due when a final report is due</td>
</tr>
<tr>
<td>Bi-Annual Progress Reports</td>
<td>Six months from the Task Order award date</td>
<td>Electronic copies to COR, BPCA-DCC, and CO/CS</td>
<td>Submit within 15 days after the anniversary date of the Task Order. An annual report is not due when a final report is due</td>
</tr>
<tr>
<td>Bi-Annual Performance Evaluations of All Subcontractors</td>
<td>Six months from the Task Order award date</td>
<td>Electronic copies to COR, BPCA-DCC, and CO/CS</td>
<td>Submit on the first six months of each reporting year. A biannual report is not due when a final report is due</td>
</tr>
<tr>
<td>Annual Reports</td>
<td>Every 12 months from Task Order award date</td>
<td>Electronic copies to COR, and CO/CS</td>
<td></td>
</tr>
<tr>
<td>Final Report</td>
<td>Within 10 days prior to completion of the Task Order</td>
<td>Electronic copy to COR and CO/CS</td>
<td>Task Order completion</td>
</tr>
</tbody>
</table>

Copies of reports shall be sent to the following:

Consulting Officer’s Representative (COR)
To Be Determined

Consulting Officer (CO)
To Be Determined

Consultant Specialist (CS)
To Be Determined
SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS

Updated through FAC 2005-89
Last updated: 07/2016

This SECTION is made up of six parts as follows:
1. Annual Representations and Certifications, FAR 52.204-8
2. Commercial and Government Entity Code Reporting, FAR 52.204-16
3. Predecessor of Offeror, FAR 52.204-20
4. Information Regarding Responsibility Matters, FAR 52.209-7
5. Cost Accounting Standards
6. Certification Regarding Trafficking in Persons Compliance Plan
7. Certification Regarding Environmental Tobacco Smoke
8. Certification of Institutional on Financial Conflicts of Interest
9. Disaster or Emergency Area Representation

To Be Completed by the Offeror: This document must be completed and included as part of your Business Proposal. By submission of its signed offer, the offeror makes the following Representations and Certifications:

1. ANNUAL REPRESENTATIONS AND CERTIFICATIONS (APRIL 2016), FAR Provision 52.204-8

   (a) (1) The North American Industry Classification System (NAICS) code for this acquisition is [insert NAICS code].
   
   i. The Small Business Size Standard is [insert size standard].
   
   ii. The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

   (b) (1) If the provision at 52.204-7, System for Award Management, is included in this solicitation, paragraph (d) of this provision applies.
   
   i. If the provision at 52.204-7 is not included in this solicitation, and the offeror is currently registered in System for Award Management (SAM), and Representations and Certifications section of SAM has completed the Representations and Certifications section of SAM electronically, the offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:

      [ ] (i) Paragraph (d) applies.
      [ ] (ii) Paragraph (d) does not apply and the offeror has completed the individual representations and certifications in the solicitation. [See Individual Representations and Certifications]

   (c) (1) The following representations or certifications in SAM are applicable to this solicitation as indicated:

   (i) 52.203-2, Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless—
(A) The acquisition is to be made under the simplified acquisition procedures in Part 13;
(B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or
(C) The solicitation is for utility services for which rates are set by law or regulation.

(ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed $150,000.

(iii) 52.204-3, Taxpayer Identification. This provision applies to solicitations that do not include the provision at 52.204-7, System for Award Management.

(iv) 52.204-5, Women-Owned Business (Other Than Small Business). This provision applies to solicitations that—

(A) Are not set aside for small business concerns;
(B) Exceed the simplified acquisition threshold; and
(C) Are for contracts that will be performed in the United States or its outlying areas.

(v) 52.209-2, Prohibition on Contracting with Inverted Domestic Corporations—Representation.

(vi) 52.209-5, Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.

(vii) 52.209-11, Representation by Corporations Regarding Delinquent Tax Liability or Felony Conviction under any Federal Law.

(viii) 52.214-14, Place of Performance—Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.

(ix) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.

(x) 52.219-1, Small Business Program Representations (Basic & Alternate I). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.

(A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.
(B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.

(xi) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.

(xii) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.
(xii) 52.222-25, Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.

(xiii) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial items.

(xiv) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA-designated items; or include the clause at 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts.

(xv) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA-designated items.

(xvi) 52.225-2, Buy American Certificate. This provision applies to solicitations containing the clause at 52.225-1.

(xvii) 52.225-4, Buy American—Free Trade Agreements—Israeli Trade Act Certificate. (Basic, Alternates I, II, and III.) This provision applies to solicitations containing the clause at 52.225-3.

(A) If the acquisition value is less than $25,000, the basic provision applies.
(B) If the acquisition value is $25,000 or more but is less than $50,000, the provision with its Alternate I applies.
(C) If the acquisition value is $50,000 or more but is less than $79,507, the provision with its Alternate II applies.
(D) If the acquisition value is $79,507 or more but is less than $100,000, the provision with its Alternate III applies.

(xviii) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.

(xix) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan—Certification. This provision applies to all solicitations.

(xx) 52.225-25, Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certification. This provision applies to all solicitations.

(xxi) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions.
(2) The following certifications are applicable as indicated by the Contracting Officer: [Contracting Officer check as appropriate.]

- (i) 52.204-17, Ownership or Control of Offeror
- (ii) 52.204-20, Predecessor of Offeror
- (iii) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.
- (iv) 52.222-48, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment Certification.
- (v) 52.222-52 Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Certification.
- (vi) 52.223-9, with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA-Designated Products (Alternate I only).
- (vii) 52.227-6, Royalty Information.  
  (A) Basic.  
  (B) Alternate I.
- (viii) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.

(d) The offeror has completed the annual representations and certifications electronically via the SAM website accessed through https://sam.gov. After reviewing the SAM database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [offeror to insert changes, identifying change by clause number, title, date]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

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Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on SAM.

(End of Provision)
2. COMMERCIAL AND GOVERNMENT ENTITY CODE REPORTING, (JUL 2016) FAR Provision 52.204-16

Note to Offeror: This provision is incorporated by reference and is applicable when the resultant contract will contain FAR Provision 52.204-6 or FAR Provision 52.204-7.

3. PREDECESSOR OF OFFEROR, (JUL 2016) FAR Provision 52.204-20

(a) Definitions. As used in this provision—

Commercial and Government Entity (CAGE) code means—

(1) An identifier assigned to entities located in the United States and its outlying areas by the Defense Logistics Agency (DLA) Commercial and Government Entity (CAGE) Branch to identify a commercial or government entity; or

(2) An identifier assigned by a member of the North Atlantic Treaty Organization (NATO) or by NATO's Support Agency (NSPA) to entities located outside the United States and its outlying areas that DLA Commercial and Government Entity (CAGE) Branch records and maintains in the CAGE master file. This type of code is known as an NCAGE code.

Predecessor means an entity that is replaced by a successor and includes any predecessors of the predecessor.

Successor means an entity that has replaced a predecessor by acquiring the assets and carrying out the affairs of the predecessor under a new name (often through acquisition or merger). The term “successor” does not include new offices/divisions of the same company or a company that only changes its name. The extent of the responsibility of the successor for the liabilities of the predecessor may vary, depending on State law and specific circumstances.

(b) The Offeror represents that it [ ] is or [ ] is not a successor to a predecessor that held a Federal contract or grant within the last three years.

(c) If the Offeror has indicated “is” in paragraph (b) of this provision, enter the following information for all predecessors that held a Federal contract or grant within the last three years (if more than one predecessor, list in reverse chronological order):

Predecessor CAGE code: ____ (or mark “Unknown”).

Predecessor legal name: ____.

(Do not use a “doing business as” name).

(End of provision)

4. INFORMATION REGARDING RESPONSIBILITY MATTERS, (JUL 2013) FAR Provision 52.209-7

Note to Offeror: This provision is applicable when the resultant contract is expected to exceed $500,000.

(a) Definitions. As used in this provision—
**Administrative proceeding** means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative proceedings, Civilian Board of Contract Appeals Proceedings, and Armed Services Board of Contract Appeals Proceedings). This includes administrative proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include agency actions such as contract audits, site visits, corrective plans, or inspection of deliverables.

**Federal contracts and grants with total value greater than $10,000,000 means**—

1. The total value of all current, active contracts and grants, including all priced options; and
2. The total value of all current, active orders including all priced options under indefinite-delivery, indefinite-quantity, 8(a), or requirements contracts (including task and delivery and multiple-award Schedules).

**Principal** means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a division or business segment; and similar positions).

(b) The offeror [ ] has [ ] does not have current active Federal contracts and grants with total value greater than $10,000,000.

(c) If the offeror checked “has” in paragraph (b) of this provision, the offeror represents, by submission of this offer, that the information it has entered in the Federal Awardee Performance and Integrity Information System (FAPIIS) is current, accurate, and complete as of the date of submission of this offer with regard to the following information:

1. Whether the offeror, and/or any of its principals, has or has not, within the last five years, in connection with the award to or performance by the offeror of a Federal contract or grant, been the subject of a proceeding, at the Federal or State level that resulted in any of the following dispositions:

   (i) In a criminal proceeding, a conviction.
   (ii) In a civil proceeding, a finding of fault and liability that results in the payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more.
   (iii) In an administrative proceeding, a finding of fault and liability that results in—

      (A) The payment of a monetary fine or penalty of $5,000 or more; or
      (B) The payment of a reimbursement, restitution, or damages in excess of $100,000.

   (iv) In a criminal, civil, or administrative proceeding, a disposition of the matter by consent or compromise with an acknowledgment of fault by the Contractor if the proceeding could have led to any of the outcomes specified in paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of this provision.

2. If the offeror has been involved in the last five years in any of the occurrences listed in (c)(1) of this provision, whether the offeror has provided the requested information with regard to each occurrence.
(d) The offeror shall post the information in paragraphs (c)(1)(i) through (c)(1)(iv) of this provision in FAPIIS as required through maintaining an active registration in the System for Award Management database at www.acquisition.gov (see 52.204-7).

5. COST ACCOUNTING STANDARDS

(1) Cost Accounting Standards Notices and Certification (October 2015), FAR Provision 52.230-1

Note: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, Part II does not apply unless the contemplated contract will be subject to full or modified CAS-coverage pursuant to 48 CFR 9903.201-2(C)(5) or 9903.201-2(c)(6), respectively.

I. Disclosure Statement -- Cost Accounting Practices and Certification

(a) Any contract in excess of $750,000 resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR Chapter 99), except for those contracts which are exempt as specified in 9903.201-1.

(b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR Chapter 99 must, as a condition of contracting, submit a Disclosure Statement as required by 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of Part I of this provision.

CAUTION: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.
(c) Check the appropriate box below:

☐ (1) **Certificate of Concurrent Submission of Disclosure Statement.**

The offeror hereby certifies that, as part of the offer, copies of the Disclosure Statement have been submitted as follows:

(i) original and one copy to the cognizant Administrative Contracting Officer (ACO), or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable, and;

(ii) one copy to the cognizant Federal auditor.

*(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable. Forms may be obtained from the cognizant ACO or Federal official and/or from the looseleaf version of the Federal Acquisition Regulation.)*

Date of Disclosure Statement: ________________________________

Name and Address of Cognizant ACO or Federal Official Where Filed:

________________________________________________________________________

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

☐ (2) **Certificate of Previously Submitted Disclosure Statement.**

The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement: ________________________________

Name and Address of Cognizant ACO or Federal Official Where Filed:

________________________________________________________________________

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

☐ (3) **Certificate of Monetary Exemption.**

The offeror hereby certifies that the offeror together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling more than $50 million or more in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status
changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

☐ (4) Certificate of Interim Exemption.

The offeror hereby certifies that:

(i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted, and

(ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under subparagraph (c)(1) or (c)(2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

CAUTION: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of $50 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

☐ (5) Certificate of Disclosure Statement Due Date by Educational Institution.

(ALTERNATE I - April 1996)

If the offeror is an educational institution that, under the transition provisions of 48 CFR 9903-202-1(f), is or will be required to submit a Disclosure Statement after receipt of this award, the offeror hereby certifies that (check one and complete):

☐ (i) A Disclosure Statement filing Due Date of ___________ has been established with the cognizant Federal agency.

☐ (ii) The Disclosure Statement will be submitted within the 6-month period ending ___________ months after receipt of this award.

Name and Address of Cognizant ACO or Federal Official Where Filed:

__________________________________________________________

__________________________________________________________
II. Cost Accounting Standards—Eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

☐ The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than $50 million in awards of CAS-covered prime contracts and subcontracts. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

CAUTION: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of $50 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of $50 million or more.

III. Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with subparagraph (a)(3) of the Cost Accounting Standards Clause, require a change in established cost accounting practices affecting existing contracts and subcontracts.

☐ YES ☐ NO

(2) Proposal Disclosure-Cost Accounting Practice Changes, (March 2005)(FAR Provision 52.230-7)

The offeror shall check “yes” below if the contract award will result in a required or unilateral change in cost accounting practice, including unilateral changes requested to be desirable changes.

☐ YES ☐ NO

If the offeror checked “Yes” above, the offeror shall—

(1) Prepare the price proposal in response to the solicitation using the changed practice for the period of performance for which the practice will be used; and
(2) Submit a description of the changed cost accounting practice to the Contracting Officer and the Cognizant Federal Agency Official as pricing support for the proposal.
6. CERTIFICATION REGARDING TRAFFICKING IN PERSONS COMPLIANCE PLAN (March 2015), FAR Provision 52-222-56

Note to offeror: This provision is applicable when services will be performed outside of the United States; and the estimated value exceeds $500,000.

(a) The term “commercially available off-the-shelf (COTS) item,” is defined in the clause of this solicitation entitled “Combating Trafficking in Persons” (FAR clause 52.222-50).
(b) The apparent successful offeror shall submit, prior to award, a certification, as specified in paragraph (c) of this provision, for the portion (if any) of the contract that—
   (1) Is for supplies, other than commercially available off-the-shelf, to be acquired outside of the United States, or services to be performed outside the United States; and
   (2) Has an estimated value that exceeds $500,000.
(c) The certification shall state that—
7. It has implemented a compliance plan to prevent any prohibited activities identified in paragraph (b) of the clause at 52.222-50, Combating Trafficking in Persons, and to monitor, detect, and terminate the contract with a subcontractor engaging in prohibited activities identified at paragraph (b) of the clause at 52.222-50, Combating Trafficking in Persons; and
8. After having conducted due diligence, either—
   (a) To best of the offeror’s knowledge and belief, neither it nor any of its proposed agents, subcontractors, or their agents is engaged in any such activities; or
   (b) If abuses relating to any of the prohibited activities identified in 52.222-50(b) have been found, the offeror or proposed subcontractor has taken the appropriate remedial and referral actions.

(End of Provision)

6. CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE (December 1994)

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law also applies to children’s services that are provided in indoor facilities that are constructed, operated, or
maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable federal funds is Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

By submission of its signed offer, the offeror/contractor (for acquisitions) or applicant/grantee (for grants) certifies that the submitting organization will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act.

The submitting organization agrees that it will require that the language of this certification be included in any subawards which contain provisions for children's services and that all subrecipients shall certify accordingly.

7. CERTIFICATION OF INSTITUTIONAL POLICY ON FINANCIAL CONFLICTS OF INTEREST

Note: This certification is applicable to all Research and Development (R&D) Contracts except Phase I SBIR/STTR and Contracts with Federal Agencies.

By Submission of its signed offer, the offeror certifies that:

(1) there is in effect at the Institution (the term Institution includes any contractor, public or private, excluding a Federal agency) an up-to-date, written and enforced administrative process to identify and manage, financial conflicts of interest with respect to all research projects for which funding is sought or received from the NIH;

(2) the Institution shall promote and enforce Investigator compliance with this part’s requirements including those pertaining to disclosure of significant financial interests;

(3) the Institution shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to NIH consistent with this part;

(4) the Institution agrees to make information available, promptly upon request, to the Contracting Officer relating to any Investigator disclosure of financial interests and the Institution’s review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution’s determination of a financial conflict of interest; and

(5) the Institution shall fully comply with the requirements of 45 CFR Part 94.

8. DISASTER OR EMERGENCY AREA REPRESENTATION, (Aug 2006), FAR Provision 52.226-3

Note: This provision is applicable for acquisitions that are set-aside for a Disaster or Emergency Area under FAR Subpart 26.2. See Section L.1. of the Solicitation, paragraph entitled “Notice of Disaster or Emergency Area Set-Aside.”

a. Set-aside area. The area covered in this contract is: 
[Contracting Officer to fill in with definite geographic boundaries.]
b. *Representations.* The offeror represents as part of its offer that it ☐ is, ☐ is not a firm residing or primarily doing business in the designated area.

c. Factors to be considered in determining whether a firm resides or primarily does business in the designated area include—

(1) Location(s) of the firm’s permanent office(s) and date any office in the designated area(s) was established;
(2) Existing state licenses;
(3) Record of past work in the designated area(s) *(e.g., how much and for how long)*;
(4) Number of permanent employees the firm employs in the designated area;
(5) Membership in local and state organizations in the designated area; and
(6) Other evidence that establishes the firm resides or primarily does business in the designated area.

e) If the offeror represents it is a firm residing or primarily doing business in the designated area, the offeror shall furnish documentation to support its representation if requested by the Contracting Officer. The solicitation may require the offeror to submit with its offer documentation to support the representation.

(End of Provision)