## Solicitation

**Section A - Solicitation/Contract Form**

| 1. Requisition or other Purchase Authority: |
| 2. Request for Proposal (RFP) Number: | 3. Issue Date: | 4. Set Aside: |
| | N02CM77011-50 | 10/31/2017 | [X] No [ ] Yes See Part IV Section L |
| 5. Title: | Drug Shelf Life Testing |
| 6. Issued By: | Andrew May, Contracting Officer  
National Cancer Institute, OA, TSB  
National Institutes of Health |
| 7. Submit Offers To: | See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation. |
| 8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 11/30/2017 local time on 8 a.m.. 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: Andrew May, Contracting Officer  
PHONE: 301-624-8755  
e-MAIL: Andrew.May@nih.gov |

COLLECT CALLS WILL NOT BE ACCEPTED. | Andrew May, Contracting Officer  
NCI Office of Acquisitions, TSB  
(OA/TSB) Email: Andrew.May@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 [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror’s proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

To evaluate shelf life of samples of investigational clinical drug formulations. The products may include parenteral, oral, and other types of dosage forms. These reports will be used for:

- providing NCI and its investigators with information regarding the proper storage and handling of various drug products under investigation,
- determining appropriate expiration dates for the products, and
- to support NCI’s Investigational New Drug Applications (INDs) filed with the Food and Drug Administration (FDA).

ARTICLE B.2. PRICES/COSTS

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

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 Statement of Work, dated 10/12/2017, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format.

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

a. Technical Progress Reports

1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award.

   [Note: Beginning May 25, 2008, the Contractor shall include the applicable PubMed Central or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

   The reports that will be required are:

   a. Technical Progress Reports

   In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award.

   1. Shelf life Evaluation Protocol

      A written shelf life protocol for each drug and dosage form to be tested should be established and testing initiated within 10 days of assignment of the project.

   2. Analytical Method Qualification Report
A qualification report of each analytical method should be provided within 30 days of completion.

3. Evaluation Results Report

A report of the results of each shelf life evaluation should be submitted within 30 days of the scheduled date and subsequent completion of analyses. Shelf life reports shall be submitted in the format as directed by the Project Officer. The report shall be cumulative, showing the results of all previous testing on the batch.

4. Annual Progress Reports

The Contractor shall submit annual reports which document and summarize the results of the entire contract work for the period covered. These reports shall be in sufficient detail to explain comprehensively the results achieved.

5. Final Report

The Contractor shall submit a final report which documents and summarizes the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to explain comprehensively the results achieved.

6. Sample Inventory Report

An annual inventory of all samples being held for shelf life evaluation shall be provided within 30 days of conducting the inventory.

Deliveries

Satisfactory performance of the final contract shall be deemed to occur upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

<table>
<thead>
<tr>
<th>Item</th>
<th>Description of Report</th>
<th>Quantity</th>
<th>Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>(a)</td>
<td>Shelf Life Evaluation Protocol</td>
<td>1</td>
<td>within 10 days of assignment of the project</td>
</tr>
<tr>
<td>(b)</td>
<td>Analytical Method Qualification Report</td>
<td>1</td>
<td>within 30 days of completion</td>
</tr>
<tr>
<td>(c)</td>
<td>Evaluation Results report</td>
<td>1</td>
<td>within 30 days of completion of analysis</td>
</tr>
<tr>
<td>(d)</td>
<td>Annual Progress Report</td>
<td>1</td>
<td>within 30 days of the anniversary date of each contract year *</td>
</tr>
<tr>
<td>(e)</td>
<td>Final Report</td>
<td>1</td>
<td>within 30 days of contract completion</td>
</tr>
</tbody>
</table>
### 2. Reporting on Dual Use Research of Concern

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

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

### 3. Reporting on Select Agents or Toxins and/or Highly Pathogenic Agents

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

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

2. If work with a new or additional **Select Agent or Toxin** and/or a Highly Pathogenic Agent will be conducted in the upcoming reporting period, provide:
   
   a. A list of each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent that will be studied;
b. A brief description of the work that will be done with each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent and whether or not the work is a Select Agent or Toxin restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (http://www.selectagents.gov/Regulations.html) or listed on the U.S. National Select Agents Registry restricted experiments website (http://www.selectagents.gov/index.html);

c. The name and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or institutional biosafety official. It must be noted if the work is being done in a new location or different location.

d. For work with Select Agents performed in the U.S. provide documentation of registration status of all domestic organizations where Select Agent(s) will be used. For work with Select Agents performed in a non-U.S. country prior NCI approval is required.

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

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

b. Other Reports/Deliverables

a. 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.)

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)(iii)) shall be submitted to the Contracting Officer on the expiration date of the contract.
The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Andrew May, Contracting Officer
National Institutes of Health
Office of Acquisition, TSB
8490 Progress Drive
Frederick, MD 21701-4998

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

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

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

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

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

c. Inspection and acceptance will be performed at:
   National Cancer Institute
   9609 Medical Center Drive
   Rockville, MD 20850

   The Government reserves the right to an Inspection period of 30 calendar days, unless a different time period is stated when (the Record of Call/elsewhere in the contract). The receiving report, completed and signed by the appropriate official, constitutes acceptance and shall be acknowledged to the payment office (OFM).

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 **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).
SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

a. The period of performance of this contract is estimated to be from 02/01/2018 through 01/31/2019.

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

<table>
<thead>
<tr>
<th>Option</th>
<th>Option Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 1</td>
<td>Estimated 02/01/2019 - 01/31/2020</td>
</tr>
<tr>
<td>Option 2</td>
<td>Estimated 02/01/2021 - 01/31/2022</td>
</tr>
<tr>
<td>Option 3</td>
<td>Estimated 02/01/2022 - 01/31/2023</td>
</tr>
<tr>
<td>Option 4</td>
<td>Estimated 02/01/2023 - 01/31/2023</td>
</tr>
</tbody>
</table>

ARTICLE F.2. DELIVERIES

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

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

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Quantity</th>
<th>Delivery Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1)</td>
<td>Shelf Life Evaluation Protocol</td>
<td>1</td>
<td>Within 10 days of assignment of the project</td>
</tr>
<tr>
<td>(2)</td>
<td>Analytical Method Qualification Report</td>
<td>1</td>
<td>Within 30 days of completion</td>
</tr>
<tr>
<td>(3)</td>
<td>Evaluation Results Report</td>
<td>1</td>
<td>Within 30 days of completion of analysis</td>
</tr>
<tr>
<td>(4)</td>
<td>Annual Progress Report</td>
<td>1</td>
<td>Within 30 days of the anniversary date of each contract year*</td>
</tr>
<tr>
<td>(5)</td>
<td>Final Report</td>
<td>1</td>
<td>Within 60 days of contract completion</td>
</tr>
<tr>
<td>(6)</td>
<td>Samples Inventory Report</td>
<td>1</td>
<td>Within 30 days of conducting the inventory</td>
</tr>
<tr>
<td>(7)</td>
<td>Section 508 Report</td>
<td>1</td>
<td>Within 15 days of the anniversary date of each contract year</td>
</tr>
<tr>
<td>(8)</td>
<td>Invention Report</td>
<td>1</td>
<td>Within 15 days of the anniversary date of each contract year</td>
</tr>
<tr>
<td>(9)</td>
<td>Information Technology Report</td>
<td>1</td>
<td>As required by the COR</td>
</tr>
<tr>
<td></td>
<td>*no annual report is due when the final report is due</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Addressee</th>
<th>Deliverable Item No</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Contracting Officer (CO)</td>
<td>1,2,3,4,5,6,7,8,9</td>
<td>1 each</td>
</tr>
</tbody>
</table>
ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989)

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

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

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

To be specified prior to award

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

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

The Government may unilaterally change its COR designation.

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

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

(End of Clause)

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

<table>
<thead>
<tr>
<th>Name</th>
<th>Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>TBD</td>
<td>TBD</td>
</tr>
</tbody>
</table>

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

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

E-mail: Andrew.May@nih.gov

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

Central Point of Distribution: ncibranchcinvoices@mail.nih.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 payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice." ]

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

a. The original invoice shall be submitted to the following designated billing office:

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

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

1. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.

2. Save the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "Ash Stevens_Invoice 123456") [Note: Please do not use special characters such as (#, $, %,*, &, !) when saving your attachment. Only the underscore symbol (_) is permitted.]

3. Transmit the saved single attachment via e-mail to the appropriate branch's Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NCI OA Branch C - ncibranchcinvoices@mail.nih.gov . Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number_ Contract Title_ Contractor's Name_ unique Invoice number

(e.g. HHSN2612XXXXXXC_Clinical Genetics Support_Ash Stevens_Invoice 12345) [Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office listed in subparagraph a, above, to meet the requirements]
of a "proper invoice." Also, The Contractor must certify on the payment request that the electronic courtesy copy is a duplicate of the original invoice mailed to NIH's Office of Financial Management.

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

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

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

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

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

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

   f. The Contract Title is:

   Shelf Life Evaluation of Investigational Dosage Forms

   g. Contract Line Items as follows:

<table>
<thead>
<tr>
<th>Line Item #</th>
<th>Line Item Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Shelf Life Evaluation of Investigational Dosage Forms</td>
</tr>
</tbody>
</table>

   b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6088.
ARTICLE G.4. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

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

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

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

(End of Clause)

ARTICLE G.5. 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.6. 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.7. 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, an Interim evaluations will be prepared on the anniversary date of the contract.

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

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

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address:
SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

ARTICLE H.2. DUAL USE RESEARCH OF CONCERN

The contractor shall comply with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) or “DURC policy”. The responsibilities of the contractor include but are not limited to:

1. Establishing internal policies and practices that provide for the identification and effective oversight of DURC;
2. Establishing an institutional review entity (IRE);
3. Ensuring that laboratory personnel conducting research have received education and training;
4. Maintaining records of institutional DURC reviews and completed risk mitigation plans related to research conducted under this contract, for the term of the contract plus three years after its completion, but no less than eight years, unless a shorter period is required by law or regulation;
5. Promptly providing records upon request by the U.S. Government, of institutional DURC reviews and completed risk mitigation plans related to research conducted under this contract;
6. Obtaining pre-approval from the Contracting Officer's Representative for all communications with third-parties, involving DURC funded by this contract, and;
7. Obtaining pre-approval from the Contracting Officer for subcontracts, subgrants, consultant agreements, or any other subaward involving research subject to the DURC policy and funded by this contract. The contractor shall ensure that the substantive requirements of this article are included in any such agreements.

Non-compliance with the DURC policy or with this article may result in suspension, debarment or termination for default.

ARTICLE H.3. 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.4. 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.5. 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.6. 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.7. GUN CONTROL

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

ARTICLE H.8. OPTION PROVISION

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

ARTICLE H.9. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

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

b. Subcontracting Reports

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

1. Individual Subcontract Reports (ISR)

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

April 30th
October 30th
Expiration Date of Contract

2. Summary Subcontract Report (SSR)

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

October 30th

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:
ARTICLE H.10. HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS

ARTICLE H.10.1. INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

A. Baseline Security Requirements

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

   a. Access (Physical or Logical) to Government Information: A Contractor (and/or any subcontractor) employee will have or will be given the ability to have, routine physical (entry) or logical (electronic) access to government information.

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

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

   a. Protect government information and information systems in order to ensure:

      - **Confidentiality**, which means preserving authorized restrictions on access and disclosure, based on the security terms found in this contract, including means for protecting personal privacy and proprietary information;
      - **Integrity**, which means guarding against improper information modification or destruction, and ensuring information non-repudiation and authenticity; and
      - **Availability**, which means ensuring timely and reliable access to and use of information.

   b. Provide security for any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor on behalf of HHS regardless of location. In addition, if new or unanticipated threats or hazards are discovered by either the agency or contractor, or if existing safeguards have ceased to function, the discoverer shall immediately, **within one (1) hour or less**, bring the situation to the attention of the other party.

   c. Adopt and implement the policies, procedures, controls, and standards required by the HHS Information Security Program to ensure the confidentiality, integrity, and availability of government information and government information systems for which the Contractor is responsible under this contract or to which the Contractor may otherwise have access under this contract. Obtain the HHS Information Security Program security requirements, outlined in the HHS Information Security and Privacy Policy (IS2P), by contacting the CO/COR or emailing fisma@hhs.gov.
d. Comply with the Privacy Act requirements.

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

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

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

- [x] No PII [ ] Yes PII

**Personally Identifiable Information (PII).** Per the Office of Management and Budget (OMB) Circular A-130, "PII is information that can be used to distinguish or trace an individual's identity, either alone or when combined with other information that is linked or linkable to a specific individual." Examples of PII include, but are not limited to the following: social security number, date and place of birth, mother's maiden name, biometric records, etc.

4. **Controlled Unclassified Information (CUI)** - CUI is defined as "information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information." The Contractor (and/or any subcontractor) must comply with Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR, part 2002) when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term "handling" refers to "...any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, shall be:

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

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

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

The confidentiality, integrity, and availability of such information shall be protected in accordance with HHS and NIH policies. Unauthorized disclosure of information will be subject to the HHS/NIH sanction policies and/or governed by the following laws and regulations:

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

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


Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the "Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: 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.


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

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

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

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

b. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with FIPS 140-2 validated encryption solution.

c. Secure all devices (i.e., desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and NIH-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).
d. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer’s Technical Representative within 15 days of the validation.

e. Use the Key Management system on the HHS personal identification verification (PIV) card or establish and use a key recovery mechanism to ensure the ability for authorized personnel to encrypt/decrypt information and recover encryption keys. Encryption keys shall be provided to the COR upon request and at the conclusion of the contract.

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

12. Privacy Threshold Analysis (PTA)/Privacy Impact Assessment (PIA)- The Contractor shall assist the NIH Office of the Senior Official for Privacy (SOP) or designee with conducting a PTA for the information system and/or information handled under this contract to determine whether or not a full PIA needs to be completed. The NIH PIA guide is located at https://oma.od.nih.gov/forms/Privacy%20Documents/Documents/NIH%20PIA%20Guide.pdf.

a. If the results of the PTA show that a full PIA is needed, the Contractor shall assist the OpDiv SOP or designee with completing a PIA for the system or information within 60 days after completion of the PTA and in accordance with HHS policy and OMB M-03-22, Guidance for Implementing the Privacy Provisions of the E-Government Act of 2002.

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

B. TRAINING

1. Mandatory Training for All Contractor Staff- All Contractor (and/or any subcontractor) employees assigned to work on this contract shall complete the applicable HHS/NIH Contractor Information Security Awareness, Privacy, and Records Management training course at http://irtsectraining.nih.gov/ before performing any work under this contract. Thereafter, the employees shall complete NIH Information Security Awareness, Privacy, and Records Management training at least annually, during the life of this contract. All provided training shall be compliant with HHS training policies.

2. Role-based Training- All Contractor (and/or any subcontractor) employees with significant security responsibilities (as determined by the program manager) must complete role-based training annually commensurate with their role and responsibilities in accordance with HHS policy and the HHS Role-Based Training (RBT) of Personnel with Significant Security Responsibilities Memorandum. Read further guidance about the NIH Role-based Training https://ocio.nih.gov/aboutus/publicinfosecurity/securitytraining/Pages/rolebasedtraining.aspx

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


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

D. INCIDENT RESPONSE

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams within 24 hours, whether the response is positive or negative.

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

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

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

1. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.

2. NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send NIH approved notifications to affected individuals individuals in accordance with [https://ocio.nih.gov/InfoSecurity/IncidentResponse/Pages/ir_guidelines.aspx](https://ocio.nih.gov/InfoSecurity/IncidentResponse/Pages/ir_guidelines.aspx)

3. Report all suspected and confirmed information security and privacy incidents and breaches to the NIH Incident Response Team (IRT) via email at [IRT@mail.nih.gov](mailto:IRT@mail.nih.gov), COR, CO, the NIH Office of the SOP (or his or her designee), and other stakeholders, including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable NIH and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum:
company and point of contact information, contract information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor shall:

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

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

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

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

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

E. POSITION SENSITIVITY DESIGNATIONS

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

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

F. HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

The Contractor (and/or any subcontractor) and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; FIPS 201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; and Executive Order 13467, Part 1 §1.2.

For additional information, see HSPD-12 policy at: https://www.dhs.gov/homeland-security-presidential-directive-12

Roster-

a. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster shall be submitted to the COR and/or CO within fourteen (14) calendar days after the effective date of this contract. Any revisions
to the roster as a result of staffing changes shall be submitted within seven (7) calendar days of the change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member. An electronic template, “Roster of Employees Requiring Suitability Investigations,” is available for contractor use at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx.

b. If the Contractor is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate suitability level. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

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

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

e. All contractor and subcontractor employees shall comply with the conditions established for their designated position sensitivity level prior to performing any work under this contract. Contractors may begin work after the fingerprint check has been completed.

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

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

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

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

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

G. CONTRACT INITIATION AND EXPIRATION

1. General Security Requirements- The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the contractor shall follow the HHS EPLC framework and methodology or and in accordance with the HHS Contract Closeout Guide (2012).

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

2. System Documentation- Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-64, Security Considerations in the System Development Life Cycle, at a minimum, for system development and
provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.

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

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

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

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

**H. RECORDS MANAGEMENT AND RETENTION**

The Contractor (and/or any subcontractor) shall maintain all information in accordance with Executive Order 13556 -- Controlled Unclassified Information, National Archives and Records Administration (NARA) records retention policies and schedules and HHS/NIH policies and shall not dispose of any records unless authorized by HHS/NIH. In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, it shall be documented and reported as an incident in accordance with HHS/NIH policies.
ARTICLE H.10.2. GOVERNMENT INFORMATION PROCESSED ON GOCO OR COCO SYSTEMS

A. SECURITY REQUIREMENTS FOR GOVERNMENT-OWNED/CONTRACTOR-OPERATED (GOCO) AND CONTRACTOR-OWNED/CONTRACTOR-OPERATED (COCO) RESOURCES

1. Federal Policies - The Contractor (and/or any subcontractor) shall comply with applicable federal laws that include, but are not limited to, the HHS Information Security and Privacy Policy (IS2P), Federal Information Security Modernization Act (FISMA) of 2014, (44 U.S.C. 101); National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53, Security and Privacy Controls for Federal Information Systems and Organizations; Office of Management and Budget (OMB) Circular A-130, Managing Information as a Strategic Resource; and other applicable federal laws, regulations, NIST guidance, and Departmental policies.

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

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

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

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

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

• Security Assessment Plan/Report (SAP/SAR) - due 30 days after the contract award. The security assessment shall be conducted by the assessor and be consistent with NIST SP 800-53A, NIST SP 800-30, and HHS and NIH policies. The assessor will document the assessment results in the SAR.

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

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

• **POA&M** - due 30 days after contract award. The POA&M shall be documented consistent with the HHS Standard for Plan of Action and Milestones and NIH policies. All high-risk weaknesses must be mitigated within 30 days and all medium weaknesses must be mitigated within 60 days from the date the weaknesses are formally identified and documented. The NIH will determine the risk rating of vulnerabilities. Identified risks stemming from deficiencies related to the security control baseline implementation, assessment, continuous monitoring, vulnerability scanning, and other security reviews and sources, as documented in the SAR, shall be documented and tracked by the Contractor for mitigation in the POA&M document. Depending on the severity of the risks, NIH may require designated POAM weaknesses to be remediated before an ATO is issued. Thereafter, the POA&M shall be updated at least quarterly.

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

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

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

b. **Information Security Continuous Monitoring** - Upon the government issuance of an Authority to Operate (ATO), the Contractor (and/or subcontractor)-owned/operated systems that input, store, process, output, and/or transmit government information, shall meet or exceed the information security continuous monitoring (ISCM) requirements in accordance with FISMA and NIST SP 800-137, *Information Security Continuous Monitoring (ISCM) for Federal Information Systems and Organizations*, and HHS IS2P. The following are the minimum requirements for ISCM:

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

• **Asset Management** - Using any available Security Content Automation Protocol (SCAP)-compliant automated tools for active/passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing HHS-owned information/data. It is anticipated that this inventory information will be required to be produced at least 60 days after contract award. IT asset inventory information shall include IP address, machine name, operating system level, security patch level, and SCAP-compliant format information. The contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.

• **Configuration Management** - Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process
government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.

- **Configuration Management** - Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.

- **Vulnerability Management** - Use SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process government information. Contractors shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS policy. Automated tools shall be compliant with NIST-specified SCAP standards for vulnerability identification and management. The contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP-compliant automated tools and report to the agency at least within 30 days of the contract award.

- **Patching and Vulnerability Remediation** - Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeframes.

- **Secure Coding** - Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.

- **Boundary Protection** - The contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).

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

   a. At any tier handling or accessing information, consent to and allow the Government, or an independent third party working at the Government's direction, without notice at any time during a weekday during regular business hours contractor local time, to access contractor and subcontractor installations, facilities, infrastructure, data centers, equipment (including but not limited to all servers, computing devices, and portable media), operations, documentation (whether in electronic, paper, or other forms), databases, and personnel which are used in performance of the contract.

   The Government includes but is not limited to the U.S. Department of Justice, U.S. Government Accountability Office, and the HHS Office of the Inspector General (OIG). The purpose of the access is to facilitate performance inspections and reviews, security and compliance audits, and law enforcement investigations. For security audits, the audit may include but not be limited to such items as buffer overflows, open ports, unnecessary services, lack of user input filtering, cross site scripting vulnerabilities, SQL injection vulnerabilities, and any other known vulnerabilities.
b. At any tier handling or accessing protected information, fully cooperate with all audits, inspections, investigations, forensic analysis, or other reviews or requirements needed to carry out requirements presented in applicable law or policy. Beyond providing access, full cooperation also includes, but is not limited to, disclosure to investigators of information sufficient to identify the nature and extent of any criminal or fraudulent activity and the individuals responsible for that activity. It includes timely and complete production of requested data, metadata, information, and records relevant to any inspection, audit, investigation, or review, and making employees of the contractor available for interview by inspectors, auditors, and investigators upon request. Full cooperation also includes allowing the Government to make reproductions or copies of information and equipment, including, if necessary, collecting a machine or system image capture.

c. Segregate Government protected information and metadata on the handling of Government protected information from other information. Commingling of information is prohibited. Inspectors, auditors, and investigators will not be precluded from having access to the sought information if sought information is commingled with other information.

d. Cooperate with inspections, audits, investigations, and reviews.

4. **End of Life Compliance** - The Contractor (and/or any subcontractor) must use Commercial off the Shelf (COTS) software or other software that is supported by the manufacturer. In addition, the COTS/other software need to be within one major version of the current version; deviation from this requirement will only be allowed via the HHS waiver process (approved by HHS CISO). The contractor shall retire and/or upgrade all software/systems that have reached end-of-life in accordance with HHS End-of-Life Operating Systems, Software, and Applications Policy.

5. **Desktops, Laptops, and Other Computing Devices Required for Use by the Contractor** - The Contractor (and/or any subcontractor) shall ensure that all IT equipment (e.g., laptops, desktops, servers, routers, mobile devices, peripheral devices, etc.) used to process information on behalf of HHS are deployed and operated in accordance with approved security configurations and meet the following minimum requirements:

   a. Encrypt equipment and sensitive information stored and/or processed by such equipment in accordance with HHS and FIPS 140-2 encryption standards.

   b. Configure laptops and desktops in accordance with the latest applicable United States Government Configuration Baseline (USGCB), and HHS Minimum Security Configuration Standards;

   c. Maintain the latest operating system patch release and anti-virus software definitions within 15 days.

   d. Validate the configuration settings after hardware and software installation, operation, maintenance, update, and patching and ensure changes in hardware and software do not alter the approved configuration settings; and

   e. Automate configuration settings and configuration management in accordance with HHS security policies, including but not limited to:

      • Configuring its systems to allow for periodic HHS vulnerability and security configuration assessment scanning; and

      • Using Security Content Automation Protocol (SCAP)-validated tools with USGCB Scanner capabilities to scan its systems at least on a monthly basis and report the results of these scans to the CO and/or COR, Project Officer, and any other applicable designated POC.
ARTICLE H.11. PUBLICATION AND PUBLICITY

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

"This project has been funded in whole or in part with Federal funds from the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. TBD"

a. Advanced Copies of Press Releases

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The Contractor shall not publish a press release related to this contract without receiving prior concurrence from the Contracting Officer. The Contractor shall submit an advance copy of the press release to the Contracting Officer and Contracting Officer's Representative (COR). Upon acknowledgment of receipt, the Contracting Officer will have five (5) working days to respond with concurrence or comments. In the event that the Contracting Officer does not communicate concurrence or comments to the Contractor within five (5) working days following acknowledgement of receipt of the press release advance copy, concurrence may be presumed.

ARTICLE H.12. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

ARTICLE H.13. CONSTITUTION DAY

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

SECTION I - CONTRACT CLAUSES

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

The complete listing of these clauses may be accessed at:

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

e. FAR Clause 52.225-1, **Buy American--Supplies** (May 2014) is deleted in its entirety and FAR Clause 52.225-5, **Trade Agreements** (October 2016) is substituted therefor.

f. **Alternate I** (April 1984), of FAR Clause 52.227-1, **Authorization and Consent** (December 2007) is deleted in its entirety.

FAR Clause 52.227-11, **Patent Rights--Ownership by the Contractor** (May 2014) is deleted in its entirety.

**Alternate IV** (December 2007), of FAR Clause 52.227-14, **Rights In Data--General** (May 2014) is deleted in its entirety.

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

g. FAR Clause 52.227-14, **Rights in Data-General** (May 2014) is deleted in its entirety.

h. FAR Clause 52.232-20, **Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause 52.232-22, **Limitation Of Funds** (April 1984) is substituted therefor. **[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

i. FAR Clause 52.216-11, **Cost Contract--No Fee** (April 1984) is deleted in its entirety and FAR Clause 52.216-8 **Fixed Fee** (June 2011) is substituted therefor.

FAR Clause 52.232-17, **Interest** (May 2014) is added.

FAR Clause 52.249-5, **Termination for Convenience of the Government (Educational and Other Non-Profit Institutions)** (August 2016) is deleted in its entirety and FAR Clause 52.249-6, **Termination (Cost-Reimbursement)** (May 1986) is substituted therefor.
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 52.204-14, Service Contract Reporting Requirements (October 2016).

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

3. FAR Clause 52.217-8, Option to Extend Services (November 1999).

   "...The Contracting Officer may exercise the option by written notice to the Contractor within 30 Days of expiration.

4. 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."

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

6. FAR Clause 52.222-26, Equal Opportunity (September 2016)

7. FAR Clause 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts (September 2013).

8. FAR Clause 52.223-3, Hazardous Material Identification and Material Safety Data (January 1997), with Alternate I (July 1995).


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

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


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

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


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


20. FAR Clause 52.248-1, Value Engineering (October 2010).

21. 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 352.219-71, Mentor-Protégé Program Reporting Requirements (December 2015).

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

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

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

   *See the following website for Executive Schedule rates of pay: [https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/](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.)*
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 52.204-21, Basic Safeguarding of Covered Contractor Information Systems (June 2016)

   a. Definitions. As used in this clause--

   "Covered contractor information system" means an information system that is owned or operated by a contractor that processes, stores, or transmits Federal contract information.

   "Federal contract information" means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government, but not including information provided by the Government to the public (such as on public Web sites) or simple transactional information, such as necessary to process payments.

   "Information" means any communication or representation of knowledge such as facts, data, or opinions, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual (Committee on National Security Systems Instruction (CNSSI) 4009).

   "Information system" means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information (44 U.S.C. 3502).

   "Safeguarding" means measures or controls that are prescribed to protect information systems.

   b. Safeguarding requirements and procedures.

      1. The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:

      i. Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

      ii. Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

      iii. Verify and control/limit connections to and use of external information systems.

      iv. Control information posted or processed on publicly accessible information systems.

      v. Identify information system users, processes acting on behalf of users, or devices.

      vi. Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

      vii. Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.
viii. Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

ix. Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

x. Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

xi. Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

xii. Identify, report, and correct information and information system flaws in a timely manner.

xiii. Provide protection from malicious code at appropriate locations within organizational information systems.

xiv. Update malicious code protection mechanisms when new releases are available.

xv. Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

2. Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

c. Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial items, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

2. 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)

3. FAR Clause 52.217-9, Option to Extend the Term of the Contract (March 2000).

a. The Government may extend the term of this contract by written notice to the Contractor within 30 days before the contract expires; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 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 5 years.

4. FAR Clause 52.223-11, Ozone-Depleting Substances and High Global Warming Potential Hydrofluorocarbons (June 2016)

a. Definitions. As used in this clause--
"Global warming potential" means how much a given mass of a chemical contributes to global warming over a given time period compared to the same mass of carbon dioxide. Carbon Dioxide's global warming potential is defined as 1.0.

"High global warming potential hydrofluorocarbons" means any hydrofluorocarbons in a particular end use for which EPA's Significant New Alternatives Policy (SNAP) program has identified other acceptable alternatives that have lower global warming potential. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables of alternatives available at (http://www.epa.gov/snap/).

"Hydrofluorocarbons" means compounds that only contain hydrogen, fluorine, and carbon.

"Ozone-depleting substance" means any substance the Environmental Protection Agency designates in 40 CFR Part 82 as--

1. Class I, including, but not limited to, chlorofluorocarbons, halons, carbon tetrachloride, and methyl chloroform; or
2. Class II, including, but not limited to hydrochlorofluorocarbons.

b. The Contractor shall label products which contain or are manufactured with ozone-depleting substances in the manner and to the extent required by 42 U.S.C. 7671j (b), (c), (d), and (e) and 40 CFR Part 82, Subpart E, as follows:

Warning

Contains (or manufactured with, if applicable) *________, a substance(s) which harm(s) public health and environment by destroying ozone in the upper atmosphere.

* The Contractor shall insert the name of the substance(s).

c. **Reporting.** For equipment and appliances that normally each contain 50 or more pounds of hydrofluorocarbons or refrigerant blends containing hydrofluorocarbons, the Contractor shall-

i. Track on an annual basis, between October 1 and September 30, the amount in pounds of hydrofluorocarbons or refrigerant blends containing hydrofluorocarbons contained in the equipment and appliances delivered to the Government under this contract by-

   i. Type of hydrofluorocarbon (e.g., HFC-134a, HFC-125, R-410A, R-404A, etc.);
   ii. Contract number; and
   iii. Equipment/appliance;

   ii. Report that information to the Contracting Officer for FY16 and to www.sam.gov, for FY17 and after00

   i. Annually by November 30 of each year during contract performance; and
   ii. At the end of contract performance.

d. The Contractor shall refer to EPA's SNAP program (available at http://www.epa.gov/snap) to identify alternatives. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables available at http://www.epa.gov/snap

5. FAR Clause 52.223-20, Aerosols (June 2016)

a. **Definitions.** As used in this clause--
"Global warming potential" means how much a given mass of a chemical contributes to global warming over a given time period compared to the same mass of carbon dioxide. Carbon dioxide’s global warming potential is defined as 1.0.

"High global warming potential hydrofluorocarbons" means any hydrofluorocarbons in a particular end use for which EPA's Significant New Alternatives Policy (SNAP) program has identified other acceptable alternatives that have lower global warming potential. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables of alternatives available at http://www.epa.gov/snap/.

"Hydrofluorocarbons" means compounds that contain only hydrogen, fluorine, and carbon.

b. Unless otherwise specified in the contract, the Contractor shall reduce its use, release, or emissions of high global warming potential hydrofluorocarbons, when feasible, from aerosol propellants or solvents under this contract. When determining feasibility of using a particular alternative, the Contractor shall consider environmental, technical, and economic factors such as--

1. In-use emission rates, energy efficiency;
2. Safety, such as flammability or toxicity;
3. Ability to meet technical performance requirements; and
4. Commercial availability at a reasonable cost.

c. The Contractor shall refer to EPA's SNAP program to identify alternatives. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables available at http://www.epa.gov/snap/.

6. FAR Clause 52.223-21, Foams (June 2016)

a. Definitions. As used in this clause--

"Global warming potential" means how much a given mass of a chemical contributes to global warming over a given time period compared to the same mass of carbon dioxide. Carbon dioxide's global warming potential is defined as 1.0.

"High global warming potential hydrofluorocarbons" means any hydrofluorocarbons in a particular end use for which EPA's Significant New Alternatives Policy (SNAP) program has identified other acceptable alternatives that have lower global warming potential. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables of alternatives available at http://www.epa.gov/snap/.

"Hydrofluorocarbons" means compounds that contain only hydrogen, fluorine, and carbon.

b. Unless otherwise specified in the contract, the Contractor shall reduce its use, release, and emissions of high global warming potential hydrofluorocarbons and refrigerant blends containing hydrofluorocarbons, when feasible, from foam blowing agents, under this contract. When determining feasibility of using a particular alternative, the Contractor shall consider environmental, technical, and economic factors such as--

1. In-use emission rates, energy efficiency, and safety;
2. Ability to meet performance requirements; and;
3. Commercial availability at a reasonable cost.
c. The Contractor shall refer to EPA's SNAP program to identify alternatives. The SNAP list of alternatives is found at 40 CFR part 82, subpart G, with supplemental tables available at http://www.epa.gov/snap/.

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:
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>
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### TECHNICAL PROPOSAL ATTACHMENTS

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### BUSINESS PROPOSAL ATTACHMENTS

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<th>Attachment No.</th>
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<tbody>
<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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### Attachment No. | Title | Location
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### INFORMATIONAL ATTACHMENTS

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<tbody>
<tr>
<td>Attachment 19:</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

Offerors may submit WRITTEN questions requesting clarification of the Request for Proposal (RFP) contents. Information provided with each question must include the document name, specific page, paragraph, clause or other definitive citation requiring clarification. All questions must be submitted ELECTRONICALLY to Andrew May at Andrew.May@nih.gov and Tim Crilley at tcrilley@mail.nih.gov. FACSIMILE, TELEPHONE OR MAILED QUESTIONS WILL NOT BE ACCEPTED.

Note: It is respectfully requested that all questions be received by Eastern Prevailing Time to allow NCI adequate time to prepare and issue an amendment prior to receipt of proposals. NCI will continue to accept questions up to the closing date and time for the RFP. HOWEVER, time may not permit responses to questions received after to be prepared and issued prior to receipt of proposals.

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

a. Definitions. As used in this provision--

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

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

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

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

"Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

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

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

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

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

i. The solicitation number;

ii. The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
iii. A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

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

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

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

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

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

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

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

(3) It is the only proposal received.

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

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

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

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

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

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

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

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

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

(e) Restriction on disclosure and use of data.

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

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes. The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act. If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act. The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification)."

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

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

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

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

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

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

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

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

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

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

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

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

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

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

   (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
   
   (ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
   
   (iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;

   (iv) A summary of the rationale for award.

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

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

d. 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 325412.
2. The small business size standard is 1,250 employees.

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 award will be made from this solicitation and that the award will be made on/about 1/30/2018.
2. It is anticipated that the award from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a Term of 5 Years, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).
3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

d. ESTIMATE OF EFFORT

It is expected that a completion type contract will be awarded as a result of this SOLICITATION. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 4500 labor hours.
per year. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

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. 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.

g. 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.

h. PREPARATION COSTS

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

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

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

Contracting Officer
Office of Acquisitions
8490 Progress Drive
Frederick, MD 21701 Room 4032

(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)

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 a cost-reimbursement completion type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

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. **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.

10. **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 technical acceptable will be subjected to a cost and price analysis, management analysis, etc.

c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror’s past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d. If the Government intends to conduct discussions prior to awarding a contract -

1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain. Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

2. The Contracting Officer will, in concert with program staff, decide which proposals are in the competitive range. The competitive range will be comprised of all of the most highly rated proposals. Oral or written discussions will be conducted with all offerors in the competitive range.

While it is NCI’s policy to conduct discussions with all offerors in the competitive range, NCI 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 NCI 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 NCI requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

11. 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.

12. 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)

13. Past Performance Information

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

A list of the last 5 contracts completed during the past Two years and all contracts currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as is any subcontract valued over $150,000.
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.

14. **Information and Physical Access Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

**IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical 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. Additional NIH Requirements

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

   a. Information Type:

       [ ] Administrative, Management and Support Information:

       [X] Mission Based Information:

       D14.5 Health Care Research - access to existing system only not hosted by contractor
b. Security Categories and Levels:

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

Overall Level:               [X] Low       [ ] 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
15. **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 Technology (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.


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

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

(End of provision)

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

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

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

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

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

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


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 PROJECT OFFICER, 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 Professional Staff
List all other 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.

Dual Use Research of Concern
The offeror shall demonstrate compliance with the United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (http://www.phe.gov/s3/dualuse/Documents/durc-policy.pdf) or “DURC” policy. The offeror shall provide in its technical proposal each of the following items:

a. Identification of the agents or toxins subject to the DURC policy.

b. A description of the categories of experiments in which the identified agents or toxins produces or aims to produce or can be reasonably anticipated to produce one or more of the effects identified in Section 6 of the DURC policy.

c. For projects involving any of the agents listed in the DURC policy and that involve or are anticipated to involve any of the categories of experiments listed in the DURC policy, an indication of whether or not the project meets the definition of “dual use research of concern” in Section 4C of the policy.

d. For projects meeting the definition of “dual use research of concern,” a draft risk mitigation plan.

e. Certification that the offeror is or will be in compliance with all aspects of the DURC policy prior to use of pertinent agents or toxins.

The Government shall not award a contract to an offeror who fails to certify compliance or whose draft risk mitigation plan is unsatisfactory to the Government. If selected for award, an approved risk mitigation plan shall be incorporated into the contract.

5. Obtaining and Disseminating Biomedical Research Resources

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

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

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


a. Sharing Research Data

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


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

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:

36 CFR Part 1194

c. **BUSINESS PROPOSAL INSTRUCTIONS**

1. **Basic Cost/Price Information**

   The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. **Proposal Cover Sheet**

   The following information shall be provided on the first page of your pricing proposal:

   1. Solicitation, contract, and/or modification number;
   2. Name and address of Offeror;
   3. Name and telephone number of point of contact;
   4. Name, address, and telephone number of Contract Administration Office, (if available);
   5. Name, address, and telephone number of Audit Office (if available);
   6. Proposed cost and/or price; profit or fee (as applicable); and total;
   7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time
before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.

8. Date of submission; and

9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with FAR 15.406-2.

3. 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.

b. The data submitted shall be at the level of detail described below.

a. Direct Labor

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

b. Materials

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

c. Subcontracted Items

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $750,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

d. Raw Materials

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.
e. **Purchased Parts**

   Includes material items not covered above. Provide priced quantities of items required for the proposal.

f. **Fringe Benefits**

   Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

g. **Indirect Costs**

   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

h. **Special Equipment**

   If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

i. **Travel**

   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

j. **Other Costs**

   List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

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
Office. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:

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

2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and/or Service Disabled Veteran-Owned Small 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-Protégé Program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU) approved mentor-protégé agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protege firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at [www.esrs.gov](http://www.esrs.gov). The mentor firm and protege firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a $10,000 subcontract awarded to a protege firm and provision of $5,000 of developmental assistance as $15,000 of subcontracting plan credit.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.

   b. The program consists of--

      1. Mentor firms--large businesses that:
         (i) Demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and
         (ii) Have a Mentor-Protégé 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-Protégé agreement approved by HHS’ OSDBU; and

      3. Mentor-Protégé agreements--joint agreements, approved by HHS’ OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

   (End of provision)

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](http://www.sba.gov/hubzone).

9. **Total Compensation Plan**

   a. **Instructions**

      1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business
Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. Evaluation

1. **Total Compensation Plan (Professional Employees)**

   In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. **Cost (Professional Compensation)**

   Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3. **Other (Labor Relations)**

   An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4. **Federal Acquisition Regulation Clauses incorporated by Reference**

   FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees.

10. **Other Administrative Data**

   a. **Property**

   1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by
the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:

a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.

b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. Government Property

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);

b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;

c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and

d. A description of the offeror's property management system, plan, and any customary commercial practices, voluntary consensus standards, or industry-leading practices and standards to be used in the offeror in managing Government property.

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from an offeror or contractor possessing Government property. This will be done by adjusting the offers by applying, for evaluation purposes only, a rental equivalent evaluation factor, as specified in FAR 52.245-9.

3. Government-Furnished Property

No Government Furnished Property is offered for this acquisition

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

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

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

(End of Provision)

c. Financial Capacity

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

d. Adequate Accounting System

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

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

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

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

• Accounting system provides financial information:
  • Required by contract clause concerning limitation of cost (FAR 52.232-20) or limitation on payments (FAR 52.216-16).
  • Required to support requests for progress payments.
• Accounting system was designed, and records are maintained in such a manner that adequate, reliable data are developed for use in pricing follow-on acquisitions.
• Accounting system is currently in full operation.

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

e. Incremental Funding

An incrementally funded contract is a contract in which funds are obligated, as they become available, to cover specific periods of performance.

Incremental Funding, HHSAR 352.232-70 (December 2015)

The Government intends to negotiate and award a cost-reimbursement contract using incremental funding as described in the clauses at FAR 52.232-22, “Limitation of Funds.” The initial obligation of funds under the contract is expected to cover the first 3 months of performance. The Government intends to obligate additional funds up to and including the full estimated cost of the contract for the remaining years of performance by unilateral contract modification. However, the Government is not required to reimburse the Contractor for costs incurred in excess of the total amount obligated, nor is the Contractor required to perform beyond the level supported by the total amount obligated.

(End of provision)

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.

11. Qualifications of the Offeror

You are requested to submit a summary of your “General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts.”

a. General Experience
General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b. Organizational Experience Related to the RFP
Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, but not the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c. Performance History
Performance history is defined as meeting contract objectives within delivery and cost schedules on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d. Pertinent Contracts
Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. Pertinent Grants
List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.
You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

12. **Subcontractors**

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

a. Willingness to perform as a subcontractor for specific duties (list duties).

b. What priority the work will be given and how it will relate to other work.

c. The amount of time and facilities available to this project.

d. Information on their cognizant field audit offices.

e. How rights to publications and patents are to be handled.

f. A complete cost proposal in the same format as the offeror’s cost proposal.

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

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

14. **Travel Costs/Travel Policy**

a. **Travel Costs - Commercial**

   Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

b. **Travel Policy**

   One copy of the offeror’s (and any proposed subcontractor’s) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.
SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

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, past performance, and cost. 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 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

Offerors 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 offerors technical proposal.

Cost Realism will be evaluated only on the offerors 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. MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria. THE OFFEROR SHALL [INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS TECHNICAL PROPOSAL. / PROVIDE AN INDEX WITHIN ITS TECHNICAL PROPOSAL WHICH DIRECTS THE REVIEWER(S) TO THE SPECIFIC AREA(S) OF THE TECHNICAL PROPOSAL THAT ADDRESS A PARTICULAR MANDATORY QUALIFICATION.]

The qualification criteria establishes conditions that must be met at the time of receipt of Final Proposal Revisions (FPRs) by the Contracting Officer in order for your proposal to be considered any further for award.

FDA registration of an organization (Contractor must submit proof of registration).

4. EVALUATION OF OPTIONS

It is anticipated that any contracts awarded from this solicitation will contain option provisions and periods.
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 options.

5. TECHNICAL EVALUATION FACTORS

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

<table>
<thead>
<tr>
<th>Weight</th>
<th>a. Personnel</th>
</tr>
</thead>
</table>

1) Documented academic training and work experience of the Project Director/Manager (PD/M). The PD/M shall be thoroughly familiar with analysis and evaluation of finished clinical dosage forms and shall have at least three years of pharmaceutical experience in this area. The PD/M shall also possess a Ph.D. degree in either chemistry or pharmaceutics analysis along with experience that would qualify him/her to lead this project. The PD/M shall devote at least 25% of his/her time to this contract effort. Identify the PD/M (by name) and describe the background, training, experience, and accomplishments that qualify him/her to lead this project. Include the PD/M's updated curriculum vitae. Indicate the individual's availability and proposed level of effort.

2) Documented academic training and work experience of the Project Director/Manager (PD/M) Assistant. The Assistant will be responsible for the day-to-day operation of this contract effort shall also be thoroughly familiar with the analysis and evaluation of finished clinical dosage forms and shall have at least three years of experience in the area of pharmaceutical dosage form analysis. The Assistant shall possess training and background in all aspect(s) of chemical or pharmaceutical analysis which would qualify her/him to direct the day-to-day operation of this project. It is recommended that the Assistant devote 100% of her/his time to this contract effort. Identify the Assistant (by name) and describe the background, training, experience, and accomplishments that justify him/her to direct the day-to-day operation of this project. Also include the Assistant's curriculum vitae. Indicate this individual's availability and proposed level of effort.

3) Other personnel as to training and experience. Additional personnel shall possess suitable technical experience and training to ensure satisfactory performance of all phases of work under their purview, including shelf life evaluation of clinical drug products, performance of other evaluations, and meeting the reporting requirements. Describe the background, training, experience, and accomplishments that qualifies each individual to perform in their area of responsibility. Also, include each individual's updated curriculum vitae. Indicate each individual's availability and proposed level of effort. If new staff are to be hired, describe the qualifications sought for these individuals.

4) Availability of all proposed personnel to the contract.

b. Facilities and Equipment 30 Points

1) Describe and demonstrate availability and adequacy of the proposed facilities, equipment, and analytical instrumentation to perform all the necessary functions of this contract as described in the Statement of Work and Technical Proposal Instructions.
The offeror shall have adequate facilities and equipment as outlined in the Statement of Work to accomplish the goals and objectives of this contract.

The antineoplastic substances under study shall be considered to be very toxic agents. Describe in detail your proposed approach for the handling and disposal of toxic substances.

(a) The Contractor shall provide at a minimum the controlled temperature storage capabilities stated in the following Table:

<table>
<thead>
<tr>
<th>Storage Condition</th>
<th>Approximate Capacity (sq. ft.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elevated Temperature (40 EC, 75%RH)</td>
<td>10</td>
</tr>
<tr>
<td>Controlled Room Temperature (22-25 EC)</td>
<td>100</td>
</tr>
<tr>
<td>Refrigeration (2-8 EC)</td>
<td>200</td>
</tr>
<tr>
<td>Freezer (-10 to -20 EC)</td>
<td>30</td>
</tr>
<tr>
<td>Deep Freeze (-70 to -80 EC)</td>
<td>if needed</td>
</tr>
</tbody>
</table>

(b) The Contractor shall dedicate two (2) four high performance liquid chromatographic (HPLC) systems equipped with auto-samplers, variable wavelength detectors, data acquisition system, and other ancillary equipment for exclusive use on this contract to accomplish the work. A third HPLC shall be available for use during peak periods of analysis.

(c) Describe in detail the facility that will be directly utilized and available for this project, and provide a detailed floor plan of the proposed facility. Such description and floor plan with dimensions must be in sufficient detail to allow for proper evaluation of the proposed facility.

(d) Discuss in detail the compliance of your facilities with FDA promulgated cGMPs and how these impact upon this contract work. Further, discuss your approach to assure compliance with all cGMP requirements.

(e) Describe security arrangements available to safeguard Government owned materials to prevent theft, misuse, or damage.

(f) Identify the exact location of the facility proposed for this contract.

(g) Describe in detail the equipment, facilities, and analytical instrumentation including make and model number to perform the shelf life evaluation of oral and injectable clinical drug products. Note the availability of the equipment and analytical instruments for this project. Indicate which equipment will be dedicated for use on this contract. If any facility, laboratory, equipment, or apparatus are not under the complete control of the PD/M, describe the arrangement you have that assures the availability of this equipment when needed.

(h) Describe facilities for holding shelf life samples at low, ambient, and elevated temperatures, and proper humidity. Include a statement of the storage capacities.
(i) Describe the monitoring of the storage conditions to guarantee and document continuous proper storage. Indicate whether such equipment will be shared with other projects.

(j) Describe the procedures for routine maintenance and repairs of equipment and analytical instruments.

(k) Describe your dissolution equipment available for this project.

c. Understanding the Project and Technical Approach

25 Points

1) Document/describe the adequacy of the offeror’s approach to analytical method development and adoption to conform to the FDA requirements.

2) Document/describe the adequacy of the timeliness and completeness of the proposed approach to accomplishing the transition to a new location, if applicable.

3) Document/describe the adequacy of the project management plan proposed to insure that all of the required activities described in the Statement of Work will be performed at the correct time points and none will be missed or delayed.

4) Document/describe the awareness and understanding of problems involved in evaluating clinical dosage forms and the approaches to the resolution of such problems.

5) Document/describe adequacy of your proposed approach for handling and disposal of toxic materials and the organization’s general safety program.

(a) As of January, 2012, about 20 lots of NCI drug products were undergoing shelf life evaluation. These will require approximately 20-25 separate evaluations per year. It is anticipated that there will be 10 to 15 new lots (2-3 new chemical entities) each year requiring analytical method qualification and shelf life protocol preparation. An equal number of stability lots will be expected per year from the shelf-life evaluation. The Contractor shall store and properly evaluate each of these insuring that no scheduled time points are missed or overlooked batches (See Statement of Work, Section C, Tasks). A complete schedule of these ongoing lots, and all of the analytical methods and protocols for these items will be available for review through the contracting officer.

(b) Indicate the systems and procedures to be used to insure that various activities will be scheduled so that all are performed at proper times.

(c) Describe your awareness and understanding of problems associated with shelf life evaluation of finished clinical drug products. Discuss proposed approaches to the resolution of such problems.

(c) Discuss in detail your approach to the transportation of the test samples from their current location in Kansas City, MO, to the new site in a manner to insure the safe, intact, and timely arrival of the samples while maintaining and documenting an adequate controlled temperature required for all samples. The plan shall include, but shall not be limited to providing guidelines for prevention of loss of the collection during shipment, freezer preparations(s), insurance and how broken bottles will be handled. Additionally, identify any potential problems associated with the move. Please provide a cost estimate for this move. Consideration shall be given to how the Government provided equipment will be moved, protection against loss of temperature condition, the desirability of multiple shipments, and any other considerations that the Offeror feels are pertinent. Provide an estimated timetable for performing and cost
associated with the transition. Moreover, the cost for transition and move shall be provided as a separate budget as well as a category in the total estimated budget.

(d) Describe your general safety program in case of fire, acid spills, explosions, etc. Provide a copy of your organization's safety manual, if available.

d. Organizational Support and Experience  10 Points

1) Demonstrated experience in analysis and evaluation of finished clinical dosage forms.

2) Demonstrated organizational awareness of and conformance with relevant and applicable regulations.

(a) Describe overall organizational experience in the analysis and evaluation of clinical pharmaceuticals that qualifies you to respond to this project.

(b) Describe in detail organizational activities currently ongoing or recently completed that would indicate satisfactory experience and capabilities in the analysis and evaluation of finished clinical drug products.

(c) Discuss your organization's overall ability to respond to work requirements. Describe possible interfering commitments which might cause delays in completion of the effort required. Indicate the priority to be placed on this effort as compared to other existing commitments.

(d) Indicate by chart and/or descriptive form how the various activities will be coordinated so as to demonstrate an awareness of organizational influences on project implementation and control.

TOTAL 100 Points

6. 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.

7. PAST PERFORMANCE FACTOR
Offerors' past performance information will be evaluated prior to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.
Attachment 1
Attachment 1 - Packaging and Delivery of Proposals 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 [Contract specialist must select either: FAR Clause 52.215-1 Instructions to Offerors – Competitive Acquisition or HHSAR 352.215-70, 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. Each of the proposals, Technical and Business, must be separate and complete in itself. Do not reference one proposal in another.
5. 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:
Business Proposal: XYZ Company_NIHAI2012001_Business.pdf
Excel Workbook: XYZ Company_NIHAI2012001_Business.xlsx

II. FORMATTING AND PAGE LIMITATIONS: [Contract specialist must include Section II if page limitations will be used. Otherwise, Section II may be deleted].

A. Formatting for proposals

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

B. Page limitations:

1. The total page count of the Technical proposal shall not exceed ____ pages. [Contract specialist must specify a page limit].
2. Total page count does not include: Title and Back Page; Table of Contents; and Section Dividers that do not contain information other than title of Section. CVs shall not exceed ____ pages. [Contract specialist must specify a page limit].
3. Pages in excess of this limitation will be removed from the proposal and will not be considered.