

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

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| 1. Requisition or other Purchase Authority: _____ | | |
| 2. Request for Proposal (RFP) Number: N02CO61002-38 | 3. Issue Date: May 3, 2016 | 4. Set Aside: <input checked="" type="checkbox"/> No <input type="checkbox"/> Yes See Part IV Section L |
| 5. Title : Inherited Bone Marrow Failure Syndromes Support Services Contract | | |
| 6. ISSUED BY: Office of Acquisitions National Cancer Institute National Institutes of Health 9609 Medical Center Drive Room 1E612, MSC 9705 Rockville, MD 20850-9705 | 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 2:00 PM local time on June 7, 2016. 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 | | |
| 11. FOR INFORMATION CALL: Sean Dalenberg PHONE: 240.276.6950 e-MAIL: sean.dalenberg@gmail.com COLLECT CALLS WILL NOT BE ACCEPTED. | | |
| The cutoff date for questions is May 24, 2016. The page limit for Technical Proposals is 100 pages. Please see "Additional Technical Proposal Instructions (Attachment 9)." | Jill Johnson Contracting Officer Office of Acquisitions | |

RFP TABLE OF CONTENTS

| | |
|---|----|
| PART I - THE SCHEDULE | 4 |
| SECTION A - SOLICITATION/CONTRACT FORM | 1 |
| SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS | 4 |
| SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT | 7 |
| SECTION D - PACKAGING, MARKING AND SHIPPING | 11 |
| SECTION E - INSPECTION AND ACCEPTANCE | 12 |
| SECTION F - DELIVERIES OR PERFORMANCE | 13 |
| SECTION G - CONTRACT ADMINISTRATION DATA | 16 |
| SECTION H - SPECIAL CONTRACT REQUIREMENTS | 20 |
| PART II - CONTRACT CLAUSES | 33 |
| PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS | 41 |
| SECTION J - LIST OF ATTACHMENTS | 41 |
| SOLICITATION ATTACHMENTS..... | 41 |
| TECHNICAL PROPOSAL ATTACHMENTS..... | 41 |
| BUSINESS PROPOSAL ATTACHMENTS..... | 42 |
| INFORMATIONAL ATTACHMENTS..... | 42 |
| PART IV - REPRESENTATIONS AND INSTRUCTIONS | 44 |
| SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS | 44 |
| SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS | 45 |
| 1. GENERAL INFORMATION..... | 45 |
| a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION..... | 45 |
| b. NAICS CODE AND SIZE STANDARD..... | 49 |
| c. TYPE OF CONTRACT AND NUMBER OF AWARDS..... | 49 |
| d. COMMITMENT OF PUBLIC FUNDS..... | 49 |
| e. PROMOTING EFFICIENT SPENDING..... | 49 |
| f. COMMUNICATIONS PRIOR TO CONTRACT AWARD..... | 50 |
| g. RELEASE OF INFORMATION..... | 50 |
| h. PREPARATION COSTS..... | 50 |
| i. SERVICE OF PROTEST..... | 50 |
| 2. INSTRUCTIONS TO OFFERORS..... | 50 |
| a. GENERAL INSTRUCTIONS..... | 50 |
| 1. Contract Type and General Clauses..... | 50 |
| 2. Authorized Official and Submission of Proposal..... | 51 |
| 3. Proposal Summary and Data Record (NIH-2043)..... | 51 |
| 4. Separation of Technical and Business Proposals..... | 51 |
| 5. Alternate Proposals..... | 51 |
| 6. Evaluation of Proposals..... | 52 |
| 7. Potential Award Without Discussions..... | 52 |
| 8. Use of the Metric System of Measurement..... | 52 |
| 9. Privacy Act - Treatment of Proposal Information..... | 52 |
| 10. Selection of Offerors..... | 53 |
| 11. Certification of Filing and Payment of Taxes..... | 54 |

| | |
|--|-----------|
| 12. Past Performance Information..... | 54 |
| 13. Information and Physical Access Security..... | 55 |
| 14. Electronic Information Technology Accessibility Notice, HHSAR 352.239-73 (December 2015).... | 65 |
| 15. Solicitation Provisions Incorporated by Reference..... | 65 |
| b. TECHNICAL PROPOSAL INSTRUCTIONS..... | 66 |
| 1. Technical Discussions..... | 66 |
| 2. Other Considerations..... | 68 |
| 3. Technical Evaluation..... | 68 |
| 4. Human Subjects..... | 68 |
| Notice to Offerors of Requirements, Protection of Human Subjects, HHSAR 270-4(a)..... | 68 |
| Instructions to Offerors Regarding Protection of Human Subjects..... | 70 |
| Required Education in the Protection of Human Research Participants..... | 72 |
| Inclusion of Women and Minorities in Research Involving Human Subjects..... | 73 |
| Inclusion of Children in Research Involving Human Subjects..... | 75 |
| Research Involving Human Fetal Tissue..... | 77 |
| Human Embryonic Germ Cell (HEGC) Research..... | 78 |
| Human Embryonic Stem Cell (HESC) Research..... | 79 |
| 5. Electronic and Information Technology Accessibility, HHSAR 352.239-73(a)..... | 79 |
| 6. Instructions to Offerors-Sustainable Acquisition, HHSAR Provision 352.223-71 (December 2015)..... | 80 |
| c. BUSINESS PROPOSAL INSTRUCTIONS..... | 81 |
| 1. Basic Cost/Price Information..... | 81 |
| 2. Proposal Cover Sheet..... | 81 |
| 3. Information Other than Cost or Pricing Data..... | 81 |
| 4. Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data..... | 83 |
| 5. Salary Rate Limitation..... | 84 |
| 6. Small Business Subcontracting Plan..... | 84 |
| 7. Mentor Protege Program, HHSAR 352.219-70..... | 86 |
| 8. HUBZone Small Business Concerns..... | 87 |
| 9. Total Compensation Plan..... | 87 |
| 10. Other Administrative Data..... | 89 |
| 11. Qualifications of the Offeror..... | 92 |
| 12. Subcontractors..... | 92 |
| 13. Proposer's Annual Financial Report..... | 93 |
| 14. Travel Costs/Travel Policy..... | 93 |
| SECTION M - EVALUATION FACTORS FOR AWARD..... | 94 |
| 1. GENERAL..... | 94 |
| 2. COST/PRICE EVALUATION..... | 94 |
| 3. HUMAN SUBJECT EVALUATION..... | 94 |
| 4. EVALUATION OF OPTIONS..... | 97 |
| 5. TECHNICAL EVALUATION FACTORS..... | 97 |
| 6. EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY- SECTION 508..... | 99 |
| 7. PAST PERFORMANCE FACTOR..... | 99 |

PART I - THE SCHEDULE

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

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Inherited Bone Marrow Failure Syndromes (IBMFS) include seven major syndromes (FA, dyskeratosis congenita [DC], Diamond-Blackfan anemia [DBA], Shwachman-Diamond Syndrome [SDS], severe congenital neutropenia [SCN], amegakaryocytic thrombocytopenia [Amega], and thrombocytopenia absent radii [TAR]), all of which have high risks of acute myeloid leukemia (AML); the first 3 also manifest high risks of solid tumors.

This study embodies the CGB research mission: Saving lives and improving quality of life in individuals predisposed to cancer. CGB defines the role of cancer susceptibility genes in cancer etiology, and translates this knowledge into evidence-based management strategies for persons at increased genetic risk of cancer, including counseling and clinical interventions. Cancer-prone families with IBMFS provide a unique opportunity to systematically study individuals with extremely high risks of specific cancers, and to offer targeted cancer screening and prevention strategies, genetic and cancer risk counseling, and evaluate germline and somatic genetic factors that may ultimately prove relevant to cancer etiology in the general population.

Participants start enrollment by speaking with the Family Studies Referral Nurse (a support services contract employee). If study team review confirms eligibility; family history and individual information questionnaire data are obtained, as well as medical records. These individuals and their family members become members of the IBMFS Field Cohort (FC), a subset of which comes to the NIH Clinical Center (CC) for detailed clinical evaluations. All first-degree family members are evaluated to quantify cancer risks for carriers of IBMFS genes, and to determine which features are syndrome-specific, and which are family-specific.

Data on cancer types and risks in the IBMFS are now understood by both the medical and patient communities in large part as a direct result of CGB IBMFS research. This has been accomplished through analyses of a growing cohort, an increasing number of reviews of the literature, and a collaborative analyses of data from other cohorts that expand or validate the findings.

In general, the contractor's tasks are similar for all of the syndromes, but it must be stressed that the IBMFS Program includes more than seven discrete cancer-prone disorders, which vary considerably in their presentation, phenotype and clinical needs.

This is a renewal procurement. The IBMFS Program was initially supported within the existing CGB Support Services Contract, but it grew to a size that made independent funding more appropriate. A separate IBMFS Contract was established in Jan 2006 and was funded continuously through 2011 and again from 2012-2016. The existing contract is HHSN261201100018C with Westat. This procurement is for the Support Services Contract for the subsequent 5 years, from December 1, 2016 through November 30, 2016

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. ESTIMATED COST - OPTION

- a. The estimated cost of the Base Period of this contract is \$_____.
- b. The fixed fee for the Base Period of this contract is \$_____. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.
- c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is \$_____.
- d. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

| | Estimated Cost (\$) | Fixed Fee (\$) | Estimated Cost Plus Fixed Fee (\$) |
|---------------------------------|----------------------------|-----------------------|---|
| Base Period | TBD | TBD | TBD |
| Option Period(s): | | | |
| | TBD | TBD | TBD |
| Total Base Period and Option(s) | TBD | TBD | TBD |

ARTICLE B.4. ESTIMATED COST - INCREMENTALLY FUNDED CONTRACT

- a. The total estimated cost to the Government for full performance of this contract, including all allowable direct and indirect costs, is \$_____.
- b. The following represents the schedule* by which the Government expects to allot funds to this contract:

| CLIN, Task, Number, or Description | Start Date of Period or Increment of Performance | End Date of Period or Increment of Performance | Estimated Cost (\$) | Fee (\$) (as appropriate) | Estimated Cost Plus Fee (\$) (as appropriate) |
|---|---|---|----------------------------|--------------------------------------|--|
| TBD | TBD | TBD | TBD | TBD | TBD |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | TBD | TBD | TBD |

*To be inserted after negotiation

- c. Total funds currently obligated and available for payment under this contract are \$_____ .
- d. The Contracting Officer may issue unilateral modifications to obligate additional funds to the contract and make related changes to paragraphs b. and/or c., above.
- e. Until this contract is fully funded, the requirements of the clause at FAR 52.232-22, Limitation of Funds, shall govern. Once the contract is fully funded, the requirements of the clause at FAR 52.232-20, Limitation of Cost, shall govern.

ARTICLE B.5. 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.6. 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 March 1, 2016, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

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

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

All reports required herein shall be submitted in an electronic format via email as attachments to the following NCI Branch Distribution Mailbox:

ncibranchinvoices@mail.nih.gov

NOTE: Hard copies of reports are no longer required and shall no longer be mailed to the NCI OA. Each email submission shall contain only one deliverable. If the attached file for the deliverable exceeds 50MB, the contractor shall divide the deliverable into files of 50MB each. All deliverables should be limited to five file attachments or less. In cases where it is necessary, more than five attachments will be accepted.

The subject line of the email shall read as follows:

Deliverable_Contract Number_Vendor's Name_Deliverable Description_Due Date

All data transfer of PII or sensitive information to the NCI must be encrypted.

a. Technical Progress Reports

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

For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s) 1 hard copies of these reports will be required as follows:

- Monthly
- Quarterly
- Semi-Annually
- Annually
- Annually (with a requirement for a Draft Annual Report)

- [] Final - Upon final completion of the contract
 [X] Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

2. Summary of Salient Results

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

3. Annual Technical Progress Report for Clinical Research Study Populations

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

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

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

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

b. Other Reports/Deliverables

1. Source Code and Object Code

Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

2. Information Security and Physical Access Reporting Requirements

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

a. Roster of Employees Requiring Suitability Investigations

The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract

who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. (Reference subparagraph A.e. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

b. IT Security Plan (IT-SP)

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

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

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

c. IT Risk Assessment (IT-RA)

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

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

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

d. FIPS 199 Assessment

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

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

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

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

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

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

f. Reporting of New and Departing Employees

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

- a. **New Employees who have or will have access to HHS Information systems or data:** Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.
- b. **Departing Employees:** 1) Provide the name, position title, and security clearance level held by or pending for the individual; and 2) Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the COR and/or Contracting Officer upon request.

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

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

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

3. Section 508 Annual Report

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

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, Blanche Alter is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:
9609 Medical Center Drive
Rockville, MD 20850

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

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

FAR Clause **52.246-5, 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 shall be from December 1, 2016 through November 30, 2017.
- b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

| Option | Option Period |
|------------------|--------------------------------------|
| Option 1, Year 2 | December 1, 2017 - November 30, 2018 |
| Option 2, Year 3 | December 1, 2018 - November 30, 2019 |
| Option 3, Year 4 | December 1, 2019 - November 30, 2020 |
| Option 4, Year 5 | December 1, 2020 - November 30, 2021 |

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 and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract:

| Item | Description | Quantity | Delivery Schedule |
|------|-----------------------------------|----------|---|
| (1) | Monthly Progress Report | 1 | Due on or before the 15th of each month. |
| (2) | Annual Progress Report | 1 | Due 30 days after each annual reporting period. |
| (3) | Final Progress Report | 1 | Due on or before contract completion date. |
| (4) | Summary of Salient Results | 1 | Due on or before contract completion date. |
| (5) | Computerized Data File | 1 | Due quarterly beginning on 03/31/2016 and as required by the Statement of Work. |
| (6) | Procedure Manual | 1 | Due 30 days prior to contract completion date. |
| (7) | Monthly CAS Transaction Data File | 1 | Due on or before the 15th of each month. |
| (8) | Master Study File | 1 | Draft is due 60 days before contract completion date; Final is due on contract completion date. |
| (9) | Transition Plan | 1 | Draft is due 60 days before contract completion date; Final is due 30 days before contract completion date. |
| (10) | Source Code and Object Code | 1 | Due on or before contract completion date. |

| Item | Description | Quantity | Delivery Schedule |
|-------------|--|-----------------|---|
| (11) | Roster of Employees Requiring Suitability Investigations | 1 | Due within 15 days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. |
| (12) | IT Security Plan (IT-SP) | 1 | Due within 30 days after contract award. Thereafter, the Contractor shall review and update the IT-SP in accordance with NIST SP 800-53A, Guide for Information Technology Systems, on an annual basis. |
| (13) | IT Risk Assessment (IT-RA) | 1 | Due within 30 days after contract award. Thereafter, the ITRA shall be updated on an annual basis. |
| (14) | FIPS 199 Assessment | 1 | Due within 30 days after contract award. |
| (15) | IT Security Certification and Accreditation | 1 | Due within three (3) months after contract award. Thereafter, the Contractor shall perform an annual security control assessment and provide verification that the IT-SC&A remains valid. |
| (16) | Section 508 Annual Report | 1 | Due prior to exercising an option, if applicable, and contract completion date. |

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

| Addressee | Deliverable Item No | Submit To: |
|---|----------------------------|--|
| Contracting Officer's Representative (COR) EBP, DCEG National Cancer Institute, NIH | Items 1-11 | NCIBranchEInvoices@mail.nih.gov AND CC: COR Email |
| Contracting Officer (CO) ETSB, Officer of Acquisitions National Cancer Institute, NIH | Items 1-4, 9, 11-16 | NCIBranchEInvoices@mail.nih.gov |

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989)

Alternate I (April 1984) is 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:

Blanche Alter

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

The alternate COR is responsible for carrying out the duties of the COR only in the event that the COR can no longer perform his/her duties as assigned.

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

The Government may unilaterally change its COR designation.

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:

| Name | Title |
|------|------------------------|
| TBD | Principal Investigator |

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

- a. Invoice Submission/Contract Financing Request, NIH(RC)-1 for NIH Cost-Reimbursement Type Contracts are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.
1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**
 - a. The original invoice shall be submitted to the following designated billing office:

National Institutes of Health
Office of Financial Management
Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500
 - b. One courtesy copy of the original invoice shall be submitted electronically as follows:
 1. The Contractor shall scan the original payment request (invoice) in Adobe Portable Document Format (PDF) along with the necessary supporting documentation as one single attachment.
 2. **Save** the single attachment (scanned invoice along with any supporting documentation) in the following format: YourVendorName_Invoice number (e.g., if you are submitting Invoice 123456, save the single attachment as "Ash Stevens_Invoice 123456") [Note: Please do not use special characters such as (#, \$, %, *, &, !) when saving your attachment. Only the underscore symbol (_) is permitted.]
 3. **Transmit** the saved single attachment via e-mail to the appropriate branch's Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NCI OA Branch A - ncibranchinvoices@mail.nih.gov . Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number_ Contract Title_ Contractor's Name_ unique Invoice number

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

Inherited Bone Marrow Failure Syndromes Support Services Contract
- g. Contract Line Items as follows:

| Line Item # | Line Item Description |
|-------------|-----------------------|
| TBD | TBD |

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

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, Interim evaluation(s) will be prepared Annually as follows on end of Period of Performance [Insert Dates].

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

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

b. Electronic Access to Contractor Performance Evaluations

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

<http://www.cpars.gov>

SECTION H - SPECIAL CONTRACT REQUIREMENTS

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

- a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR part 46 and with the Contractor's current Federal-wide Assurance (FWA) on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR part 46 and the Assurance of Compliance.
- b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without creating liability on the part of the Government for the acts of the Contractor or its employees.
- c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP Website at: <http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf>).
- d. If at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.
- e. (End of clause)

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

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

<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html>.

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

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

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

ARTICLE H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

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

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

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

ARTICLE H.4. NEEDLE EXCHANGE, HHSAR 352.270-12 (December 2015)

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

(End of clause)

ARTICLE H.5. 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.6. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

- a. The Contractor shall not use any funds obligated under this contract for any abortion.
- b. The Contractor shall not use any funds obligated under this contract for the following:
 1. The creation of a human embryo or embryos for research purposes; or
 2. Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
- c. The term ``human embryo or embryos" includes any organism,

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

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

(End of clause)

ARTICLE H.7. 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.8. PRIVACY ACT, HHSAR 352.224-70 (December 2015)

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

(End of clause)

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

The Privacy Act System of Records applicable to this project is Number TBD. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: <http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm>.

ARTICLE H.9. OMB CLEARANCE

In accordance with HHSAR 352.211-3, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Contracting Officer's Representative (COR) and the Contracting Officer has issued written approval to proceed.

ARTICLE H.10. 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.11. GUN CONTROL

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

ARTICLE H.12. CERTIFICATION OF FILING AND PAYMENT OF TAXES

The contractor must be in compliance with Section 518 of the Consolidated Appropriations Act of FY 2014.

ARTICLE H.13. 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 52.217-8, Option to Extend Services 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 30 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.14. 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:

jilljohnson2@nih.gov
Contracting Officer

ARTICLE H.15. INFORMATION AND PHYSICAL ACCESS SECURITY

A. HHS-Controlled Facilities and Information Systems Security

- a. To perform the work specified herein, Contractor personnel are expected to have routine (1) physical access to an HHS-controlled facility; (2) physical access to an HHS-controlled information system; (3) access to sensitive HHS data or information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- b. To gain routine physical access to an HHS-controlled information system, and/or access to sensitive data or information, the Contractor and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; Office of Management and Budget Memorandum (M-05-24); and Federal Information Processing Standards Publication (FIPS PUB) Number 201; and with the personal identity verification and investigations procedures contained in the following documents:
 1. HHS-OCIO Information Systems Security and Privacy Policy (<http://www.hhs.gov/ocio/policy/#Security>)
 2. HHS HSPD-12 Policy Document, v. 2.0 (<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf>)
 3. Information regarding background checks/badges (<http://idbadge.nih.gov/background/index.asp>)
- c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

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

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

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

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

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

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

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

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

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

- e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.
- f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the additional investigation(s).
- g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).
- h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.
- i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

B. Standard for Security Configurations

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

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

- b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:
TBD
- c. The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings - see <http://scap.nist.gov/validation>. The Contractor shall test applicable product versions with all relevant and current

updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest FDCC major version and subsequent major versions.

- d. The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.
- e. The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.
- f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (<http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf>), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.
- g. The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

C. Standard for Encryption language

- a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004).
- b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see <http://csrc.nist.gov/groups/STM/cmvp/>) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.
- c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see <http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf>). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.
- d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).
- e. The Contractor shall ensure that this standard is incorporated into the Contractor's property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.
- f. The Contractor shall ensure that its subcontractors (all tiers) which perform work under this contract comply with the requirements contained in this clause.

D. Security Requirements For Federal Information Technology Resources

- a. **Applicability.** This clause applies whether the entire contract or order (hereafter "contract"), or portion thereof, includes information technology resources or services in which the Contractor has physical or logical (electronic) access to, or operates a Department of Health and Human Services (HHS) system containing, information that directly supports HHS' mission. The term "information technology (IT)", as used in this clause, includes computers, ancillary equipment (including imaging peripherals, input, output, and storage devices necessary for security and surveillance), peripheral equipment designed to be controlled by the central processing unit of a computer, software, firmware and similar procedures, services (including support services) and related resources. This clause does not apply to national security systems as defined in FISMA.
- b. **Contractor responsibilities.** The Contractor is responsible for the following:
1. Protecting Federal information and Federal information systems in order to ensure their -
 - a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;
 - b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and
 - c. Availability, which means ensuring timely and reliable access to and use of information.
 2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.
 3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.
- c. **Contractor security deliverables.** In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:
1. **IT Security Plan (IT-SP)** - due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.
 - a. The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:
 - i. Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automation Information Resources.
 - ii. National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of Federal

Information Processing Standard (FIPS) 200, Recommend Security Controls for Federal Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.

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

2. **IT Risk Assessment (IT-RA)** - due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor's final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.
3. **FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment)** - due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor's final version into the contract.
4. **IT Security Certification and Accreditation (IT-SC&A)** - due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems - see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security, Certification and Accreditation of Federal Information Systems; and NIST 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provided it to the Contracting Officer for review, comment, and acceptance.
 - a. After resolution of any comments provided by the Government on the draft IT SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor's final version into the contract as a compliance requirement.
 - b. The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:
 - i. Annual testing of the system contingency plan; and
 - ii. The performance of security control testing and evaluation.
- d. **Personal identity verification.** The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer's Representative (COR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in "HHS-Controlled Facilities and Information Systems Security" requirements specified in the SOW/PWS of this contract.
- e. **Contractor and subcontractor employee training.** The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COR evidencing that Contractor employees have completed the required training.
- f. **Government access for IT inspection.** The Contractor shall afford the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the

integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.

- g. **Subcontracts.** The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -
- a. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or
 - b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.
- h. **Contractor employment notice.** The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.
- i. **Document information.** The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.
- j. **Contractor responsibilities upon physical completion of the contract.** The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.
- k. **Failure to comply.** Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

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

E. Additional NIH Requirements

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

a. Information Type:

Administrative, Management and Support Information:

Mission Based Information:

b. Security Categories and Levels:

| | | | |
|------------------------|---|---|--------------------------------------|
| Confidentiality Level: | <input checked="" type="checkbox"/> Low | <input type="checkbox"/> Moderate | <input type="checkbox"/> High |
| Integrity Level: | <input type="checkbox"/> Low | <input checked="" type="checkbox"/> Moderate | <input type="checkbox"/> High |
| Availability Level: | <input checked="" type="checkbox"/> Low | <input type="checkbox"/> Moderate | <input type="checkbox"/> High |
| Overall Level: | <input type="checkbox"/> Low | <input checked="" type="checkbox"/> Moderate | <input type="checkbox"/> High |

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

2. INFORMATION SECURITY TRAINING

The contractor shall comply with the below training:

a. Mandatory Training

- i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information, shall complete the NIH Computer Security Awareness Training course at <http://irtsectraining.nih.gov/> before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.
- ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COR and/or Contracting Officer upon request.

b. Role-based Training

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

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

c. Rules of Behavior

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

3. PERSONNEL SECURITY RESPONSIBILITIES

The contractor shall comply with the below personnel security responsibilities:

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

name, position title and position sensitivity level held by the former incumbent. If an employee is filling a new position, the Contractor shall provide a position description and the Government will determine the appropriate position sensitivity level.

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

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

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

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

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

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

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

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

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

ARTICLE H.16. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the Contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each Contractor employee's computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

ARTICLE H.17. CONFIDENTIALITY OF INFORMATION

- a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
- b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
- e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

The following information is covered by this article:

Any data relating to studies associated with this contract, including abstracts, preprints, and materials to be presented at conferences or public forums.

ARTICLE H.18. 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.19. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

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

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

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

The complete listing of these clauses may be accessed at:

<https://oamp.od.nih.gov/DGS/reference-material-prospective-offerors-and-contractors>

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. *FAR Clause 52.215-23, Limitations on Pass-Through Charges (October 2009), is added.*
- b. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (October 2015) is added.
- c. FAR Clause **52.227-14, Rights in Data-General** (May 2014) is deleted in its entirety.
- d. 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.]**

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (October 2015).
2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (October 2015).

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

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

3. FAR Clause **52.204-9, Personal Identity Verification of Contractor Personnel** (January 2011).
4. FAR Clause **52.209-10, Prohibition on Contracting With Inverted Domestic Corporations** (November 2015).
5. FAR Clause **52.210-1, Market Research** (April 2011).

6. FAR Clause **52.217-6, Option for Increased Quantity** (March 1989).

"....The Contracting Officer may exercise the option by written notice to the Contractor within 30 days prior to contract completion.

7. FAR Clause **52.217-7, Option for Increased Quantity - Separately Priced Line Item** (March 1989).

"....The Contracting Officer may exercise the option by written notice to the Contractor within 30 days prior to contract completion.

8. 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 prior to contract completion.

9. 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."

10. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013).
 11. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).
 12. FAR Clause **52.224-2, Privacy Act** (April 1984).
 13. FAR Clause **52.227-14, Rights in Data - General** (May 2014).
 14. FAR Clause **52.228-11, Pledges of Assets** (September 2009).
 15. FAR Clause **52.230-2, Cost Accounting Standards** (October 2015).
 16. FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (October 2015).
 17. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (June 2010).
 18. FAR Clause **52.232-18, Availability of Funds** (April 1984).
 19. FAR Clause **52.237-3, Continuity of Services** (January 1991).
 20. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2014).
 21. FAR Clause **52.242-4, Certification of Final Indirect Costs** (January 1997).
 22. FAR Clause **52.246-23, Limitation of Liability** (February 1997).
 23. 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 **352.219-71, Mentor-Protégé Program Reporting Requirements** (December 2015).
 2. HHSAR Clause **352.231-70, Salary Rate Limitation** (December 2015)

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

See the following website for Executive Schedule rates of pay: <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/>.

(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

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

There are no applicable clauses at this time.

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

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

This contract incorporates the following clauses in full text.

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

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

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

- a. *The Contractor shall update the information in the Federal Awardee Performance and Integrity Information System (FAPIS) 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 FAPIS on or after April 15, 2011, except past performance reviews, will be publicly available. FAPIS 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 FAPIS 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 FAPIS 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 FAPIS 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 FAPIS.*
 2. *The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.*

3. *As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.*
- d. *Public requests for system information posted prior to April 15, 2011, will be handled under Freedom of Information Act procedures, including, where appropriate, procedures promulgated under E.O. 12600.*

(End of clause)

2. FAR Clause **52.217-9, 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 prior to contract completion. 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 66 months.

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

1. HHSAR Clause **352.237-74, Non-Discrimination in Service Delivery** (December 2015).

It is the policy of the Department of Health and Human Services that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of HHS programs and services based on non-merit factors such as race, color, national origin, religion, sex, gender identity, sexual orientation, or disability (physical or mental).

By acceptance of this contract, the contractor agrees to comply with this policy in supporting the program and in performing the services called for under this contract. The contractor shall include this clause in all sub-contracts awarded under this contract for supporting or performing the specified program and services. Accordingly, the contractor shall ensure that each of its employees, and any sub-contractor staff, is made aware of, understands, and complies with this policy.

(End of Clause)

Any contract awarded from this RFP will contain the following article:

ARTICLE I.6. SERVICE CONTRACT LABOR STANDARDS

This contract is subject to the Service Contract Labor Standards. The following clauses are hereby incorporated and made a part of this contract. All clauses incorporated by reference have the same force and effect as if they were given full text. Upon request, the Contracting Officer will make their full text available.

- a. FAR Clause **52.222-17 Nondisplacement of Qualified Workers** (May 2014).
- b. FAR 52.222-55 **Minimum Wages Under Executive Order 13658** (December 2015)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

| Attachment No. | Title | Location |
|----------------|---|--|
| Attachment 1: | Packaging and Delivery of Proposal (Non R & D) | Please refer to the attachment at the end of the RFP or the following link: Att1PackagingDelivery.pdf |
| Attachment 2: | Proposal Intent Response Sheet | http://ncioa.cancer.gov/oa-internet/forms/intent.jsp ATT2ProposallIntentResponse.pdf |
| Attachment 3: | Statement of Work | Please refer to the attachment at the end of the RFP or the following link: Att3_SOW.pdf |
| Attachment 4: | Section K - Representations, Certifications, and Other Statements of Offerors | Please refer to the attachment at the end of the RFP or the following link: Attachment 4 SectionK.pdf |

TECHNICAL PROPOSAL ATTACHMENTS

| Attachment No. | Title | Location |
|----------------|--|---|
| Attachment 5: | Technical Proposal Cost Summary | http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf ATT5TechPropCostSumm.pdf |
| Attachment 6: | Summary of Related Activities | http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf ATT6SummaryRelatedActivities.pdf |
| Attachment 7: | Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310) | http://www.hhs.gov/ohrp/assurances/forms/of310.pdf Att7ProtectionofHumanSubjects.pdf |
| Attachment 8: | HHS Section 508 Product Assessment Template | http://www.hhs.gov/web/508/contracting/technology/vendors.html ATT8Section508PAT.pdf |
| Attachment 9: | Additional Technical Proposal Instructions | Please refer to the attachment at the end of the RFP or the following link: |

| Attachment No. | Title | Location |
|----------------|-------|--|
| | | Attachment9_Additional_Technical_Proposal_Instructions.pdf |

BUSINESS PROPOSAL ATTACHMENTS

| Attachment No. | Title | Location |
|----------------|--|---|
| Attachment 10: | Proposal Summary and Data Record, NIH-2043 | http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf ATT10ProposalSummaryDataRecord.pdf |
| Attachment 11: | Small Business Subcontracting Plan | http://www.hhs.gov/asfr/ogapa/osbdu/smallbusiness/subcontractplan.html Att11SubcontractingPlan.pdf |
| Attachment 12: | Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet | http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/buscost.htm http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx Att12Breakdown_of_Proposed_Estimated_Cost-1.pdf |
| Attachment 13: | Offeror's Points of Contact | http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf ATT13PointsofContact.pdf |
| Attachment 14: | Disclosure of Lobbying Activities, OMB Form SF-LLL | http://www.gsa.gov/portal/forms/download/116430 ATT14SFLLL.pdf |

INFORMATIONAL ATTACHMENTS

| Attachment No. | Title | Location |
|----------------|---|--|
| Attachment 15: | Invoice/Financing Request Instructions-CR-NIH(RC)-1 | http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc1_508.pdf ATT15NIHRC1.pdf |
| Attachment 16: | Privacy Act System of Records | http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm Att16SystemofRecordsnotice.pdf |
| Attachment 17: | Commitment to Protect Non-Public Information Contractor Agreement | https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf Att17_Nondisclosure.pdf |
| Attachment 18: | Roster of Employees Requiring Suitability Investigations | https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx ATT18_Employees.pdf |

| Attachment No. | Title | Location |
|-----------------------|-------------------------------|--|
| Attachment 19: | Employee Separation Checklist | https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf ATT19_EmployeeSeperationChecklist.pdf |

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the **System for Award Management (SAM)** and complete the Representations and Certifications. The SAM website may be accessed at: <http://www.sam.gov> ; and
2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**
SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS
which is included as an Attachment in Section J-LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation.

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

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

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

(End of Clause)

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2006)]

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

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

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

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

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

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

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

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

a. 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.

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

i. The solicitation number;

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

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

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

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

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

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

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

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

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

(3) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) *Contract award.*

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

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

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

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

limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

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

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

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

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

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

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

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

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

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

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

(iv) A summary of the rationale for award.

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

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

(End of Provision)

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

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

b. NAICS CODE AND SIZE STANDARD

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this RFP), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is 541990.
2. The small business size standard is \$15M.

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(s) will be made on/about November 30, 2016.
2. It is anticipated that the award from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a Period of Performance of a base year and 4 one-year options, 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. 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.

e. PROMOTING EFFICIENT SPENDING

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

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

Any contract awarded as a result of this solicitation will:

- Specifically prohibit the use of contract funds for the provision of food for meals, light refreshments and beverages for any NIH funded meeting or conference; and

- Limit the procurement of meeting space, promotional items, printing and publications.

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 Room E570
NCI/NIH/DHHS MSC 9705
Rockville, MD 20850- 9705

(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 [research] contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal found to be technical acceptable will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -

1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

Such communications shall not be used to cure proposal deficiencies or omissions that alter the technical or cost elements of the proposal, and/or otherwise revise the proposal, but may be considered in rating proposals for the purpose of establishing the competitive range.

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

While it is 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's requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

11. Certification of Filing and Payment of Taxes

None of the funds appropriated or otherwise made available by the Consolidated Appropriations Act of FY 2014, may be used to enter into a contract in an amount greater than \$5,000,000 unless the prospective contractor certifies in writing to the agency awarding the contract that, to the best of its knowledge and belief, the contractor has filed all Federal tax returns required during the 3 years preceding the certification, has not been convicted of a criminal offense under the Internal Revenue Code of 1986, and has not, more than 90 days prior to certification, been notified of any unpaid Federal tax assessment for which the liability remains unsatisfied, unless the assessment is the subject of an installment agreement or offer in compromise that has been approved by the Internal Revenue Service and is not in default, or the assessment is the subject of a non-frivolous administrative or judicial proceeding.

12. Past Performance Information

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

A list of the last three contracts completed during the past three years 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 \$25,000 or more.

Include the following information for each contract or subcontract listed:

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

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

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

13. **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:
1. HHS-OCIO Information Systems Security and Privacy Policy (<http://www.hhs.gov/ocio/policy/#Security>)
 2. HHS HSPD-12 Policy Document, v. 2.0 (<http://www.whitehouse.gov/sites/default/files/omb/assets/omb/memoranda/fy2005/m05-24.pdf>)
 3. Information regarding background checks/badges (<http://idbadge.nih.gov/background/index.asp>)

- c. Position Sensitivity Levels:

This contract will entail the following position sensitivity levels:

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

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

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

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

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

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

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

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

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

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

- e. Investigations are expensive and may delay performance, regardless of the outcome of the investigation. Delays associated with rejections and consequent re-investigations may not be excusable in accordance with the FAR clause, Excusable Delays - see FAR 52.249-14. Accordingly, the Contractor shall ensure that any additional employees whose names it submits for work under this contract have a reasonable chance for approval.
- f. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the additional investigation(s). Accordingly, if position sensitivity levels are specified in paragraph (d) above, the Offeror shall ensure that the employees it proposes for work under this contract/order have a reasonable chance for approval.
- g. The Contractor shall include language similar to this "HHS Controlled Facilities and Information Systems Security" language in all subcontracts that require subcontractor personnel to have the same frequency and duration of (1) physical access to

an HHS-controlled facility; (2) logical access to an HHS-controlled information system; (3) access to sensitive HHS data/information, whether in an HHS-controlled information system or in hard copy; or (4) any combination of circumstances (1) through (3).

- h. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer.
- i. Within 7 calendar days after the Government's final acceptance of the work under this contract, or upon termination of the contract, the Contractor shall return all identification badges to the Contracting Officer or designee.

B. Standard for Security Configurations

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

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

- b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:
- c. The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings - see <http://scap.nist.gov/validation>. The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest FDCC major version and subsequent major versions.
- d. The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.
- e. The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.
- f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (<http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf>), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.

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

C. Standard for Encryption language

- a. The Contractor shall use Federal Information processing Standard (FIPS) 140-2-compliant encryption (Security) Requirements for Cryptographic Module, as amended) to protect all instances of HHS sensitive information during storage and transmission. (Note: The Government has determined that HHS information under this contract is considered "sensitive" in accordance with FIPS 199, Standards for Security Categorization of Federal Information and Information Systems, dated February 2004).
- b. The Contractor shall verify that the selected encryption product has been validated under the Cryptographic Module Validation Program (see <http://csrc.nist.gov/groups/STM/cmvp/>) to confirm compliance with FIPS 140-2 (as amended). The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative.
- c. The Contractor shall use the Key Management Key (see FIPS 201, Chapter 4, as amended) on the HHS personal identification verification (PIV) card; or alternatively, the Contractor shall establish and use a key recovery mechanism to ensure the ability for authorized personnel to decrypt and recover all encrypted information (see <http://csrc.nist.gov/drivers/documents/ombencryption-guidance.pdf>). The Contractor shall notify the Contracting Officer and the Contracting Officer's Technical Representative of personnel authorized to decrypt and recover all encrypted information.
- d. The Contractor shall securely generate and manage encryption keys to prevent unauthorized decryption of information in accordance with FIPS 140-2 (as amended).
- e. The Contractor shall ensure that this standard is incorporated into the Contractor's property management/control system or establish a separate procedure to account for all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive HHS information.
- f. The Contractor shall ensure that its subcontractors (all tiers) which perform work under this contract comply with the requirements contained in this clause.

D. Security Requirements For Federal Information Technology Resources

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

- b. **Contractor responsibilities.** The Contractor is responsible for the following:
1. Protecting Federal information and Federal information systems in order to ensure their -
 - a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;
 - b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and
 - c. Availability, which means ensuring timely and reliable access to and use of information.
 2. Providing security of any Contractor systems, and information contained therein, connected to an HHS network or operated by the Contractor, regardless of location, on behalf of HHS.
 3. Adopting, and implementing, at a minimum, the policies, procedures, controls and standards of the HHS Information Security Program to ensure the integrity, confidentiality, and availability of Federal information and Federal information systems for which the Contractor is responsible under this contract or to which it may otherwise have access under this contract. The HHS Information Security Program is outlined in the HHS Information Security Program Policy, which is available on the HHS Office of the Chief Information Officer's (OCIO) Web site.
- c. **Contractor security deliverables.** In accordance with the timeframes specified, the Contractor shall prepare and submit the following security documents to the Contracting Officer for review, comment, and acceptance:
1. **IT Security Plan (IT-SP)** - due within 30 days after contract award. The IT-SP shall be consistent with, and further detail the approach to, IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The IT-SP shall describe the processes and procedures that the Contractor will follow to ensure appropriate security of IT resources that are developed, processed, or used under this contract. If the IT-SP only applies to a portion of the contract, the Contractor shall specify those parts of the contract to which the IT-SP applies.
 - a. The Contractor's IT-SP shall comply with applicable Federal laws that include, but are not limited to, the Federal Information Security Management Act (FISMA) of 2002 (Title III of the E-Government Act of 2002, Public Law 107-347), and the following Federal and HHS policies and procedures:
 - i. Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automation Information Resources.
 - ii. National Institutes of Standards and Technology (NIST) Special Publication (SP) 800-18, Guide for Developing Security Plans for Information Systems, in form and content, and with any pertinent contract Statement of Work/Performance Work Statement (SOW/PWS) requirements. The IT-SP shall identify and document appropriate IT security controls consistent with the sensitivity of the information and the requirements of Federal Information Processing Standard (FIPS) 200, Recommend Security Controls for Federal

Information Systems. The Contractor shall review and update the IT-SP in accordance with NIST SP 800-26, Security Self-Assessment Guide for Information Technology Systems and FIPS 200, on an annual basis.

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

2. **IT Risk Assessment (IT-RA)** - due within 30 days after contract award. The IT-RA shall be consistent, in form and content, with NIST SP 800-30, Risk Management Guide for Information Technology Systems, and any additions or augmentations described in the HHS-OCIO Information Systems Security and Privacy Policy. After resolution of any comments provided by the Government on the draft IT-RA, the Contracting Officer shall accept the IT-RA and incorporate the Contractor's final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.
3. **FIPS 199 Standards for Security Categorization of Federal Information and Information Systems Assessment (FIPS 199 Assessment)** - due within 30 days after contract award. The FIPS 199 Assessment shall be consistent with the cited NIST standard. After resolution of any comments by the Government on the draft FIPS 199 Assessment, the Contracting Officer shall accept the FIPS 199 Assessment and incorporate the Contractor's final version into the contract.
4. **IT Security Certification and Accreditation (IT-SC&A)** - due within 3 months after contract award. The Contractor shall submit written proof to the Contracting Officer that an IT-SC&A was performed for applicable information systems - see paragraph (a) of this clause. The Contractor shall perform the IT-SC&A in accordance with the HHS Chief Information Security Officer's Certification and Accreditation Checklist; NIST SP 800-37, Guide for the Security, Certification and Accreditation of Federal Information Systems; and NIST 800-53, Recommended Security Controls for Federal Information Systems. An authorized senior management official shall sign the draft IT-SC&A and provided it to the Contracting Officer for review, comment, and acceptance.
 - a. After resolution of any comments provided by the Government on the draft IT SC&A, the Contracting Officer shall accept the IT-SC&A and incorporate the Contractor's final version into the contract as a compliance requirement.
 - b. The Contractor shall also perform an annual security control assessment and provide to the Contracting Officer verification that the IT-SC&A remains valid. Evidence of a valid system accreditation includes written results of:
 - i. Annual testing of the system contingency plan; and
 - ii. The performance of security control testing and evaluation.
- d. **Personal identity verification.** The Contractor shall identify its employees with access to systems operated by the Contractor for HHS or connected to HHS systems and networks. The Contracting Officer's Representative (COR) shall identify, for those identified employees, position sensitivity levels that are commensurate with the responsibilities and risks associated with their assigned positions. The Contractor shall comply with the HSPD-12 requirements contained in "HHS-Controlled Facilities and Information Systems Security" requirements specified in the SOW/PWS of this contract.

- e. **Contractor and subcontractor employee training.** The Contractor shall ensure that its employees, and those of its subcontractors, performing under this contract complete HHS-furnished initial and refresher security and privacy education and awareness training before being granted access to systems operated by the Contractor on behalf of HHS or access to HHS systems and networks. The Contractor shall provide documentation to the COR evidencing that Contractor employees have completed the required training.
- f. **Government access for IT inspection.** The Contractor shall afford the Government access to the Contractor's and subcontractors' facilities, installations, operations, documentation, databases, and personnel used in performance of this contract to the extent required to carry out a program of IT inspection (to include vulnerability testing), investigation, and audit to safeguard against threats and hazards to the integrity, confidentiality, and availability, of HHS data or to the protection of information systems operated on behalf of HHS.
- g. **Subcontracts.** The Contractor shall incorporate the substance of this clause in all subcontracts that require protection of Federal information and Federal information systems as described in paragraph (a) of this clause, including those subcontracts that -
 - a. Have physical or electronic access to HHS' computer systems, networks, or IT infrastructure; or
 - b. Use information systems to generate, store, process, or exchange data with HHS or on behalf of HHS, regardless of whether the data resides on a HHS or the Contractor's information system.
- h. **Contractor employment notice.** The Contractor shall immediately notify the Contracting Officer when an employee either begins or terminates employment (or is no longer assigned to the HHS project under this contract), if that employee has, or had, access to HHS information systems or data.
- i. **Document information.** The Contractor shall contact the Contracting Officer for any documents, information, or forms necessary to comply with the requirements of this clause.
- j. **Contractor responsibilities upon physical completion of the contract.** The Contractor shall return all HHS information and IT resources provided to the Contractor during contract performance and certify that all HHS information has been purged from Contractor-owned systems used in contract performance.
- k. **Failure to comply.** Failure on the part of the Contractor or its subcontractors to comply with the terms of this clause shall be grounds for the Contracting Officer to terminate this contract.

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

E. Additional NIH Requirements

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

- a. Information Type:

Administrative, Management and Support Information:

Mission Based Information:

b. Security Categories and Levels:

| | | | |
|------------------------|---|---|--------------------------------------|
| Confidentiality Level: | <input checked="" type="checkbox"/> Low | <input type="checkbox"/> Moderate | <input type="checkbox"/> High |
| Integrity Level: | <input type="checkbox"/> Low | <input checked="" type="checkbox"/> Moderate | <input type="checkbox"/> High |
| Availability Level: | <input checked="" type="checkbox"/> Low | <input type="checkbox"/> Moderate | <input type="checkbox"/> High |
| Overall Level: | <input type="checkbox"/> Low | <input checked="" type="checkbox"/> Moderate | <input type="checkbox"/> High |

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

2. INFORMATION SECURITY TRAINING

The contractor shall comply with the below training:

a. Mandatory Training

- i. All Contractor employees having access to (1) Federal information or a Federal information system or (2) sensitive data/information, shall complete the NIH Computer Security Awareness Training course at <http://irtsectraining.nih.gov/> before performing any work under this contract. Thereafter, Contractor employees having access to the information identified above shall complete an annual NIH-specified refresher course during the life of this contract. The Contractor shall also ensure subcontractor compliance with this training requirement.
- ii. The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working on this contract and having access of the kind in paragraph 1.a(1) above, who has completed the NIH required training. Any additional security training completed by the Contractor/Subcontractor staff shall be included on this listing. The list shall be provided to the COR and/or Contracting Officer upon request.

b. Role-based Training

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

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

c. Rules of Behavior

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

3. **PERSONNEL SECURITY RESPONSIBILITIES**

The contractor shall comply with the below personnel security responsibilities:

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

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

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

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

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

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

Each employee, including subcontractors, having access to non-public Department information under this acquisition shall complete the

"Commitment to Protect Non-Public Information - Contractor Employee Agreement" located at: <https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf>. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer/COR prior to performing any work under this acquisition.

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

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

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

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

5. VULNERABILITY SCANNING REQUIREMENTS

This acquisition requires the Contractor to host an NIH webpage or database.

The Contractor shall conduct periodic and special vulnerability scans, and install software/hardware patches and upgrades to protect automated federal information assets. The minimum requirement shall be to protect against vulnerabilities identified on the SANS Top-20 Internet Security Attack Targets list (<http://www.sans.org/top20/?ref=3706#w1>). The Contractor shall report the results of these scans to the Project Officer/COR on a monthly basis, with reports due 10 calendar days following the end of each reporting period.

The Contractor shall ensure that all of its subcontractors (at all tiers), where applicable, comply with the above requirements.

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

- a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.
- b. Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of the Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards>.
- c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility. In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site <http://www.hhs.gov/web/508>. In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.
- d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

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

15. 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. Central Contractor Registration, FAR Provision 52.204-7 (July 2013).

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

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

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

- d. SAFETY Act--Equitable Adjustment, FAR Clause 52.250-5, (February 2009).

b. TECHNICAL PROPOSAL INSTRUCTIONS

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

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

1. Technical Discussions

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

a. Statement of Work

1. Objectives

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

2. Approach

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

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

3. Methods

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

4. Schedule

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

b. Personnel

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

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

1. Other Investigators

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

2. 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.

3. Resumes

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

2. Other Considerations

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

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

3. Technical Evaluation

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

4. Human Subjects

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

- a. **Notice to Offerors of Requirements, Protection of Human Subjects, HHSAR 352.270-4(a) (December 2015)**
 - a. The Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR part 46, are available on the Office for Human Research Protections (OHRP) Web site at: <http://www.hhs.gov/ohrp/index.html>. These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of human subjects participating in research activities supported or conducted by HHS.

- b. The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable public information through intervention or interaction with the individual, or identifiable private information. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. 45 CFR part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.
- c. Activities which involve human subjects in one or more of the categories set forth in 45 CFR 46.101(b)(1)-(6) are exempt from complying with 45 CFR part 46. See <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.
- d. Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal.
- e. In accordance with 45 CFR part 46, offerors considered for award shall file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board shall ensure that: The risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; see <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111> for additional requirements regarding initial and continuing review. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP Web site (at <http://www.hhs.gov/ohrp/assurances/index.html>).
- f. Offerors may consult with OHRP only for general advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. ONLY the contracting officer may offer information concerning a solicitation.
- g. The offeror shall document in its proposal the approved FWA from OHRP, related to the designated Institutional Review Board (IRB) reviewing and overseeing the research. If the offeror does not have an approved FWA from OHRP, the offeror must obtain an FWA before the deadline for proposal submission. When possible, the offeror shall also certify the IRB's review and approval of the research. If the offeror cannot obtain this certification by the time of proposal submission they must include an explanation in their proposal. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.
(End of provision)

Alternate I (DEC 2015).

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

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

b. Instructions to Offerors Regarding Protection of Human Subjects

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

a. Risks to the subjects

- Human Subjects Involvement and Characteristics:
 - Describe the proposed involvement of human subjects in response to the solicitation.
 - Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
 - Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.
- Sources of Materials:
 - Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
- Potential Risks:
 - Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
 - Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

b. Adequacy of Protection Against Risks

- Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the Contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the Contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.
- Protection Against Risk:
 - Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
 - Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
 - In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.
- c. Potential Benefits of the Proposed Research to the Subjects and Others
 - Discuss the potential benefits of the research to the subjects and others.
 - Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
 - Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.
- d. Importance of the Knowledge to be Gained
 - Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
 - Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

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

Collaborating Site(s)

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

c. Required Education in the Protection of Human Research Participants

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

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

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

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

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

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

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

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

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

Information Required for ALL Clinical Research Proposals

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

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

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

NOTE 1: For all proposals, use the ethnic and racial categories and complete the "Planned Enrollment Report" in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at: http://www.whitehouse.gov/omb/fedreg_notice_15.

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

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

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

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference).

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

by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

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

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

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

OR

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

OR

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

Use the form entitled, "Planned Enrollment Report," when preparing your response to the solicitation requirements for inclusion of women and minorities. (See Section J-List of Documents, Exhibits and Other Attachments of the RFP)

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the form entitled, "Cumulative Inclusion Enrollment Report," for reporting in the resultant contract.

e. Inclusion of Children in Research Involving Human Subjects

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

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

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

<http://www.nih.gov/grants/guide/notice-files/not98-024.html>

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

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

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

Justifications for Exclusion of Children

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

- The objective of the solicitation is not relevant to children.
 - There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
 - The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
 - A separate, age-specific study in children is warranted and preferable. Examples include:
 - The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
 - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
 - Issues of study design preclude direct applicability of hypotheses and/ or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
 - Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
 - Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
 - Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

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

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person

age 18 to be an adult and therefore one who can provide consent without parental permission.

Research Involving Prisoners as Subjects

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

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

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

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

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

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

f. **Research Involving Human Fetal Tissue**

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

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

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

with the collection processing, preservation, storage, quality control or transportation of these tissues.

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

g. Human Embryonic Germ Cell (HEGC) Research

1. Guidelines.

Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (<http://stemcells.nih.gov/policy/guidelines.asp>) (only the information regarding human embryonic germ cells is relevant). Embryonic germ cells are pluripotent stem cells derived from human embryos. See NIH Guide for Grants and Contracts Notice NOT OD 02 049, requiring that offerors/contractors submit certain documents to the Human Pluripotent Stem Cell Review Group (HPSCRG), which will be reviewed in a public meeting. Research using human embryonic germ cells may not be performed prior to approval by the HPSCRG.

All offerors should read the "NIH Guidelines" (<http://stemcells.nih.gov/policy/guidelines.asp>) if they either: (1) propose to respond to the Statement of Work requirements by conducting research that uses human embryonic germ cells or, (2) are responding to a Statement of Work that requires the use of human embryonic germ cells.

Offerors may obtain copies of these Guidelines from the website above or from the contact person listed in this solicitation.

2. Procedure for Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

If the offeror intends to fulfill the requirements of the Statement of Work by performing research using human embryonic germ cells, it must so state in its proposal.

If the offeror's proposal includes research using human embryonic germ cells and it receives a contract award, the Contractor may not perform any research using these human embryonic germ cells until the Human Pluripotent Stem Cell Review Group (HPSCRG) has reviewed and approved the documentation furnished as prescribed in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (<http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html>) and the Contracting Officer has notified the Contractor of the approval in writing.

The resultant contract will be divided into discrete phases or option period(s). During the base period of the contract, the Contractor shall submit the original and two copies of the required documentation and assurances that address the areas covered in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," at:

(http://grants2.nih.gov/grants/guide/notice_files/NOT_OD_02_049.html)

to the Contracting Officer. This documentation will be forwarded for review and approval to the HPSCRG.

If the HPSCRG disapproves the documentation presented by the Contractor, the Contracting Officer may elect to either terminate the contract in accordance with the Termination for Convenience clause of the contract OR determine not to exercise subsequent option(s) as appropriate based the terms of the specific contract. Otherwise, when the HPSCRG approves the documentation, the Contracting Officer

will notify the Contractor in writing that research using the human embryonic germ cells may commence.

Research involving the use of human embryonic germ cells shall not be conducted under the contract until the HPSCRG review and approval have been obtained, and the Contracting Officer has provided written notice of such approval to the Contractor.

h. Human Embryonic Stem Cell (hESC) Research

On March 9, 2009, the President issued Executive Order (EO) 13505: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*. The NIH has published Guidelines on Human Stem Cell Research at: <http://stemcells.nih.gov/policy/pages/2009guidelines.aspx>. The Guidelines implement EO 13505 with regard to extramural NIH-funded stem cell research, establish policy and procedure under which the NIH will fund such research, and help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law. Specific eligibility requirements for NIH funding of hESCs are included in Section II, *Eligibility of Human Embryonic Stem Cells for Research with NIH Funding*. Ineligible sources and uses of hESCs are addressed in Section IV, *Research Using hESCs and/or Human Induced Pluripotent Stem Cells That, Although the Cells May Come from Eligible Sources, is Nevertheless Ineligible for NIH Funding*, and Section V, *Other Research Not Eligible for NIH Funding*.

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

Research involving the derivation of new stem cells from human embryos or the use of human embryonic stem cells that are not listed on the NIH Registry may not be conducted with Federal funding.

5. **Electronic and Information Technology Accessibility, Section 508 Compliance** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal, entitled, "Section 508 Compliance."

Electronic and Information Technology Accessibility, HHSAR 352.239-73(a) (January 2010)

- a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit--
 - i. Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and
 - ii. Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access

and use of information and data by members of the public who are not individuals with disabilities.

- b. Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility standards. Information about Section 508 visions is available at <http://www.section508.gov/>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/guidelines-and-standards>.
- c. The Section 508 accessibility standards applicable to this solicitation are identified in the Statement of Work. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Evaluation Template may be found on the HHS Web site (<http://www.hhs.gov/web/508/contracting/technology/vendors.html>).
- d. Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 accessibility standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government -- i.e., after award of a contract/order, that products or services delivered do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor and at its expense.

(End of provision)

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

6. Instructions to Offerors-Sustainable Acquisition, HHSAR Provision 352.223-71 (December 2015)

Offerors must include a Sustainable Acquisition Plan in their technical proposals. The Plan must describe their approach and the quality assurance mechanisms in place for applying FAR 23.1 Sustainable Acquisition Policy (and other Federal Laws, regulations and Executive Orders governing sustainable acquisition purchasing) to this acquisition. the Plan shall clearly identify those products and services included in Federal sustainable acquisition preference programs by categorizing them along with their respective price/cost in the following eight groups: Recycled Content, Energy Efficient, Biobased, Environmentally Preferable, Electronic Product Environment Assessment Tool, Water-Efficient, Non-Ozone Depleting Substances, and Alternative Fuels.

(End of Provision)

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.

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

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 \$700,000, 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)

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

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

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

5. Salary Rate Limitation

Offerors are advised that no NIH funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II*. The Executive Schedule, Level II* annual salary rate limitation also applies to individuals proposed under subcontracts and to consultants. **LINK TO EXECUTIVE SCHEDULE RATES OF PAY:**

<https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/>

(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

***Note to Offerors:** The current Fiscal Year Executive Level II Salary Rate shall be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year Executive Level II Salary rates.

6. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$650,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance

with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

- a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c. The offeror understands that:
 1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
 2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
 3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
 4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
 5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
 6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d. Each plan must contain the following:
 1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
 2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to

Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

4. A description of the method used to develop the subcontracting goals.
5. A description of the method used to identify potential sources for solicitation purposes.
6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$650,000 adopt a plan similar to the plan agreed upon by the offeror.
10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government.
11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

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

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

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

7. Mentor-Protégé Program, HHSAR 352.219-70 (December) 2015

- a. Large business prime contractors serving as mentors in the HHS Mentor-Protege Program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU) approved mentor-protege agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protege firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at www.esrs.gov. The mentor firm and protege firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a \$10,000 subcontract awarded to a protege firm and provision of \$5,000 of developmental assistance as \$15,000 of subcontracting plan credit.) The mentor firm may

use this additional credit towards attaining its subcontracting plan participation goal under this contract.

b. The program consists of--

1. Mentor firms--large businesses that:
 - (i) Demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and
 - (ii) Have a Mentor-Protege agreement approved by HHS' OSDBU;
2. Protege firms--firms that:
 - (i) Seek developmental assistance;
 - (ii) Qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned small businesses; and
 - (iii) Have a Mentor-Protege agreement approved by HHS' OSDBU; and
3. Mentor-Protege agreements--joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

8. HUBZone Small Business Concerns

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

9. 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

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "HHS Contracting Guide for Contract of Government Property," which can be found at: <https://web.archive.org/web/20111015044731/http://www.hhs.gov/hhsmanuals/>.

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 base period. 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)

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

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

2. COST/PRICE EVALUATION

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

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

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

3. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

a. Protection of Human Subjects from Research Risks

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

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

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

against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

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

b. Women and Minorities

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

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

OR

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

OR

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

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

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

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.

- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
 - the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
 - overriding factors dictate selection of subjects); or
 - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.
- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
 - inclusion of those groups would be inappropriate with respect to their health; or
 - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

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

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

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

c. **Children**

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

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a

sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

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

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

4. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

5. 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.

1. EXPERIENCE AND CAPABILITIES OF PERSONNEL: 45 POINTS

a) Project Director

- Experience with oversight of large, complex contracts
- Experience running multiple large, international studies simultaneously
- Experience with clinical studies involving human subjects
- Experience with biospecimen-intensive strategies

b) Research Nurses

- Experience in conducting family studies and overseeing other nurses
- Knowledge of cancer nursing and cancer genetics
- Experience in managing multidisciplinary studies with biospecimen collection
- Experience in conduct of clinical trials

c) Genetic Counselor

- Master's Degree (or equivalent) in genetic counseling or related discipline (e.g., nursing)
- Experience with inherited cancer susceptibility syndromes
- Experience with cancer risk assessment, genetic counseling in the context of testing for mutations in germline cancer susceptibility genes with the intent of results disclosure for clinical decision-making

d) Research Assistants/Biological Specimen Coordinators

- Demonstrated experience in arranging for the collection, handling, transport, storage, and analysis (including monitoring of blind quality control samples) of biologic specimens.
- Demonstrated experience in managing data generated by a wide range of laboratories, in integrating such data into epidemiologic study databases, and carrying out initial graphical and summary statistical analyses

e) Experience and capabilities of other specialists required for the conduct of the described variety of field and family studies, including but not limited to:

- nurses;
- forms designers;
- trainers;
- statistical sampling design specialists;
- nosologists;
- coding specialists in specific areas such as nutrition, therapeutic drugs, occupations, industries, exposures;
- translators;
- programmers; and
- systems analysts

f) Experience and capabilities of other personnel

- Interviewer supervisors;
- coding supervisors;
- keying supervisor;
- telephone center supervisor;
- other mid-level personnel, including abstractors, interviewers, research assistants, keyers, coders, phlebotomists, and field personnel.

2. ORGANIZATIONAL EXPERIENCE CONDUCTING AND SIMULTANEOUSLY MANAGING MULTIPLE, CONCURRENT, BIOSPECIMEN-INTENSIVE, LARGE (INCLUDING INTERNATIONAL) STUDIES, CLINICAL STUDIES, AND FAMILY STUDIES: 35 POINTS

a) Clinical activities conducted by the Offeror relevant to the RFP including, but not limited to:

- Providing nursing and nursing services;
- Providing genetic counseling and counseling services;
- Providing support to clinical trials, including FDA-related regulatory activities;
- involvement with clinical activities that targets genetic risk, cancer risk;
- Obtaining pathology and surgical specimens;
- Obtaining, verifying family history information, and constructing pedigrees;
- Identifying appropriate high-risk family members and other persons at increased risk of cancer and enrolling them in study protocols (including informed consent); and
- Collecting, handling, shipping, processing, cataloging, managing and distributing multiple types of biological specimens.

b) Survey activities conducted by the Offeror relevant to the AP including, but not limited to:

- Designing data collection forms;
- Training interviewers, abstractors, and other data collection personnel;
- Identification of cancer patients and other study subjects nationally and internationally;
- Identification of appropriate controls (both population-based and hospital-based);
- Successful enrollment of study subjects from multiple areas and cultural settings;
- Inclusion of women, children and minorities in studies, as appropriate;
- Interviewing (telephone, in person, self administered);
- Abstracting medical, occupational, and other exposure records;
- Tracing individuals to update contact information and determine vital status;
- Obtaining death certificates;
- Obtaining medical records including imaging studies;
- Coding, keying, and editing of data;
- Developing documentation, procedure manuals, quality control and assurance procedures for all phases of studies;
- Creation of computerized data bases suitable for analysis; and
- Creation and maintenance of computerized bibliographic resource files.

c) Capability of the Offeror to respond quickly to changes in priorities and to supply support to urgent new efforts as directed by the Project Officer.

d) The initial phase-in plan shall demonstrate an orderly, secure, efficient, and expedient transition of all contract activities, in the event an initial transition would be required. The phase-in plan shall address:

- Transition activities to be undertaken
- Timelines for the completion of each transition activity
- Staff to be assigned

3. MANAGERIAL APPROACH: 10 POINTS

- Position of the Project Director in relation to the organizational structure of the Offeror
- Plan to manage multiple field and family studies in widespread areas;
- Ability to mobilize additional personnel to support emergent, high-priority projects;
- Description of how frequent face-to-face meetings with NCI staff will be accomplished; and
- Discussion of women, children, and minorities in the clinical populations.

4. FACILITIES AND EQUIPMENT: 10 POINTS

- Description of security of medical record room, accessibility of medical records to NCI staff, tracking of records;
- Data processing and storage capability;
- security of data files;
- Telephone interviewing center; and
- Other facilities and equipment.

TOTAL TECHNICAL EVALUATION: 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

Offeror's past performance information will be evaluated subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the offeror concerning problems encountered on the identified contracts and corrective action taken.

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

When assessing performance risks, the Government, to the fullest extent practicable, will focus on the past performance of the offeror as it relates to all acquisition requirements, in terms of Quality, Schedule, Cost Control, Business Relations, Management, Small Business and Other factors as deemed appropriate.

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

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

8. Evaluation of Sustainable Acquisition Plan

| 8. Descriptor | Proposal qualities |
|---------------|--|
| Excellent | Documents compliance with relevant environmental laws and regulations to acquire supplies and services that promote energy and water efficiency, advance the use of renewable energy products, and help foster markets for emerging technologies. Implements cost- effective contracting preference programs promoting energy- efficiency, water conservation and the acquisition of environmentally preferable products and services (e.g., computer monitor, desktop computer, notebook computer and personal computer products). Minimizes the procurement of materials and substances that contribute to the depletion of stratospheric ozone. Gives preference to the procurement of alternative chemical, product, and manufacturing processes that reduce overall risks to human health and the environment by lessening the depletion of ozone in the upper atmosphere. Reduces paper use and acquires paper containing at least 30% postconsumer fiber. |
| Good | Documents compliance with relevant environmental laws and regulations and commits the organization to more aggressive actions such as: Develops and implements innovative policies and practices to reduce scope 3 GHG emissions in HHS operations. Manages existing buildings to reduce energy, water, and materials consumption. Implements and achieves objectives in EPA's Storm water Management Guidance. Reduces paper use and acquires paper containing at least 30% postconsumer fiber. Minimizes the acquisition, use, and disposal of toxic and hazardous materials. Employs environmentally sound practices for the disposition of all agency excess or surplus electronic products. Procures Energy Star and FEMP-designated electronic equipment. Continues implementation of existing Environmental Management System (EMS) |
| Fair | Documents existing programs that meet relevant environmental laws and regulations and proposes modest further steps. |
| Poor | Merely states that the offeror will comply with relevant environmental laws and regulations, or describes programs that merely comply with relevant laws. |