

# SOLICITATION

## SECTION A - SOLICITATION/CONTRACT FORM

|  |   |  |
|--|---|--|
| 1. Requisition or other Purchase Authority: _____  |   |  |
| 2. <b>Request for Proposal (RFP) Number:</b><br><br>N02CM61001-14  | 3. <b>Issue Date:</b><br><br>January 22, 2016 | 4. <b>Set Aside:</b><br>[ ] No<br>[X] Yes See Part IV Section L  |
| 5. Title : Operation & Support of the CTEP Protocol and Information Office (PIO)   |   |  |
| 6. ISSUED BY:<br>Office of Acquisitions<br>National Cancer Institute<br>National Institutes of Health<br>9609 Medical Center Drive, Room 1E618, MSC 9705<br>Rockville, MD 20850-9705<br><br>_____<br>_____<br>_____  |   | 7. SUBMIT OFFERS TO:<br><br>See Part III, Section J,<br>"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 2:00PM local time on February 22, 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.<br><br>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 Central Contractor Registry (CCR) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at <a href="http://www.sam.gov">http://www.sam.gov</a>  |   |  |
| 11. FOR INFORMATION CALL: James Horkan<br>PHONE: 240-276-7803<br>e-MAIL: james.horkan@nih.gov<br>COLLECT CALLS WILL NOT BE ACCEPTED.   |   |  |
| The cutoff date for questions is February 9, 2016.<br><br>The page limit for Technical Proposals is 100 pages. Please see "Additional Technical Proposal Instructions (Attachment 9)."   |   | Rukshani Levy<br>Contracting Officer<br>Office of Acquisitions<br><br>_____  |

## RFP TABLE OF CONTENTS

|   |    |
|---|----|
| <b>NOTICE TO OFFERORS</b> .....   | 4  |
| <b>PART I - THE SCHEDULE</b> .....  | 5  |
| <b>SECTION A - SOLICITATION/CONTRACT FORM</b> .....                                       | 1  |
| <b>SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS</b> .....                            | 5  |
| <b>SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT</b> .....                        | 9  |
| <b>SECTION D - PACKAGING, MARKING AND SHIPPING</b> .....                                  | 13 |
| <b>SECTION E - INSPECTION AND ACCEPTANCE</b> .....  | 14 |
| <b>SECTION F - DELIVERIES OR PERFORMANCE</b> .....  | 15 |
| <b>SECTION G - CONTRACT ADMINISTRATION DATA</b> .....                                     | 17 |
| <b>SECTION H - SPECIAL CONTRACT REQUIREMENTS</b> .....                                    | 21 |
| <b>PART II - CONTRACT CLAUSES</b> .....   | 32 |
| <b>PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS</b> .....                 | 39 |
| <b>SECTION J - LIST OF ATTACHMENTS</b> .....  | 39 |
| SOLICITATION ATTACHMENTS.....   | 39 |
| TECHNICAL PROPOSAL ATTACHMENTS.....   | 39 |
| BUSINESS PROPOSAL ATTACHMENTS.....  | 40 |
| INFORMATIONAL ATTACHMENTS.....  | 40 |
| <b>PART IV - REPRESENTATIONS AND INSTRUCTIONS</b> .....                                   | 41 |
| <b>SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS</b> ..... | 41 |
| <b>SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS</b> .....                | 42 |
| 1. GENERAL INFORMATION.....   | 42 |
| a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION.....                                 | 42 |
| b. NOTICE OF 8(a) COMPETITIVE SET-ASIDE.....  | 45 |
| c. NAICS CODE AND SIZE STANDARD.....  | 45 |
| d. TYPE OF CONTRACT AND NUMBER OF AWARDS.....   | 46 |
| e. PERFORMANCE BASED ACQUISITION.....   | 46 |
| f. ESTIMATE OF EFFORT.....  | 46 |
| g. COMMITMENT OF PUBLIC FUNDS.....  | 46 |
| h. COMMUNICATIONS PRIOR TO CONTRACT AWARD.....  | 46 |
| i. RELEASE OF INFORMATION.....  | 47 |
| j. PREPARATION COSTS.....   | 47 |
| k. SERVICE OF PROTEST.....  | 47 |
| 2. INSTRUCTIONS TO OFFERORS.....  | 47 |
| a. GENERAL INSTRUCTIONS.....  | 47 |
| 1. Contract Type and General Clauses.....   | 47 |
| 2. Authorized Official and Submission of Proposal.....                                    | 47 |
| 3. Proposal Summary and Data Record (NIH-2043).....                                       | 48 |
| 4. Separation of Technical and Business Proposals.....                                    | 48 |
| 5. Alternate Proposals.....   | 48 |
| 6. Evaluation of Proposals.....   | 48 |
| 7. Potential Award Without Discussions.....   | 48 |
| 8. Use of the Metric System of Measurement.....   | 49 |

|   |           |
|---|-----------|
| 9. Privacy Act - Treatment of Proposal Information.....                                       | 49        |
| 10. Selection of Offerors.....  | 50        |
| 11. Certification of Filing and Payment of Taxes.....   | 50        |
| 12. Past Performance Information.....   | 51        |
| 13. Information and Physical Access Security.....   | 51        |
| 14. Solicitation Provisions Incorporated by Reference.....                                    | 60        |
| <b>b. TECHNICAL PROPOSAL INSTRUCTIONS.....</b>  | <b>60</b> |
| 1. Technical Discussions.....   | 61        |
| 2. Other Considerations.....  | 62        |
| 3. Technical Evaluation.....  | 63        |
| 4. Electronic and Information Technology Accessibility, HHSAR 352.239-73(a).....              | 63        |
| <b>c. BUSINESS PROPOSAL INSTRUCTIONS.....</b>   | <b>64</b> |
| 1. Basic Cost/Price Information.....  | 64        |
| 2. Proposal Cover Sheet.....  | 64        |
| 3. Information Other than Cost or Pricing Data.....   | 65        |
| 4. Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data..... | 66        |
| 5. Other Administrative Data.....   | 66        |
| 6. Qualifications of the Offeror.....   | 70        |
| 7. Subcontractors.....  | 70        |
| 8. Proposer's Annual Financial Report.....  | 71        |
| 9. Travel Costs/Travel Policy.....  | 71        |
| <b>SECTION M - EVALUATION FACTORS FOR AWARD.....</b>  | <b>72</b> |
| 1. GENERAL.....   | 72        |
| 2. COST/PRICE EVALUATION.....   | 72        |
| 3. EVALUATION OF OPTIONS.....   | 72        |
| 4. TECHNICAL EVALUATION FACTORS.....  | 72        |
| 5. EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY- SECTION 508.....        | 74        |
| 6. PAST PERFORMANCE FACTOR.....   | 75        |

**NOTICE TO OFFERORS**

This solicitation is being processed under a Partnership Agreement (PA) between the Department of Health and Human Services (HHS) and the Small Business Administration (SBA), under which the SBA has delegated to HHS, authority to enter into 8(a) contracts directly with eligible 8(a) firms. The PA implements innovative and effective methodology designed to streamline the acquisition process for awards under the 8(a) program. The National Cancer Institute is a designated pilot agency under the PA.

Any solicitation and subsequent awards processed under the referenced PA, the National Cancer Institute will make the award directly to the 8(a) firm. SBA will not be a signatory to the award resulting from this solicitation. SBA will, however, retain responsibility for 8(a) certification, administer other eligibility related issues under the 8(a) program, and be available to 8(a) firms for counseling and assistance.

If you have any questions pertaining to this PA, please contact Courtney Carter (courtney.carter@nih.gov/301-443-8722) .

**HHS/SBA PA (OCTOBER 23, 2012 until amended)  
Servicing Small Business Administration Field Office**

To facilitate communications, it is requested that the 8(a) participant submitting this offer/bid provide the following information regarding the firm's cognizant servicing Small Business Administration (SBA) office.

Servicing SBA Office \_\_\_\_\_

Address \_\_\_\_\_

\_\_\_\_\_

Cognizant SBA Business Opportunity Specialist's Name \_\_\_\_\_

Phone \_\_\_\_\_

**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 Cancer Therapy Evaluation Program (CTEP), Division of Cancer Treatment and Diagnosis (DCTD), NCI, plans, assesses, and coordinates all aspects of cancer treatment clinical trials. The purpose of this contract is to support CTEP's Protocol and Information Office (PIO) by coordinating all administrative aspects related to clinical trial development, in order to ensure that quality protocols are developed in the most expeditious and efficient manner possible.

**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 PLUS AWARD FEE**

a. Estimated Cost and Fixed Fee

1. The total estimated cost of the Base Period of this contract is \$\_\_\_\_\_.
2. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the estimated cost shall be increased as follows:

|                                | <b>Estimated Cost (\$)</b> |
|--------------------------------|----------------------------|
| Base Period                    |                            |
| Increased Capacity Option Base |                            |
| Option Period 1                |                            |
| Increased Capacity Option 1    |                            |
| Option Period 2                |                            |
| Increased Capacity Option 2    |                            |
| Option Period 3                |                            |
| Increased Capacity Option 3    |                            |
| Option Period 4                |                            |
| Increased Capacity Option 4    |                            |

|                                   | <b>Estimated Cost (\$)</b> |
|-----------------------------------|----------------------------|
| Phase-Out Option                  |                            |
| Total [Base Period and Option(s)] |                            |

3. The total fixed fee for the Base Period of the contract is \$\_\_\_\_\_.

- a. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Office.

If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the fixed fee shall be increased as follows:

|                                   | <b>Fixed Fee (\$)</b> |
|-----------------------------------|-----------------------|
| Base Period                       |                       |
| Increased Capacity Option Base    |                       |
| Option Period 1                   |                       |
| Increased Capacity Option 1       |                       |
| Option Period 2                   |                       |
| Increased Capacity Option 2       |                       |
| Option Period 3                   |                       |
| Increased Capacity Option 3       |                       |
| Option Period 4                   |                       |
| Increased Capacity Option 4       |                       |
| Phase-Out Option                  |                       |
| Total [Base Period and Option(s)] |                       |

- b. Payment shall be subject to the withholding provision 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.

b. Award Fee Consideration

- 1. Based on the evaluation/determination described in subparagraph d. below, an award fee may be earned by the Contractor at regular intervals as defined in the paragraphs herein. The total potential award fee available is \$\_\_\_\_\_ and the evaluation periods shall be as follows:

| <b>Base Period<br/>Evaluation Period(s):</b> | <b>Available Award Fee</b> |
|--|----------------------------|
| Semiannually                                 | TBD                        |
|  |                            |
|  |                            |

- 2. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the total potential award fee available for the option years/periods and the evaluation periods shall be as follows:

| <b>OPTION(s) Period(s)</b> | <b>Evaluation Period(s) by Option</b> | <b>Available Award Fee</b> |
|----------------------------|---------------------------------------|----------------------------|
|                            | Semiannually                          | TBD                        |
|                            |                                       |                            |
|                            |                                       |                            |

c. Total Estimated Contract Amount

1. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee plus the earned award fee is \$\_\_\_\_\_.
2. 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 fixed fee plus the earned award fee and the period of performance will be increased as follows:

|                                   | Estimated Cost (\$) | Fixed Fee (\$) | Earned Award Fee (\$) | Estimated Cost Plus Fixed Fee (\$) |
|-----------------------------------|---------------------|----------------|-----------------------|------------------------------------|
| Base Period                       | TBD                 |                |                       |                                    |
| Increased Capacity Option Base    |                     |                |                       |                                    |
| Option Period 1                   |                     |                |                       |                                    |
| Increased Capacity Option 1       |                     |                |                       |                                    |
| Option Period 2                   |                     |                |                       |                                    |
| Increased Capacity Option 2       |                     |                |                       |                                    |
| Option Period 3                   |                     |                |                       |                                    |
| Increased Capacity Option 3       |                     |                |                       |                                    |
| Option Period 4                   |                     |                |                       |                                    |
| Increased Capacity Option 4       |                     |                |                       |                                    |
| Phase-Out Option                  |                     |                |                       |                                    |
| Total [Base Period and Option(s)] |                     |                |                       |                                    |

d. Methodology for Award Fee Evaluation/Determination

1. The Contractor's performance hereunder will be observed and evaluated continuously by the Government. At the end of each evaluation period, the Contracting Officer will review performance based on the standards and criteria established in the Quality Assurance Surveillance Plan, dated January 22, 2016, listed in SECTION J - LIST OF ATTACHMENTS, attached hereto and made a part of this contract.
2. The findings of the evaluation will determine the amount of the available award fee (specified in subparagraph b. above) earned by the Contractor for the identified evaluation period. In no event, however, will any unearned award fee become available in subsequent evaluation periods.
3. The Contracting Officer will notify the Contractor, in writing, of the available award fee actually earned for a given evaluation period. Upon receipt of this notification, the Contractor shall submit a public voucher for payment of the total award fee earned.
4. The evaluation/determination of award fee shall be binding on both parties and not subject to the Disputes clause included in Section I of the contract.

**ARTICLE B.4. ESTIMATED COST - INCREMENTALLY FUNDED CONTRACT, HHSAR 352.232-71 (July 2013)**

- 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 (\$)<br>(as appropriate) | Estimated Cost Plus Fee (\$)<br>(as appropriate) |
|------------------------------------|--|--|---------------------|------------------------------|--|
|                                    |  |  |                     |                              |  |
|                                    |  |  |                     |                              |  |
|                                    |  |  |                     |                              |  |
|                                    |  |  |                     |                              |  |
|                                    |  |  |                     |                              |  |
|                                    |  |  | [Total]             | [Total]                      | [Total]  |

\*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.
- (End of Clause)
- f. Payment of fee 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.

The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer.

**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 January 22, 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.

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

a. **Reports/Deliverables**

**1. Monthly Progress Report**

The Contractor shall prepare a monthly progress report that describes by sub-project (protocols, LOIs, Concepts, training, Scientific Writing, etc.), the monthly and cumulative hours and dollars spent. Projected estimates for each column shall be provided for comparison. Monthly and cumulative grand totals for the entire project shall also be provided. Hourly and dollar variance for the entire project shall be provided. Projected project and sub-project end dates shall be provided based on dollars and hours. The first report shall cover the period consisting of the first full month of this Contract. Thereafter, reports shall be due on or before the 15th calendar day following each monthly reporting period. A monthly report will be required even when the final report is due.

**2. Annual Progress Report**

The Contractor shall prepare an annual progress report that describes by sub-project (protocols, LOIs, Concepts, training, Scientific Writing, etc.), the monthly, annual and cumulative hours and dollars spent. Projected estimates for each column shall be provided for comparison. Annual and cumulative grand totals for the entire project shall also be provided. Hourly and dollar variance for the entire project shall be provided. Projected project and sub-project end dates shall be provided based on dollars and hours.

**3. Final Progress Report**

To include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the work conducted. A final report shall be submitted on or before the last day of the Contract performance period.

**4. Standard Operating Procedures**

The Contractor shall have in place a set of Standard Operating Procedures (SOPs) to describe the process for completing the tasks required by the SOW. The COR will be provided the opportunity to review and comment on the SOPs before the procedures are implemented. The SOPs shall be developed within 90 calendar days after the effective date of the contract. The Contractor shall update the SOPs whenever business processes are modified or as directed by the COR. The development of the SOPs shall be based, in part, upon current, existing CTEP business rules.

**5. Scheduled reports and special queries of CTEP-ESYS**

The Contractor shall provide any scheduled reports and conduct special queries of CTEP-ESYS, as directed by the COR. Scheduled reports will include reports required for the evaluation of the QASP. Regular scheduled reports are reports that can be generated by the Contractor through the CTEP-ESYS. The Contractor shall work

with the COR to determine the need for any additional scheduled reports to be generated, based upon CTEP business needs.

#### **6. Presentations that communicate processes or results on activities to CTEP leadership**

The Contractor shall provide presentations that communicate processes or results on activities to CTEP leadership. The Contractor shall first give the presentation to the COR for review. The Contractor shall then deliver the presentations, as directed by the COR.

#### **7. Quality Assurance Plan**

The Contractor shall develop a Quality Assurance (QA) plan that addresses all of the items that performance will be measured on in the Quality Assurance Surveillance Plan (QASP). The QA plan may address other business processes or areas that fall outside the scope of the QASP. The QA plan will provide a process to address and resolve any area of performance that falls beneath stated acceptable levels. The Contractor shall have the opportunity to research and prepare a response for the reconsideration of the assessment of a QASP measure.

#### **8. Surveys to measure satisfaction of CTEP personnel (including CTEP contractors) with PIO services**

The Contractor shall conduct one satisfaction survey annually to measure the satisfaction of CTEP personnel (including CTEP contractors) with PIO services. The COR shall have the opportunity to review the survey tool prior to distribution. The Contractor shall collect, analyze and report the findings of the survey to the COR within one month following the completion of the survey.

#### **9. Surveys to measure satisfaction of customers PIO serves outside of CTEP personnel**

The Contractor shall conduct one satisfaction survey annually to measure the satisfaction of customers outside of CTEP personnel with PIO services. The COR shall have the opportunity to review the survey tool prior to distribution. The Contractor shall collect, analyze and report the findings of the survey to the COR within one month following the completion of the survey.

#### **10. Four (4) training programs annually**

The Contractor shall conduct a minimum of four (4) training programs annually. The programs shall be delivered to CTEP personnel, CTEP contractors or submitters and submitter personnel who interact with CTEP, as directed by the COR. The Contractor shall measure the effectiveness of the programs (see the QASP for additional information on this aspect).

#### **11. Phase-In Transition Plan**

Within 5 business days of award, the draft phase-in transition plan will be revised, if necessary, and the draft Phase-in Transition Plan will become the Final Phase-in Transition Plan upon approval of the COR. The Final Phase-in Transition Plan shall be followed to ensure an orderly, secure, efficient, and expedient transition of all contract activities. Concerns anticipated or encountered shall be immediately communicated to the COR and an approved resolution pursued.

#### **12. Phase-out Transition Plan**

The Contractor shall, within 90 days before the completion of the contract, submit a plan for the transfer of all materials stored by the Contractor to the successor Contractor. This plan shall include a quality assurance element that provides for determination that all files and data have been completely and accurately transferred to the successor Contractor. This plan shall be reviewed and approved by the COR.

### **b. Other Reports/Deliverables**

#### **1. 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)**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, 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)**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, 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**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, 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)**

In accordance with HHSAR Clause 352.239-72, Security Requirements For Federal Information Technology Resources, 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.)

## 2. 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, TBD is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:  
The National Cancer Institute  
9609 Medical Center Drive  
Rockville, MD 20850-9705

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 June 1, 2016 through May 31, 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              |
|--------------------------------|----------------------------|
| Increased Capacity Option Base | POP within Base Period     |
| Option Period 1                | 06/01/2017 - 05/31/2018    |
| Increased Capacity Option 1    | POP within Option Period 1 |
| Option Period 2                | 06/01/2018 - 05/31/2019    |
| Increased Capacity Option 2    | POP within Option Period 2 |
| Option Period 3                | 06/01/2019 - 05/31/2020    |
| Increased Capacity Option 3    | POP within Option Period 3 |
| Option Period 4                | 06/01/2020 - 05/31/2021    |
| Increased Capacity Option 4    | POP within Option Period 4 |
| Phase-Out Option               | 06/01/2021 - 08/31/2021    |

### 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  | Delivered To   | Due Date   |
|------|--|--|--|
| 1.   | Monthly Progress Report  | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | On or before the 15 <sup>th</sup> calendar day following each monthly reporting period.  |
| 2.   | Annual Progress Report   | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | Within 30 days after anniversary date of the contract.   |
| 3.   | Final Progress Report  | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | On or before the last day of the contract performance period.  |
| 4.   | Standard Operating Procedures (SOPs)   | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | Within 90 calendar days following the effective date of the contract and updated whenever business procedures are modified or as directed by the COR. To be reviewed annually by Contractor. |
| 5.   | Scheduled reports and special queries of CTEP-ESYS                                   | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | As directed by the COR.  |
| 6.   | Presentations that communicate processes or results on activities to CTEP leadership | COR  | As directed by the COR.  |
| 7.   | Quality Assurance Plan   | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | Semi-annually  |

| Item | Description  | Delivered To   | Due Date   |
|------|--|--|--|
| 8.   | Surveys to measure satisfaction of CTEP personnel (including CTEP contractors) with PIO services | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | Annually, on or before the anniversary date of each contract year.   |
| 9.   | Surveys to measure satisfaction of customers PIO serves outside of CTEP personnel                | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | Annually, on or before the anniversary date of each contract year.   |
| 10.  | Four (4) training programs annually  | COR  | Four (4) per year, as directed by the COR                            |
| 11.  | Final Phase-In Transition Plan   | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | Within 5 business days of the contract start date                    |
| 12.  | Phase-out Transition Plan  | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | Ninety (90) days prior to the contract end date                      |
| 13.  | Roster of Employees Requiring Suitability Investigations   | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | Within fourteen (14) calendar days after contract award              |
| 14.  | IT Security Plan (IT-SP)   | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | Within thirty (30) days after contract award and annually thereafter |
| 15.  | IT Risk Assessment (IT-RA)   | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | Within thirty (30) days after contract award and annually thereafter |
| 16.  | FIPS 199 Assessment  | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | Within thirty (30) days after contract award                         |
| 17.  | IT Security Certification and Accreditation (IT-SC&A)  | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | Within three (3) months after contract award                         |
| 18.  | Section 508 Annual Report  | <a href="mailto:ncibrancheinvoices@mail.nih.gov">ncibrancheinvoices@mail.nih.gov</a> and COR | Due annually   |

### 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:

To be specified prior to award.

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

The 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 352.242-70 (January 2006)**

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

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

| Name | Title |
|------|-------|
| TBD  | TBD   |

**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 "ABC\_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 E - 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, HHSN2612XXXXC\_Clinical Genetics Support\_ABC\_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:  
  - Operation & Support of the CTEP Protocol and Information Office (PIO)
- 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) 496-6088.

**ARTICLE G.4. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)**

- a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.
- b. The acceleration of payments under this clause does not provide any new rights under the prompt Payment Act.
- c. Include the substance of this clause, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of Clause)

**ARTICLE G.5. INDIRECT COST RATES**

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

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

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

## ARTICLE G.6. ON-SITE CONTRACTOR ACCESS TO GOVERNMENT PROPERTY

The Contractor shall be held responsible for Government Property, regardless of dollar value, when:

- The contract requires contractor personnel to be located on a Government site or installation;
- The property utilized by contractor personnel is incidental to the place of performance; and,
- The property used by the contractor remains accountable to the Government

**Responsibility** includes physical presence, proper use and handling, normal maintenance, and reporting loss, damage or destruction.

Responsibility for government property shared by two or more contractors or located in space shared by two or more contractors, shall be determined and documented by the contractors involved. In cases where the parties cannot reach agreement on shared responsibility, the matter will be referred to the NIH Property Officer for resolution.

## 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 at the end of each contract period.

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. HUMAN SUBJECTS**

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

### **ARTICLE H.2. NEEDLE DISTRIBUTION**

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

### **ARTICLE H.3. ACKNOWLEDGEMENT OF FEDERAL FUNDING**

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

### **ARTICLE H.4. RESTRICTION ON ABORTIONS**

The Contractor shall not use contract funds for any abortion.

### **ARTICLE H.5. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION**

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

### **ARTICLE H.6. OMB CLEARANCE**

In accordance with HHSAR 352.201-70, 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.7. 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.8. GUN CONTROL**

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

### **ARTICLE H.9. 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.10. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-9, Option to Extend the Term of the Contract set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 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.11. 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](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 Encryption language, HHSAR 352.239-71, (January 2010)**

- 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.

**C. Security Requirements For Federal Information Technology Resources, HHSAR 352.239-72, (January 2010)**

- 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.

(End of Clause)

**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).

#### D. 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:

D14.5 Health Care Research and Evaluation

###### 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        |
| <b>Overall Level:</b>  | <input type="checkbox"/> <b>Low</b>     | <input checked="" type="checkbox"/> <b>Moderate</b> | <input type="checkbox"/> <b>High</b> |

- c. In accordance with HHSAR Clause 352.239-72, 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

In addition to any training covered under paragraph (e) of HHSAR 352.239-72, 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 as defined at HHSAR 304.1300(a) (4), 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.

a. 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.

b. 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

In addition to any personnel security responsibilities covered under HHSAR 352.239-72, the contractor shall comply with the below personnel security responsibilities:

- a. In accordance with Paragraph (h) of HHSAR 352.239-72, 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.

## **ARTICLE H.12. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-73(b) (January 2010)**

- a. Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply 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. Information about Section 508 provisions 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>.
- b. The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each contract/order exceeding \$100,000 when the contract/order duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor 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 Contractor's Product Assessment Template will be the responsibility of the Contractor at its own expense.
- c. In the event of a modification(s) to this contract/order, which adds new EIT products or services or revises the type of, or specifications for, products or services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products or services support Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found on the HHS Web site ( <http://www.hhs.gov/web/508/contracting/technology/vendors.html>).

[(End of HHSAR 352.239-73(b))]

- d. Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Project Officer. Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available in the Section 508 policy on the HHS Office on Disability Web site under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding funding, as applicable.

### **Schedule for Contractor Submission of Section 508 Annual Report:**

Annually, upon the anniversary of contract award.

[(End of HHSAR 352.239-73(c))]

## **ARTICLE H.13. 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.14. CONFIDENTIALITY OF INFORMATION**

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

The following information is covered by this article:

All information and materials handled by the Protocol and Information Office are considered proprietary and/or confidential unless otherwise marked, including protocols which shall be totally confidential in the pre-approval stage.

## **ARTICLE H.15. 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.16. 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:

<http://oamp.od.nih.gov/dgs/general-clauses>

### **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 IV (October 2010) of FAR Clause 52.215-21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data--Modifications (October 2010) is added.*
- c. FAR Clauses **52.219-9, Small Business Subcontracting Plan** (October 2015), and **52.219-16, Liquidated Damages--Subcontracting Plan** (January 1999) are deleted in their 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 | <a href="http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf">http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf</a> |

3. FAR Clause **52.204-9, Personal Identity Verification of Contractor Personnel** (January 2011).
4. FAR Clause **52.204-14, Service Contract Reporting Requirements** (January 2014).
5. FAR CLAUSE **52.204-18 Commercial and Government Entity Code Maintenance** (July 2015)
6. FAR Clause **52.209-10, Prohibition on Contracting With Inverted Domestic Corporations** (November 2015).
7. FAR Clause **52.210-1, Market Research** (April 2011).
8. 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.
9. 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.
10. FAR Clause **52.219-14, Limitations on Subcontracting** (November 2011).
11. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013).

12. FAR Clause **52.223-5, Pollution Prevention and Right-to-Know Information** (May 2011).  
Alternate I (May 2011) is not applicable to this contract.  
Alternate II (May 2011) is not applicable to this contract.
  13. FAR Clause **52.227-14, Rights in Data - General** (May 2014).
  14. FAR Clause **52.232-18, Availability of Funds** (April 1984).
  15. FAR Clause **52.237-2, Protection of Government Buildings, Equipment and Vegetation** (April 1984).
  16. FAR Clause **52.237-3, Continuity of Services** (January 1991).
  17. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).
  18. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2014).
  19. FAR Clause **52.244-2, Subcontracts** (October 2010) Alternate I (June 2007).
  20. FAR Clause **52.244-5, Competition in Subcontracting** (December 1996).
  21. FAR Clause **52.248-1, Value Engineering** (October 2010).
- b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CHAPTER 3) CLAUSES:
1. HHSAR Clause **352.201-70, Paperwork Reduction Act** (January 2006).
  2. HHSAR Clause **352.242-71, Tobacco-Free Facilities** (January 2006).
  3. HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).

## 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 provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.
- b. If the Government exercises this option, the extended contract shall be considered to include this option clause.
- c. The total duration of this contract, including the exercise of any options under this clause, shall not exceed 63 months.

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

1. HHSAR Clause **352.237-73, Non-Discrimination in Service Delivery** (March 2012).

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.

Any contract resulting from this RFP will contain the following Article:

**ARTICLE I.5. SMALL BUSINESS ADMINISTRATION - 8(a) PROGRAM**

This contract has been awarded in accordance with the program established in Section 8(a) of the Small Business Act (15 U.S.C. 637(a)) and the Partnership Agreement (PA) between the U.S. Small Business Administration (SBA) and the U.S. Department of Health and Human Services (HHS) effective October 23, 2012 until amended. 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 **52.219-18, Notification Of Competition Limited To Eligible 8(a) Concerns** (June 2003) **with Alternate For Acquisitions Under FAR 19.800 (Deviation)** (HHS/SBA PA - October 23, 2012 until amended)
- (a) Offers are solicited only from small business concerns expressly certified by the Small business Administration (SBA) for participation in the SBA's 8(a) Program and which meet the following criteria at the time of submission of offer--
- (1) The Offeror is in conformance with the 8(a) support limitation set forth in its approved business plan; and
  - (2) The Offeror is in conformance with the Business Activity Targets set forth in its approved business plan or any remedial action directed by the SBA.
- (b) By submission of its offer, the Offeror represents that it meets all of the criteria set forth in paragraph (a) of this clause.
- (c) Any award resulting from this solicitation will be made directly by the Contracting Officer to the successful 8(a) offeror selected through the evaluation criteria set forth in this solicitation.)
- (d) Agreement.
- (1) A small business concern submitting an offer in its own name shall furnish, in performing the contract, only end items manufactured or produced by small business concerns in the United States or its outlying areas. If this procurement is processed under simplified acquisition procedures and the total amount of this contract does not exceed \$25,000, a small business concern may furnish the product of any domestic firm. This subparagraph does not apply to construction or service contracts.
  - (2) The \_\_\_\_\_ [INSERT THE NAME OF SBA's CONTRACTOR] will notify the NCI's Contracting Officer in writing immediately upon entering an agreement (either oral or written) to transfer all or part of its stock or other ownership interest to any other party.

## 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:<br><br><a href="#">Att1PackagingDelivery.pdf</a>   |
| Attachment 2:  | Proposal Intent Response Sheet  | <a href="http://ncioa.cancer.gov/oa-internet/forms/intent.jsp">http://ncioa.cancer.gov/oa-internet/forms/intent.jsp</a><br><br><a href="#">ATT2ProposallIntentResponse.pdf</a> |
| Attachment 3:  | Statement of Work   | Please refer to the attachment at the end of the RFP or the following link:<br><br><a href="#">Att3_SOW.pdf</a>  |
| 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:<br><br><a href="#">Att4SectionK.pdf</a>  |
| Attachment 5:  | Quality Assurance Surveillance Plan   | Please refer to the attachment at the end of the RFP or the following link:<br><br><a href="#">Att5_QASP.pdf</a>   |

#### TECHNICAL PROPOSAL ATTACHMENTS

| Attachment No. | Title                                       | Location  |
|----------------|---|---|
| Attachment 6:  | Technical Proposal Cost Summary             | <a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf</a><br><br><a href="#">ATT6TechPropCostSumm.pdf</a>                       |
| Attachment 7:  | Summary of Related Activities               | <a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf</a><br><br><a href="#">ATT7SummaryRelatedActivities.pdf</a> |
| Attachment 8:  | HHS Section 508 Product Assessment Template | <a href="http://www.hhs.gov/web/508/contracting/technology/vendors.html">http://www.hhs.gov/web/508/contracting/technology/vendors.html</a><br><br><a href="#">ATT8Section508PAT.pdf</a>  |
| Attachment 9:  | Additional Technical Proposal Instructions  | Please refer to the attachment at the end of the RFP or the following link:<br><br><a href="#">Att9AdditionalTPIs.pdf</a>   |

**BUSINESS PROPOSAL ATTACHMENTS**

| <b>Attachment No.</b> | <b>Title</b>   | <b>Location</b>   |
|-----------------------|--|---|
| Attachment 10:        | Proposal Summary and Data Record, NIH-2043                           | <a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf</a><br><br><a href="#">ATT10ProposalSummaryDataRecord.pdf</a>   |
| Attachment 11:        | Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet | <a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/buscost.htm">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/buscost.htm</a><br><br><a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx</a><br><br><a href="#">Att11Breakdown_of_Proposed_Estimated_Cost-1.pdf</a> |
| Attachment 12:        | Offeror's Points of Contact  | <a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf</a><br><br><a href="#">ATT12PointsofContact.pdf</a>   |
| Attachment 13:        | Disclosure of Lobbying Activities, OMB Form SF-LLL                   | <a href="http://www.gsa.gov/portal/forms/download/116430">http://www.gsa.gov/portal/forms/download/116430</a><br><br><a href="#">ATT13SFLLL.pdf</a>   |
| Attachment 14:        | Additional Business Proposal Instructions                            | Please refer to the attachment at the end of the RFP or the following link:<br><br><a href="#">Att14AdditionalBPIs.pdf</a>  |

**INFORMATIONAL ATTACHMENTS**

| <b>Attachment No.</b> | <b>Title</b>  | <b>Location</b>   |
|-----------------------|---|---|
| Attachment 15:        | Invoice/Financing Request Instructions-CR-NIH(RC)-1               | <a href="http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc1_508.pdf">http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc1_508.pdf</a><br><br><a href="#">ATT15NIHRC1.pdf</a>  |
| Attachment 16:        | Commitment to Protect Non-Public Information Contractor Agreement | <a href="https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf">https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf</a><br><br><a href="#">Att16_NDA.pdf</a>                          |
| Attachment 17:        | Roster of Employees Requiring Suitability Investigations          | <a href="https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx">https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx</a><br><br><a href="#">ATT_17.xls</a> |
| Attachment 18:        | Employee Separation Checklist                                     | <a href="https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf">https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf</a><br><br><a href="#">Att18_Emp-sep-checklist.pdf</a>    |

## **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)*

**b. NOTICE OF 8(a) COMPETITIVE SET-ASIDE**

Offers are solicited only from small business concerns expressly certified by the Small Business Administration (SBA) for participation in the SBA's 8(a) Program. Bids or proposals received from others will be considered non-responsive.

**c. 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 541611.
2. The small business size standard is \$15 million.

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

1. It is anticipated that one award will be made from this solicitation and that the award will be made on/about May 31, 2016.
2. It is anticipated that the award(s) from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a Period of Performance of five years, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).
3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

**e. PERFORMANCE BASED ACQUISITION**

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

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

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

**f. ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this SOLICITATION. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 7,520 labor hours per year (37,600 labor hours for the five year period of performance). This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

**g. 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.

**h. 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.

**i. 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.

**j. PREPARATION COSTS**

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

**k. 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  
National Cancer Institute  
9609 Medical Center Drive Room 1E602  
Rockville, MD 20850-9705 MSC 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 technical portion of each contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal 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 315.370.

- e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.
- f. The NCI reserves the right to make a single award, multiple awards, or no award at all to the SOLICITATION. In addition, the SOLICITATION may be amended or canceled as necessary to meet NCI requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

## 11. 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 3 contracts completed during the past Three years and all contracts currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as a subcontract in excess of \$550,000..

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
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](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 Encryption language, HHSAR 352.239-71, (January 2010)**

- 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.

**C. Security Requirements For Federal Information Technology Resources, HHSAR 352.239-72, (January 2010)**

- 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.

(End of Clause)

**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).

#### D. 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:

D14.5 Health Care Research and Evaluation

b. Security Categories and Levels:

Confidentiality Level:  Low     Moderate     High  
 Integrity Level:         Low         Moderate     High  
 Availability Level:     Low         Moderate     High  
**Overall Level:**         **Low**     **Moderate**     **High**

- c. In accordance with HHSAR Clause 352.239-72, 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

In addition to any training covered under paragraph (e) of HHSAR 352.239-72, 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 as defined at HHSAR 304.1300(a)(4), 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**

In addition to any personnel security responsibilities covered under HHSAR 352.239-72, the contractor shall comply with the below personnel security responsibilities:

a. In accordance with Paragraph (h) of HHSAR 352.239-72, 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.

#### 14. Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

- a. System for Award Management, FAR Provision 52.204-7 (July 2013).  
**Alternate I** (July 2013) is not applicable to this solicitation.
- b. Facilities Capital Cost of Money, FAR Clause 52.215-16, (June 2003).
- c. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- d. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22, (October 2009).
- e. Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).

#### b. TECHNICAL PROPOSAL INSTRUCTIONS

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

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

## 1. Technical Discussions

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

### a. Statement of Work

#### 1. Objectives

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

#### 2. Approach

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

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

#### 3. Methods

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

#### 4. Schedule

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

### b. Personnel

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

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

**GOVERNMENT WILL REQUIRE ACTION ON THE PART OF THE OFFEROR TO CORRECT THE TIME COMMITMENT.**

1. Single Principal Investigator/Project Director

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

2. Other Investigators

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

3. Additional Personnel

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

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

4. Resumes

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

**2. Other Considerations**

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

- a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.
- b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

- c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d. Other factors you feel are important and support your proposed research.
- e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

### 3. Technical Evaluation

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

4. **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/Specification/Performance Work Statement. 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.

### **Section 508 accessibility standards for HHS Web Site Content and Communications Materials**

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

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

Web-based Intranet and Internet Information and Applications (1194.22)

## **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.

1. **Direct Labor**

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

2. **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.

3. **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.

4. **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.

**5. Travel**

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

**6. 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.

**7. Fee**

The Offeror shall propose a fixed fee and award fee appropriate to their type of organization.

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

(a) Submission of certified cost or pricing data is not required.

(b) Provide information described below:

The offeror shall submit a cost proposal in the format specified in paragraph L.2.c.3., Data Other than Certified Cost or Pricing Data. The cost proposal shall be adequate to determine the reasonableness of costs proposed, to evaluate whether the proposed costs are consistent with the technical proposal and level of effort anticipated, and/or evaluate cost realism. The cost proposal shall consist of a cost-element breakdown consistent with the offeror's cost accounting system, and shall include all supporting explanations of, or rationale for, proposed costs.

(End of provision)

**5. 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 (July 2013)**

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," and 352.232-71, "Estimated Cost - Incrementally Funded Contract." The initial obligation of funds under the contract is expected to cover TBD . The Government intends to obligate additional funds up to and including the full estimated cost of the contract for the remaining years of performance by unilateral contract modification. However, the Government is not required to reimburse the Contractor for costs incurred in excess of the total amount obligated, nor is the Contractor required to perform beyond the level supported by the total amount obligated.

(End of provision)

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

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

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

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

(End of Provision)

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

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

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

## 6. 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.

## 7. 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.

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

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

**9. 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. 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).

### 4. 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.

#### A. Personnel and Experience - 50 points

The Offeror shall document staff experience to conduct this work. Documentation shall include education, training, and expertise of the offeror's proposed staff. This should also include:

1. Qualifications of Project Management [Program Manager, Deputy Program Manager and Senior Document Specialist(s)]:

- Knowledge and experience in clinical trials development processes (both scientific and administrative aspects);
- Knowledge and experience within the oncology community;
- Demonstrated experience with managing teams of health care professionals at all levels;
- Knowledge and experience with business process improvement practices;
- Demonstrated experience in dealing with health care professionals at all levels;
- Demonstrated experience with utilization of databases (including data element abstraction, milestone entry, generating queries and running canned reports), document management systems, the Internet, and Microsoft Office products;
- Knowledge of medical terminology; and
- Knowledge and experience with the development and administration of survey tools.
- Knowledge and experience with the development and administration of Microsoft SharePoint.
- Advanced experience with Microsoft Office and Adobe Acrobat Professional.

2. Qualification of Other Professional Support (Document Specialists):

- Knowledge and experience in clinical trials development processes (both scientific and administrative aspects);
- Education and knowledge of medical terminology;
- Demonstrated experience with databases, including: data element abstraction, milestone entry, generating queries and running canned reports; and
- Ability to communicate, both verbally and in writing, with health care professionals at all levels.

3. Combined range of experience:

- Breadth and depth of composite experience of the proposed team members with the tasks required by the Statement of Work to meet the protocol development needs of CTEP;
- Composite experience of the proposed team members with protocol, document, and process management; and
- Demonstration of ability to work with other contractors on projects.

4. Demonstrated evidence of a stable workforce and the ability to recruit and retain staff.

**B. Adequacy of Technical Approach and Understanding of the Project - 30 points**

The Offeror shall describe in detail the methodology and procedures planned for successfully accomplishing each area of the Statement of Work. The Offeror must demonstrate understanding of the needs of the contract; a complete discussion of potential problems and solutions in accomplishing the work; the proposed plan for accomplishing all requirements of the Statement of Work, meeting the delivery schedules, and the proposed labor mix with the time commitments of all proposed personnel.

1. Demonstration of an understanding of the needs of the project.
2. Demonstration of an understanding of the oncology community and cancer clinical research.

3. Explanation of the methods and approach for accomplishing the tasks outlined in the Statement of Work in a secure, flexible and user-friendly environment.
4. Ability to meet with CTEP personnel with two hours advance notice. Demonstrated understanding of Quality Assurance (QA) methods, goals and objectives. Specific descriptions of how the work performed will meet or exceed Quality Assurance goals shall be included.
5. Demonstration of approach to development of a QA plan, evaluation of activities covered in the QA plan, and method used to update the QA plan in accordance with the indicators measured in the QASP.
6. Demonstrate a plan to optimize data quality and timeliness of projects and tasks as detailed in the Statement of Work and the QASP.
7. Demonstration of the ability to provide daily contact with CTEP staff by the Program Manager, Deputy Program Manager and other Contractor staff as needed to discuss and advise on the administrative and operational aspects of the protocol development process as it impacts CTEP operations and data abstraction processes.
8. Demonstrated experience with best business practices regarding process improvement, continuous quality improvement principle, and change management practices.
9. Demonstration of a management plan which will provide the Project Officer with up-to-date financial, project/subproject status and staffing information.
10. Plan for providing annual training programs (including orientation of new personnel) to CTEP personnel, CTEP contractors or submitters and submitter personnel who interact with CTEP.

### **C. Organizational Experience - 20 points**

Demonstrated experience of the organization as a whole with a history leading, participating, and contributing to various projects of equivalent scope, size and mission.

1. Demonstrates an understanding for the type and amount of work done in activities involving clinical trials, oncology and other biomedical fields;
2. Demonstrates an understanding on the type and amount of work done in contracts with document management, data abstraction and data query activities;
3. Demonstrated type and amount of work done in contracts providing operations support to health care providers (both internal and external to the client organization), at all levels of education and responsibility.
4. Demonstrate corporate understanding and prioritization of project needs.

### **D. Phase-In Transition Plan - Acceptable/Unacceptable**

The offeror shall demonstrate a transition phase-in plan that would support a smooth transfer of responsibility from the incumbent contractor. This criterion will be rated as either: acceptable or unacceptable.

## **5. 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.

## **6. 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.