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SECTION A

THIS IS A DRAFT REQUEST FOR PROPOSAL (DRFP). ALL REFERENCES TO RFP HEREIN SHALL IN EFFECT BE CONSIDERED DRFP.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The scope of this Contract includes Government initiated collaborative research and research support; Government initiated Contractor executed projects; Contractor initiated and executed projects; research and research support for National Institutes of Health (NIH) Institutes and Centers (ICs) and other federal agencies as authorized by the National Cancer Institute (NCI).

The scope of the work also includes the intellectual leadership, management expertise, and scientific capability to accomplish the research and operational objectives assigned by the NCI to the Frederick National Laboratory for Cancer Research (FNLCR). As part of the Contractor's stewardship of the laboratory, they will maintain relationships with the broader research community to enhance the intellectual vitality and research relevance of the laboratory, and to bring the best possible capabilities forward as it pertains to the FNLCR mission needs through partnerships.

ARTICLE B.2. SPONSORING AGREEMENT

The Frederick National Laboratory for Cancer Research (FNLCR) is Government-Owned Contractor-Operated (GOCO), Federally Funded Research and Development Center (FFRDC), sponsored by NIH under contract by NCI and established in accordance with Federal Acquisition Regulation (FAR) 35.017.

This Contract is designated as the sponsoring agreement between the FNLCR and NCI/NIH as described in FAR 35.017-1, the requirements for which are delineated below. The sponsoring agreement between NCI/NIH and the FNLCR facilitates the long-term relationship, establishes the FNLCR's mission, and ensures periodic reevaluation of the FFRDC to ensure special research and development needs continue to be met.

In accordance with FAR 35.017-1(e), the term of this agreement will not exceed 5 years, but can be renewed, as a result of periodic review, in increments not to exceed 5 years.

1. **Statement of Purpose and Mission of the FFRDC**

   The purpose of the FNLCR is to provide a unique biomedical resource for the development of new technologies and the translation of basic science discoveries into novel agents for the prevention, diagnosis, and treatment of cancer, Human Immunodeficiency Virus (HIV)/Acquired Immune Deficiency Syndrome (AIDS), and other diseases.

2. **Provisions for Orderly Termination or Nonrenewal of the Agreement, Disposal of Assets, and Settlement of Liabilities**

   This Contract contains the general provisions and other special provisions/clauses which describe the process for orderly termination or nonrenewal of this Agreement including disposal of any assets and settlement of liabilities. Responsibility for capitalization of the FFRDC and ownership of the assets rests with the Government.

   In the event of termination, the Government shall ensure the minimum quantity stated in Article B.2. has been paid to the Contractor. Additionally, task orders issued hereunder are subject to termination provisions, the requirements for which are specified therein.

In the event of termination or nonrenewal, the Government shall deduct from the amount due to the Contractor all unliquidated advance payments. In the event of termination or nonrenewal, ownership and management of intellectual property, CRADA funds, royalty funds, rights to uncollected royalties and related records shall be transferred to a successor Contractor or the Government. In the event of termination, all source code and object code developed, modified, or enhanced under this Contract shall remain in place at the FNLCR unless different disposition is directed by the Contracting Officer.

In addition the provisions identified herein, the Government may recognize a third party as the successor in interest to the Contract when the third parties' interest in the Contract arises out of the transfer either of all the assets of the Contractor or of all of that part of the Contractor's assets involved in the performance of the Contract. In the event of a successor in interest it is the Government's intent that all assets and liabilities would novate to the successor including all subcontracts having anticipated completion dates beyond the expiration date of the Contract.

In the event of a successor in interest, the Contractor shall transfer funds to the successor Contractor(s) in an amount equal to the dollar value of the accrued vacation liability. The successor Contractor shall assume the Employee Savings Plan and the defined benefit Retirement Plan and the incumbent 401(k) Plan. The successor Contractor shall assume the Plans' respective trusts and assets and become responsible for any and all obligations to participants in the Plans as a result of the transfer in total to the successor Contractor of assets and liabilities of the plans. The amount of pension liability shall be based on the most recent actuarial calculation completed by the plan actuary. The amount of the assets that shall be transferred by the Contractor to the successor Contractor shall equal the assets in the Plans' respective Trusts.

The Government shall approve assets and liabilities as being properly calculated in compliance with applicable Cost Accounting Standards.

3. **Retained Earnings Identification, and Plan for Use and Disposition**

   The Contractor shall identify all retained earnings on a periodic basis, including a plan for the use and disposition in the events of termination or nonrenewal of the Agreement.

4. **Prohibition Against Competition**

   The operator of the FFRDC cannot compete with any non-FFRDC concern in response to a Federal agency request for proposal for other than the operation of an FFRDC. This prohibition is not applicable to the operator's parent organization, if any, or other subsidiary of the parent organization in its non-FFRDC operations. This prohibition does not apply to requests for information, qualifications or capabilities as those can be answered unless otherwise restricted by the Contracting Officer.

5. **Accepting Work from Other than the Sponsor**

   The Contractor may not accept work from other than the NIH, unless approved by the Contracting Officer. Nonsponsoring Federal agencies may use a Federally Funded Research and Development Center (FFRDC) only if the terms of the FFRDC's sponsoring agreement permit work from other than a sponsoring agency. Work placed with the FFRDC is subject to the acceptance by the Contracting Officer and must fall within the purpose, mission, general scope of effort, or special competency of the FFRDC. The nonsponsoring agency shall provide to the Contracting Officer all necessary documentation that the requested work would not place the FFRDC in direct competition with domestic private industry.

ARTICLE B.3. PRICES/COSTS

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

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

ARTICLE B.4. ESTIMATED COST PLUS AWARD FEE

a. Estimated Cost

1. The total estimated cost of the Base Period of this contract is $ TBD.
2. The negotiated award fee percentage is TBD%.
3. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the estimated cost and Award Fee Pool (Ceiling) shall be increased as follows:

Period	Estimated Cost ($)	Award Fee Pool (Ceiling)	Total Estimated Contract Amount ($)
Base Period TBD	$ TBD	$ TBD	$ TBD
Option Period 1 TBD	$ TBD	$ TBD	$ TBD
Option Period 2 TBD	$ TBD	$ TBD	$ TBD
Option Period 3 TBD	$ TBD	$ TBD	$ TBD
Total [Base Period and All Options]	$ TBD	$ TBD	$18,000,000,000

b. Total Estimated Contract Amount
The total estimated amount of the contract, represented by the sum of the estimated cost plus award fee is $18,000,000,000.

c. Award Fee Consideration
Based on the evaluation/determination described in the Award Fee Plan, listed in Section J-Attachments, award fee may be earned by the Contractor at six (6) month intervals as defined in the paragraph herein. The total Award Fee Pool (Actual) is $TBD. The Award Fee Pool (Actual) and Award Fee Earned are determined as described in ARTICLE B.4.d. The evaluation periods shall be as follows:

Period	Award Fee Period	Award Fee Pool (Actual)	Award Fee Earned	Award Fee Task Order No.
Base Period	Award Fee Period 1: TBD	TBD	TBD	TBD
	Award Fee Period 2: TBD	TBD	TBD	TBD
	Award Fee Period 3: TBD	TBD	TBD	TBD
	Award Fee Period 4: TBD	TBD	TBD	TBD
	Award Fee Period 5: TBD	TBD	TBD	TBD
	Award Fee Period 6: TBD	TBD	TBD	TBD
	Award Fee Period 7: TBD	TBD	TBD	TBD
	Award Fee Period 8: TBD	TBD	TBD	TBD
	Award Fee Period 9: TBD	TBD	TBD	TBD

Period	Award Fee Period	Award Fee Pool (Actual)	Award Fee Earned	Award Fee Task Order No.
	Award Fee Period 10: TBD	TBD	TBD	TBD
Option Period 1	Award Fee Period 11: TBD	TBD	TBD	TBD
	Award Fee Period 12: TBD	TBD	TBD	TBD
	Award Fee Period 13: TBD	TBD	TBD	TBD
	Award Fee Period 14: TBD	TBD	TBD	TBD
	Award Fee Period 15: TBD	TBD	TBD	TBD
	Award Fee Period 16: TBD	TBD	TBD	TBD
	Award Fee Period 17: TBD	TBD	TBD	TBD
	Award Fee Period 18: TBD	TBD	TBD	TBD
	Award Fee Period 19: TBD	TBD	TBD	TBD
	Award Fee Period 20: TBD	TBD	TBD	TBD
Option Period 2	Award Fee Period 21: TBD	TBD	TBD	TBD
	Award Fee Period 22: TBD	TBD	TBD	TBD
	Award Fee Period 23: TBD	TBD	TBD	TBD
	Award Fee Period 24: TBD	TBD	TBD	TBD
	Award Fee Period 25: TBD	TBD	TBD	TBD
	Award Fee Period 26: TBD	TBD	TBD	TBD
	Award Fee Period 27: TBD	TBD	TBD	TBD
	Award Fee Period 28: TBD	TBD	TBD	TBD
	Award Fee Period 29: TBD	TBD	TBD	TBD
	Award Fee Period 30: TBD	TBD	TBD	TBD
Option Period 3	Award Fee Period 31: TBD	TBD	TBD	TBD
	Award Fee Period 32: TBD	TBD	TBD	TBD
	Award Fee Period 33: TBD	TBD	TBD	TBD
	Award Fee Period 34: TBD	TBD	TBD	TBD
	Award Fee Period 35: TBD	TBD	TBD	TBD

Period	Award Fee Period	Award Fee Pool (Actual)	Award Fee Earned	Award Fee Task Order No.
	Award Fee Period 36: TBD	TBD	TBD	TBD
	Award Fee Period 37: TBD	TBD	TBD	TBD
	Award Fee Period 38: TBD	TBD	TBD	TBD
	Award Fee Period 39: TBD	TBD	TBD	TBD
	Award Fee Period 40: TBD	TBD	TBD	TBD
Total		**TBD**	**TBD**	

d. Methodology for Award Fee Execution

This contract will utilize the Award Fee Plan as described in SECTION J-Attachments to evaluate the Contractor's performance. Award fee is earned on the Contract by evaluating the Contractor's performance across all task orders for the period.

The Award Fee Pool (Actual) referenced in ARTICLE B.4.c. will be the sum of the Award Fee Pool specified on all applicable cost plus award fee task orders as recorded in Award Fee Pool Tracking Spreadsheet (Attachment # TBD), but shall not exceed the Award Fee Pool (Ceiling) set forth in ARTICLE B.4.a. by Base and Option periods.

Each cost plus award fee task order will include the following:

1. The Task Order Award Fee Pool is based on the specified award fee percentage, specified in paragraph a.(2), multiplied by the total estimated costs negotiated for the cost plus award fee task order (Task Order Estimated Cost X Award Fee percentage = Total Task Order Award Fee Pool).
2. The total Task Order Award Fee Pool will be evenly distributed across the established Award Fee Period(s) (stated in ARTICLE B.4.c.) based on the task order's period of performance (Total Task Order Award Fee Pool / number of months in the task order's period of performance = monthly Task Order Award Fee Pool).
3. The monthly Task Order Award Fee Pool will be allotted to the respective award fee period, established in ARTICLE B.4.c. Task Orders beginning less than 30 days prior to the next award fee period will be applied to the following award fee period.

Overall Award Fee Pool (Actual) for each Award Fee period is determined as follows:

The Award Fee Pool (Actual), established in ARTICLE B.4.c., will reflect the sum of all issued cost plus award fee task order Award Fee Pools for the period and be provided to the Contractor via an updated copy of the Award Fee Pool Tracking Spreadsheet (Attachment # TBD). The Award Fee Pool Tracking Spreadsheet will be updated to reflect the Task Order Award Fee Pool as task orders are awarded on an on-going basis.

At the end of each award fee period, an evaluation and subsequent fee determination will be made in accordance with the Award Fee Plan listed in SECTION J-Attachments.

The Fee Determining Official (FDO) will provide a determination specifying the Award Fee Earned for each award fee period. Upon receipt of the FDO's determination, the Contracting Officer will modify ARTICLE B.4.c. to add the FDO determined Award Fee earned and execute a fixed price Award Fee Task Order to obligate the Award Fee earned. The Contractor may bill for the Award Fee earned upon receipt of an executed copy of the relevant award fee period's Award Fee Task Order.

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
13. Research Funding
14. Any sale/barter of Government furnished or Contractor acquired property under this contract
15. Foreign or legal services subcontract costs
16. Advisory and Assistance services costs (excluding A&E services referenced above) for which costs will be incurred under this contract, or any use of Contractor personnel in an advisory or assistance service capacity
17. Severance pay, early retirement, or voluntary termination incentives not otherwise provided for in the approved Contractor retirement plan
18. Direct labor positions not approved by Task Order
19. Acquisition, by purchase or lease, of any motor vehicle
20. Prior written notice shall be provided to the Contracting Officer for awards using Other than Full and Open Competition made by the Contractor to its parent organization
21. Changes/renewals or additions to insurance coverage

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.

NOTE TO OFFERORS: PLEASE REFER TO SECTION J, ATTACHMENT 23 ENTITLED, "PROPOSED ADVANCE UNDERSTANDINGS" FOR ADDITIONAL DRAFT ARTICLES.

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 FFRDC Statement of Work, dated TBD, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

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

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format, unless otherwise requested by the Contracting Officer.

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

All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

a. **Technical Progress Reports**

1. **Technical Progress Reports**

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

2. **Cost, Schedule, Performance Reports**

   The Contractor shall submit recurring cost, schedule, performance reports. The frequency and specific content of these reports will be determined in the base IDIQ Contract for contract-wide requirements and per task order for specific task order requirements. The reports shall comprehensively describe cost, schedule, and performance metrics and issues. The reports shall include the following information:

   a. An estimate at completion (EAC) shall be calculated through the reporting period. Current spending and staff level-of-effort through the reporting period shall be compared to estimated spending rate and staff level-of-effort set at the beginning of the project/task order. Issues related to spending rate (ahead of spending rate/staff level-of-effort or behind) will be discussed at a summary level.

b. Current schedule/milestones through the reporting period shall be compared to the estimated schedule/milestones set at the beginning of the project/task order. Issues related to schedule (ahead of schedule or behind) will be discussed at a summary level.

c. Performance issues will be discussed and linked to cost/schedule issues. Potential risks identified during the performance of the project/task order are discussed as they are encountered or mitigated. Proactive solutions to performance issues should also be discussed.

3. **Award Fee**

The Contractor shall submit Goals and Objectives and Contractor Performance Status Reports (CPSR). The frequency and specific content of these reports will be determined in the base IDIQ Contract for contract-wide requirements.

4. **Financial Management**

The Contractor shall submit financial management reports. The frequency and specific content of these reports will be determined in the base IDIQ Contract for contract-wide requirements and per task order for specific task order requirements. Content of financial management reports may include, but is not limited to: annual fringe benefit rates, G&A, annual level of effort, overtime report, cost status reports, funding vs. cost analyses, initial detailed operating budget and capital equipment list, annual detailed budget, contract year estimate-to-complete, and invoice processing balance status.

5. **Environment, Health and Safety**

The Contractor shall submit Environment, Health and Safety reports. The frequency and specific content of these reports will be determined in the base IDIQ Contract for contract-wide requirements and per task order for specific task order requirements. Content of Environment, Health and Safety reports may include, but is not limited to: deviations and discrepancies, willful or repeat violations, unresolved deviations after re-inspection, emergencies and corrective actions taken, incidents, accidents, lost time, and adherence to safety and environmental regulations.

6. **Contracts and Administration**

The Contractor shall submit contracts and administration reports. The frequency and specific content of these reports will be determined in the base IDIQ Contract for contract-wide requirements and per task order for specific task order requirements. Content of contracts and administration reports may include, but is not limited to: shipments, list of business interests, subcontracting, deviations to patents and data clauses, inventions, technology transfer records, technology transfer disposition of funds, subcontracting provisions (individual and summary), open requisitions, contract office approvals, and tasks' status.

7. **Human Resources**

The Contractor shall submit human resource reports. The frequency and specific content of these reports will be determined in the base IDIQ Contract for contract-wide requirements and per task order for specific task order requirements. Content of human resource reports may include, but is not limited: employee distribution, staffing plan, list of off-site employees, headcount, and pre-hiring.

8. **Facilities, Maintenance and Engineering**

The Contractor shall submit facilities reports. The frequency and specific content of these reports will be determined in the base IDIQ Contract for contract-wide requirements and per task order for

specific task order requirements. Content of facilities reports may include, but is not limited to: space reports, steam meter readings, maintenance service requests, facility project status, work orders, and fuel energy consumption.

9. **Laboratory Animal Science Program**

   The Contractor shall submit Laboratory Animal Science Program (LASP) reports. The frequency and specific content of these reports will be determined in the base IDIQ Contract for contract-wide requirements and per task order for specific task order requirements. Content of LASP reports may include, but is not limited to: AAALAC International, Animal Care and Use Committee, Office of Laboratory Animal Welfare, and the United States Department of Agriculture.

10. **Summary of Salient Results**

    As identified in each task order, as applicable, the Contractor will be required to prepare and submit, with any final report, a summary (not to exceed 200 words) of salient results achieved during the performance. This report will be required on or before the expiration date of the task order.

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

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

    The first report shall be due on TBD. Thereafter, the report shall be due on or before the TBD day following each reporting period. The final report shall be due on TBD.

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

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

b. **Other Reports/Deliverables**

1. **Reporting of Financial Conflict of Interest (FCOI)**

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

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

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

2. **Report of USDA-Designated Biobased Products**

In accordance with FAR clause 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts, the contractor shall report to http://www.sam.gov, with a copy to the Contracting Officer any USDA-designated biobased products purchased during the period of October 1-September 30 of each contract year. This report shall be submitted no later than October 31 of each year during contract performance and **on the expiration date of the contract**.

3. **Source Code and Object Code**

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

4. **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.d. of the INFORMATION AND PHYSICAL ACCESS SECURITY Article in SECTION H of this contract.)

b. **IT Security Plan (IT-SP)**

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

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

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

c. **IT Risk Assessment (IT-RA)**

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

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

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

d. **FIPS 199 Assessment**

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

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

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

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

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

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

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

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

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

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

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

g. **Contractor - Employee Non-Disclosure Agreement(s)** The Contractor shall complete and submit a signed and witnessed "Commitment to Protect Non-Public Information

- Contractor Agreement" form for each contractor and subcontractor employee who may have access to non-public Department information under this contract. This form is located at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf.

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

h. **Vulnerability Scanning Reports**

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

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

5. **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."

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

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

The first annual utilization report shall be due on or before TBD. Thereafter, reports shall be due on or before the 10th working day following the reporting period. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of each Task Order and of the contract. All reports shall be sent to the following address:

National Cancer Institute Campus at Frederick
Contracting Officer
TBD

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with the Contract, Government regulations, and/or Government specifications as applicable. At a minimum, all deliverables shall be marked with the Contract number, Task Order number, and Contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

All packages, markings, and shipments must be in compliance with applicable federal and international regulations, including, but not limited to: Department of Transportation regulations, Export Administration Regulations (EAR), Federal Aviation Administration (FAA) regulations, International Air Transport Association (IATA) dangerous goods regulations, Hazardous Materials Regulations (49 CFR 171-180), and Occupational Safety and Health Standards (29 CFR 1910.1030).

Additional packaging, marking, and shipping specifications shall be identified in each task order.

SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized Contracting Officer's Representative (COR) will perform inspection and acceptance of materials and services to be provided.

b. Inspection and acceptance will be performed as identified in the base IDIQ Contract for contract-wide requirements and per task order for specific task order requirements.

c. Inspection and acceptance for base IDIQ Contract for contract-wide requirements will be performed at:

National Cancer Institute Campus at Frederick
TBD

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized Contracting Officer's Representative (COR) within 30 days of receipt.

c. 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 **52.246-7, Inspection of Research and Development - Fixed Price** (August 1996).

FAR Clause **52.246-8, Inspection of Research and Development - Cost-Reimbursement** (May 2001).

Alternate I (April 1984) is not applicable to this contract.

FAR Clause **52.246-16, Responsibility for Supplies** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

a. The base ordering period for this Contract shall be from TBD through TBD (five years).

b. If the Government exercises Options pursuant to the OPTION PROVISION Article in Section H of this contract, the ordering period will be extended as follows:

Option	Option Period
Option Period 1	TBD through TBD (five years)
Option Period 2	TBD through TBD (five years)
Option Period 3	TBD through TBD (five years)

ARTICLE F.2. DELIVERIES

a. Satisfactory performance of this contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this Contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized Contracting Officer's Representative (COR), of the Deliverables and Reporting Requirements specified in the Delivery Schedule which are described in SECTION C of the base IDIQ Contract for contract-wide requirements and as identified in each Task Order as applicable.

b. Deliveries required by the Contractor shall be made F.O.B. destination as set forth in FAR Clause 52.247-35, F.O.B. Destination, Within consignees Premises (April 1984) and any specifications stated in SECTION D, PACKAGING AND MARKING AND SHIPPING, of this Contract to the address/addressee listed below:

1. For deliverables identified in the base IDIQ Contract for contract-wide requirements:

   National Cancer Institute Campus at Frederick
   TBD

2. For deliverables on each task order:

   As identified on each task order.

c. Unless otherwise specified, deliveries shall be made to the Delivery Point specified above Mondays through Fridays (excluding Federal Holidays) between the hours of 8:30 a.m. and 5:30 p.m. EST only. Supplies or services scheduled for delivery on a Federal holiday shall be made the following day.

ARTICLE F.3. LEVEL OF EFFORT

a. During the period of performance of this contract, the Contractor shall provide TBD direct labor years. The labor years exclude vacation, holiday, and sick leave. These labor years exclude subcontractor labor years. It is estimated that the labor years are constituted as specified below and will be expended approximately as follows:

Labor Years

	Labor Categories					
Contract Year	**Key Personnel**	**Administrative**	**Information Technology**	**Life Sciences**	**Biotechnology/ Regulatory**	**Totals**

	Labor Categories					
Year 1	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 2	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 3	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 4	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 5	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Option Period 1						
Year 6	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 7	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 8	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 9	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 10	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Option Period 2						
Year 11	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 12	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 13	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 14	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 15	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Option Period 3						
Year 16	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 17	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 18	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 19	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 20	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**

b. The Contractor shall have satisfied the requirement herein if not less than TBD% nor more than TBD% of the total direct labor years specified herein are furnished. These terms and conditions do not supersede the requirements of either the "Limitation of Cost" or "Limitation of Funds" clause.

ARTICLE F.4. 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:

52.211-11, Liquidated Damages--Supplies, Services or Research and Development (September 2000). **(APPLICABLE TO FIXED PRICE TASK ORDERS ONLY)**

"(a) If the Contractor fails to deliver the supplies or perform the services within the time specified in this contract, the Contractor shall, in place of actual damages, pay to the Government liquidated damages of $ TBD per calendar day of delay."

52.242-15, Stop Work Order (August 1989) **(APPLICABLE TO FIXED PRICE TASK ORDERS ONLY)**

52.242-15, Stop Work Order (August 1989)

Alternate I (April 1984) **(APPLICABLE TO COST REIMBURSEMENT TASK ORDERS ONLY)**

52.247-35, F.O.B. Destination Within Consignees Premises (April 1984). **(APPLICABLE TO LEVEL OF EFFORT TASK ORDERS ONLY)**

SECTION G - CONTRACT ADMINISTRATION DATA

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

The following Contracting Officer's Representative (COR) and Alternate 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.

Additional Contracting Officer's Representatives (CORs) will be identified in each Task Order.

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

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

The following individuals are considered to be essential to the work being performed hereunder:

Name	Title
	President/Chief Executive Officer
	Chief Financial Officer
	Chief Medical Officer
	Chief Operating Officer
	Chief Science Officer
	Biopharmaceutical Development Program Director
	Contracts and Acquisitions Director

Name	Title
	Data Science and Information Technology Program Director
	Human Resources Director
	Project Management Operations Director

NOTE TO OFFERORS: OTHER ADDITIONAL KEY PERSONNEL POSITIONS MAY BE PROPOSED.

ARTICLE G.3. TASK ORDER PROCEDURE

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

a. **General**

Only the Contracting Officer may issue Task Orders to the Contractor, providing specific authorization or direction to perform work within the scope of the contract and as specified in the FFRDC Statement of Work. Unless specifically authorized by the Contracting Officer, the Contractor shall not commence work until a fully executed Task Order has been awarded. The Contractor may incur costs under this contract in performance of task orders and task order modifications issued in accordance with this ARTICLE.

No other costs are authorized unless otherwise specified in the contract or expressly authorized by the Contracting Officer.

b. **Requesting Task Order Proposals.**
A Task Order Request for Proposals (TORFP) will be prepared and issued by the Contracting Offifor each task order requirement.

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

1. Statement of Work;
2. Reporting Requirements and Deliverables;
3. Proposal Due Date and Location to Deliver Proposals;
4. Period of Performance of Task Order;
5. Anticipated type of Task Order
   a. Cost Plus Award Fee
   b. Fixed Price
   c. Severable/Non-Severable
   d. Completion/Term
6. Technical Proposal Instructions
7. Business Proposal Instructions
8. Evaluation Factors for Award

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

c. **Evaluation and Award of Task Order Proposals**

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

Upon completion of evaluations, the Contracting Officer will issue a task order to the Contractor.

ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT (APPLICABLE TO COST-REIMBURSEMENT TASK ORDERS ONLY)

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

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 CORP_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 D. Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number_ Contract Title_ Contractor's Name_ unique Invoice number

         (e.g, HHSN2612XXXXXC_Clinical Genetics Support_ABC CORP_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 the 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:

NCI FFRDC Contract

g. The Task Order Title is: Identified in each Task Order

h. The Task Order Period of Performance is: Identified in each Task Order

i. Contract Line Items as follows:

Line Item #	Line Item Description
Identified in each Task Order	Identified in each Task Order

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

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

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

ARTICLE G.5. INVOICE SUBMISSION (APPLICABLE TO FIXED PRICE TASK ORDERS ONLY)

a. Invoice Instructions for NIH Fixed-Price Type Contracts, NIH(RC)-2, 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 CORP_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 D. Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contract Number_ Contract Title_ Contractor's Name_ unique Invoice number

         (e.g, HHSN2612XXXXXC_Clinical Genetics Support_ABC CORP_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 the 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:

NCI FFRDC Contract

g. The Task Order Title is: Identified in each Task Order

h. The Task Order Period of Performance is: Identified in each Task Order

i. Contract Line Items as follows:

Line Item #	Line Item Description
Identified in each Task Order	Identified in each Task Order

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

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

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

ARTICLE G.6. 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.

ARTICLE G.7. INDIRECT COST RATES (APPLICABLE TO COST REIMBURSEMENT TASK ORDERS AWARDED TO PROFIT MAKING ORGANIZATIONS)

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.8. GOVERNMENT PROPERTY

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

ARTICLE G.9. 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 MOSB Contracting Officer for resolution.

ARTICLE G.10. 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 evaluations will be prepared Annually as follows on TBD .

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

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

b. Electronic Access to Contractor Performance Evaluations

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

http://www.cpars.gov

SECTION H - SPECIAL CONTRACT REQUIREMENTS

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

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

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

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

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

ARTICLE H.2. HUMAN SUBJECTS

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

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

ARTICLE H.3. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement

on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website:

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

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

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

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

ARTICLE H.4. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

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

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

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

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

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

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

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

- the registration of certain "applicable clinical trials" (see Definitions at: http://grants.nih.gov/ClinicalTrials_fdaaa/definitions.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

In addition, the Contractor shall notify the Contracting Officer's Representative (COR), with the trial registration number (NCT number), once the registration is accomplished. This notification may be included in the Technical Progress Report covering the period in which registration occurred, or as a stand alone notification.

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

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

ARTICLE H.6. HIV ANTIRETROVIRAL TREATMENT TRIALS

The Contractor shall work with the host countries' authorities and other stakeholders in accordance with the approved plan to develop sources to provide HIV antiretroviral treatment to participants of the trials contracted for under this contract after the participants' completion of the trial.

ARTICLE H.7. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

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

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

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

ARTICLE H.8. RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (Including Human Gene Transfer Research)

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

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

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of the contract for any work related to recombinant or synthetic nucleic acid research or a requirement for the Contracting Officer to approve any or all recombinant or synthetic nucleic acid molecule projects under this contract. This includes the requirement for the institution to have an Institutional Biosafety Committee (IBC) registered with NIH OBA that complies with the

requirements of the NIH Guidelines. Further information about compliance with the NIH Guidelines can be found on the NIH Office of Biotechnology Activities (OBA) website available at: http://oba.od.nih.gov/rdna_ibc/ibc.html.

ARTICLE H.9. HUMAN EMBRYONIC GERM CELL (HEGC) RESEARCH

Federally funded research involving the use of human embryonic germ cells derived from fetal tissue shall not be conducted under this contract until Human Pluripotent Stem Cell Review Group (HPSCRG) review and approval has been obtained. Once approved by the HPSCRG, all research shall be conducted in accordance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://stemcells.nih.gov/policy/guidelines.asp).

Any work under this contract which requires research involving the use of human embryonic germ cells shall not be conducted under this contract until the HPSCRG review and approval have been obtained, and documented by written notice of such approval by the Contracting Officer. If the HPSCRG disapproves the documentation presented by the Contractor, the contract may be terminated in accordance with the Termination of Convenience Clause referenced in Article I.1. of this contract. In addition, it may be necessary for the Contracting Officer to invoke FAR Clause 52.242-15, Stop Work Order, referenced in the CLAUSES INCORPORATED BY REFERENCE Article in Section F of this contract if the review and approval process cannot be accomplished in a time frame that allows for continuity of this research effort.

ARTICLE H.10. HUMAN EMBRYONIC STEM CELL (hESC) RESEARCH

All research conducted under this contract shall be in accordance with NIH Guidelines on Human Stem Cell Research (http://stemcells.nih.gov/policy/pages/2009guidelines.aspx), and shall involve the use of approved human embryonic stem cells (hESCs) that are listed on the NIH Human Embryonic Stem Cell Registry (http://stemcells.nih.gov/research/registry/).

ARTICLE H.11. DATA SHARING IN GENOME-WIDE ASSOCIATION STUDIES (GWAS)

The Contractor shall submit and certify data obtained in the genome-wide association study to the NIH GWAS data repository in accordance with the NIH "Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies (GWAS)" located at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html. All data and information shall be submitted to a high security network within the National Center for Biotechnology Information (NCBI), National Library of Medicine, through a secure transmission process. Data submitted to the database for genotypes and phenotypes (dbGaP) shall include the following basic study information:

- the protocol,
- questionnaires,
- study manuals,
- variables measured, and
- other supporting documentation

The curated and coded phenotype, exposure, genotype, and pedigree data, as appropriate, should be submitted to the NIH GWAS data repository as soon as quality control procedures have been completed by the Contractor. Information on submitting data to dbGaP is available at: http://www.ncbi.nlm.nih.gov/projects/gap/cgi-bin/GetPdf.cgi?document_name=HowToSubmit.pdf. Additional information about GWAS can be found at: http://gwas.nih.gov.

ARTICLE H.12. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported

in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-071.html and http://publicaccess.nih.gov.

ARTICLE H.13. NEEDLE EXCHANGE, HHSAR 352.270-12 (December 2015)

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

ARTICLE H.14. 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.15. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

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

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

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

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

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

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

ARTICLE H.16. 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.17. PRIVACY ACT, HHSAR 352.224-70 (December 2015)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act

by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct in CFR 45 part 5b and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records [5 U.S.C. 552a(m)(1)]. The contract work statement: (a) identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and (b) specifies the disposition to be made of such records upon completion of contract performance.

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

The Privacy Act System of Records applicable to this project is Number 09-25-0005, 09-25-0007, 09-25-0054, 09-25-0087, 09-25-0099, 09-25-0105, 09-25-0115, 09-25-0118, 09-25-0166, 09-25-0168, 09-25-0169, 09-25-0200, 09-25-0216, 09-25-0223, 09-90-0001, 09-90-0005, 09-90-0024, and 09-90-0777. These documents are incorporated into this contract as an Attachment in SECTION J of this contract. These documents are also available at: http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm.

ARTICLE H.18. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015)

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

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

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

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

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

ARTICLE H.19. ANIMAL WELFARE

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

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

ARTICLE H.20. INTRODUCTION OF RODENTS AND RODENT PRODUCTS

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

ARTICLE H.21. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

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

http://oma.od1.nih.gov/manualchapters/intramural/3044-2/

ARTICLE H.22. OMB CLEARANCE

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

ARTICLE H.23. 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.24. GUN CONTROL

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

ARTICLE H.25. 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.26. OPTION PROVISION

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

ARTICLE H.27. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan**

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

b. **Subcontracting Reports**

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

1. Individual Subcontract Reports (ISR)

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

   April 30th
   October 30th
   Expiration Date of Contract

2. Summary Subcontract Report (SSR)

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

   October 30th

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

TBD
Contracting Officer

ARTICLE H.28. 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).

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

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

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

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

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

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

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

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

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

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

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

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

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

B. **Standard for Security Configurations**

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

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

b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:
The Contractor shall comply with the current OMB, NIST, DHS, HHS, NIH and NCI standards.

c. The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings - see http://scap.nist.gov/validation. The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest FDCC major version and subsequent major versions.

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

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

f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.

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

C. **Standard for Encryption language**

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

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

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

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

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

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

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

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

1. Protecting Federal information and Federal information systems in order to ensure their -

a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;

b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

c. Availability, which means ensuring timely and reliable access to and use of information.

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

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

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

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

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

i. Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automation Information Resources.

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

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

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

final version into the contract for Contractor implementation and maintenance. The Contractor shall update the IT-RA on an annual basis.

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

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

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

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

        i. Annual testing of the system contingency plan; and

        ii. The performance of security control testing and evaluation.

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

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

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

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

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

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

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

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

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

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

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

E. **Additional NIH Requirements**

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

a. Information Type:

[X] Administrative, Management and Support Information:

Sections 3.2 Facility Operations and 3.3 Business Operations and Management of the FFRDC SOW

[X] Mission Based Information:

Section 3.1 Research and Research Support Programs, Projects, and Activities of the FFRDC SOW

b. Security Categories and Levels:

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

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

2. **INFORMATION SECURITY TRAINING**

The contractor shall comply with the below training:

a. Mandatory Training

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

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

b. Role-based Training

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

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

c. Rules of Behavior

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

3. **PERSONNEL SECURITY RESPONSIBILITIES**

The contractor shall comply with the below personnel security responsibilities:

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

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

c. **Departing contractor employees:** The Contractor shall provide the COR with the name, position title, and position sensitivity level held by or pending for departing employees. The

Contractor shall perform and document the actions identified in the Contractor Employee Separation Checklist (https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf) when a Contractor/subcontractor employee terminates work under this contract. All documentation shall be made available to the COR upon request.

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

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

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

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

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

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

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

5. **VULNERABILITY SCANNING REQUIREMENTS**

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

ARTICLE H.29. COMMUNICATIONS MATERIALS AND SERVICES

To build and maintain public trust; promote credibility and consistency; minimize consistency and frustration; and contribute to efforts aimed at leveraging reduced resources and eliminating waste in Government, the Contractor shall ensure that all materials generated and/or services provided under this contract, comply with all applicable NIH policy and procedures published by the NIH Office of Management Assessment in conjunction with the NIH Office of Communications and Public Liaison as set forth below.

This acquisition requires the contractor to:

[X] Prepare, review, and/or distribute NIH Publications and Audiovisuals.

NIH Policy Manual Chapter 1183, "NIH Publications & Audiovisuals: Preparation, Review, Approval & Distribution," is applicable to this contract. http://oma1.od.nih.gov/manualchapters/management/1183/.

[X] Use the NIH name and logo.

NIH Policy Manual Chapter 1186, "Use of NIH Names and Logos," is applicable to this contract. http://oma1.od.nih.gov/manualchapters/management/1186/.

[X] Create and/or Manage a Public Website which includes NIH hosted social media site(s), Web application(s) and mobile Web Site(s).

NIH Policy Manual Chapter 2804, "Public-Facing Web Management," is applicable to this contract. http://oma1.od.nih.gov/manualchapters/management/2804/.

[X] Create and/or Manage an NIH Website that maintains and disseminates personal information.

NIH Policy Manual Chapter 2805, "NIH Web Privacy Policy," is applicable to this contract. http://oma1.od.nih.gov/manualchapters/management/2805/.

[X] Create and/or Manage an NIH hosted and/or funded social media site(s), Web application(s) and mobile Web site(s).

NIH Policy Manual Chapter 2809, "NIH Social and New Media Policy," is applicable to this contract. http://oma1.od.nih.gov/manualchapters/management/2809/.

Additional Standards applicable to this contract are identified in the FFRDC Statement of Work. If it is determined by the Government that products, services, and deliverables provided by the Contractor do not conform to standards described in these directives, remediation to an acceptable level of conformance shall be the responsibility of the Contractor at its own expense.

ARTICLE H.30. STORAGE FACILITY REQUIREMENTS AND CERTIFICATION

The Contractor shall ensure that all materials generated under this contract for which commercial records storage is required, shall be stored in a facility that meets National Archives and Records Administration (NARA) requirements for safe, secure and certified storage as required by 36 CFR 1228, subpart K.

The Contractor shall provide the Contracting Officer with the name(s) and location(s) of the commercial records storage facility used to store materials under this contract. In addition, the Contractor shall provide a copy of the "Facility Standards for Records Storage Facilities Inspection Checklist," self-certifying that the facility being used to store federal records meets established NARA standards. NARA Standards are available at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=b5a00a361423743ff1a062faafcfdd89&rgn=div5&view=text&node=36:3.0.10.2.23&idno=36

Sixty (60) days prior to contract end date, the Contractor shall submit to the Contracting Officer's Representative (COR) and Contracting Officer, an inventory of all materials stored. The disposition of these materials shall be determined no later than the expiration date of the contract.

Additional information about Records Storage Facility Standards can be found at: http://www.archives.gov/records-mgmt/storage-standards-toolkit/

ARTICLE H.31. 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 (see: https://wiki.nci.nih.gov/display/COREtraining/Create+an+Email+Signature).

ARTICLE H.32. CONTRACTOR'S USE OF LIBRARY RESOURCES AT NIH

The Contractor is authorized to use library resources at NIH in the same manner as NIH staff. The Contractor's approved use of these resources is limited to performing the requirements of this contract. The Contractor shall not use library resources at NIH in a manner that exceeds the Fair Use limitations codified in 17 U.S.C. sec. 107 of the Copyright Act. Contractors shall not share access to library resources at NIH with, perform searches for, or provide results to, non-NIH users, i.e. collaborators at other universities or research centers.

ARTICLE H.33. 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:

The findings of studies or research conducted for the Biological Resources Branch (BRB), Biological Testing Branch (BTB), the Screening Technologies Branch (STB), and the Information Technology Branch (ITB), of NCI's Developmental Therapeutics Program (DTP), and the Laboratory of Population Genetics/NCI Center for Bioinformatics are considered confidential information. Additional information may also be identified as confidential on the Task Order level. Therefore, the Contractor is required to provide written advance notice to the COR (for which the work is being performed) of its intent to release such data in accordance with HHSAR Clause 352.224-71, Confidentiality of Information (December 18, 2015) which is incorporated into this contract by reference.

ARTICLE H.34. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity

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

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

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

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

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

    Significant financial interests do not include the following:

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

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

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

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

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

e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the

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

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

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

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

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

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

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

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

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

ARTICLE H.35. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of

Health whenever publicizing the work under this Contract, as identified on each Task Order, in any media by including an acknowledgment substantially as follows:

> "This project has been funded in whole or in part with Federal funds from the [specify Institute/Center], National Institutes of Health, Department of Health and Human Services, under Contract No. TBD and Task Order No. TBD"

ARTICLE H.36. REVIEW OF MANUSCRIPTS

In order to balance the oversight responsibility of the National Cancer Institute (NCI) with the authorization provided to the Contractor by the Rights in Data clause, 52.227-14 of this contract, the NCI does not require contractors to seek the Institute's approval of manuscripts and abstracts; however Government review of manuscripts and abstracts is required. This review process applies to Contractor authored or co-authored manuscripts and abstracts. Government authored or co-authored manuscripts and abstracts do not follow this review process.

The Contractor shall provide advance notice of intent to submit a manuscript to a peer reviewed journal for publication at least 10 business days prior to submission to the publisher to the appropriate Division, Office, or Center (DOC) Point of Contact. The advance notice should briefly describe the plans for publication of the manuscript and include a copy of the manuscript. Manuscripts are defined as: a scientific or technical report or abstract to be submitted to a peer-reviewed journal or conference for publication.

The Contractor shall provide advance notice of intent to submit an abstract to a conference for publication at least 2 business days prior to submission to the publisher to the appropriate Division, Office, or Center (DOC) Point of Contact. The advance notice should briefly describe the plans for publication of the abstract and include a copy of the abstract. An abstract is defined as any document that summarizes a professional publication, i.e. research article, thesis, review, conference proceeding or any in-depth analysis of a particular subject or discipline.

Any comments from the DOC Point of Contact will be provided in writing within the 10 business day review period for manuscripts and within the 2 business day review period for abstracts. In the event that no comments are received in the specified timeframes allotted above, it will result in "review with no comments" and the Contractor may proceed with submittal. Comments expressed by the DOC Point of Contact about the manuscript shall not be a cause for action under the Disputes clause of the contract by either NCI or the Contractor.

ARTICLE H.37. 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.38. INTELLECTUAL PROPERTY OPTION TO COLLABORATOR (APPLICABLE AT THE TASK ORDER LEVEL)

NCI may collaborate with an outside investigator who has proprietary rights to compounds which may be assigned under this contract. This collaborator will be identified by the Contracting Officer's Representative (COR) at the time of assignment and in this case, the following option regarding Intellectual Property Rights will be applicable.

Contractor agrees to promptly notify the NCI and "Collaborator" in writing of any inventions, discoveries or innovations made by the Contractor's principal investigator or any other employees or agents of the Contractor, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of this study using Collaborator's Study Agent (hereinafter "Contractor Inventions").

Contractor agrees to grant to Collaborator: (1) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (2) a time-limited first option to negotiate an exclusive world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all Contractor Inventions on terms to be negotiated in good faith by Collaborator and Contractor. Collaborator shall notify Contractor, in writing, of its interest in obtaining an exclusive license to any Contractor Invention within six (6) months of Collaborator's receipt of notice of such Contractor Invention(s). In the event that Collaborator fails to so notify Contractor or elects not to obtain an exclusive license, then Collaborator's option shall expire with respect to that Contractor Invention, and Contractor will be free to dispose of its interests in such Contractor Invention in accordance with its own policies. If Contractor and Collaborator fail to reach agreement within ninety (90) days, (or such additional period as Collaborator and Contractor may agree) on the terms for an exclusive license for a particular Contractor Invention, then for a period of six (6) months thereafter, Contractor shall not offer to license the Contractor Invention to any third party on materially better terms than those last offered to Collaborator without first offering such terms to Collaborator, in which case Collaborator shall have a period of thirty (30) days in which to accept or reject the offer.

Contractor agrees that notwithstanding anything herein to the contrary, any inventions, discoveries or innovations, whether patentable or not, which are not Subject Inventions as defined in 35 U.S.C. 201(e),* arising out of any unauthorized use of the Collaborator's Study Agent shall be the property of the Collaborator (hereinafter "Collaborator Inventions"). Contractor will promptly notify the Collaborator in writing of any such Collaborator Inventions and, at Collaborator's request and expense, Contractor will cause to be assigned to Collaborator all right, title and interest in an to any such Collaborator Inventions and provide Collaborator with reasonable assistance to obtain patents (including causing the execution of any invention assignment or other documents). Contractor may also be conducting other more basic research using Study Agent under the authority of a separate Material Transfer Agreement (MTA), or other such agreement with the Collaborator. Inventions arising thereunder shall be subject to the terms of the MTA, and not to this clause.

*35 U.S.C. 201(e): The term "subject invention" means any invention of the Contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, that in the case of a variety of plant, the date of determination (as defined in section 41(d)(FOOTNOTE 1) of the Plant Variety Protection Act (7 U.S.C. 2401(d)) must also occur during the period of contract performance.

Protection of Proprietary Data

Data generated using an investigational agent proprietary to a Collaborator will be kept confidential and shared only with the NCI and the Collaborator. The Contractor retains the right to publish research results subject to the terms of this contract.

ARTICLE H.39. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

a. Sharing of Model Organisms for Biomedical Research

   The plan for sharing model organisms submitted by the Contractor is acceptable. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

b. Transfer of Human Materials

All human materials transferred to the contractor under this contract for the purposes of research shall be accomplished in accordance with the Policy entitled, "Policy for the Transfer of Materials from NIH Intramural Laboratories," located at: http://www.ott.nih.gov/mta-policy.

The contractor shall coordinate with the **NCI Technology Transfer Center** (see http://ttc.nci.nih.gov) or the contracting officer will insert name and contact information of the appropriate TDC to determine the specific terms and conditions for the human materials to be transferred. Generally, the Government and Contractor will enter into Material Transfer Agreement which stipulates the specific terms and conditions relating to the materials being transferred.

ARTICLE H.40. SHARING RESEARCH DATA

The data sharing plan submitted by the Contractor is acceptable. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

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

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

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

ARTICLE H.41. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

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

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

ARTICLE H.42. CONSTITUTION DAY (APPLICABLE TO EDUCATIONAL INSTITUTIONS ONLY)

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

ARTICLE H.43. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

ARTICLE H.44. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD (APPLICABLE AT THE TASK ORDER LEVEL)

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

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

The following conferences and/or meetings have been approved by the Contracting Officer and are hereby authorized under this contract:

Conference or Meeting Title	Conference or Meeting Location	Federal/NonFederal Space	Date of Conference	Not to Exceed Estimate Cost
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		

ARTICLE H.45. REGISTRATION FEES FOR NIH SPONSORED SCIENTIFIC, EDUCATIONAL, AND RESEARCH-RELATED CONFERENCES (APPLICABLE AT THE TASK ORDER LEVEL)

In accordance with the NIH Reform Act of 2006, P.L. 109-482, the NIH may authorize a Contractor procured to assist in the development and implementation of a scientific, educational or research-related conference to collect and retain registration fees from Non-HHS Federal and Non-Federal participants to defray the costs of the contract.

Whenever possible, the Contracting Officer, prior to each conference, shall provide the Contractor with uniform assumptions of the government's estimate of the registration fee offset to include in the costs estimate for the conference. This offset should be deducted from the total cost of the conference.

Prior to each conference, the Contractor shall submit a completed "Contractor Pre-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the Contracting Officer's Representative (COR) and Contracting Officer. After the conference is held, the Contractor shall submit a completed "Post-Conference Expense Offset Worksheet" (Attachment provided in SECTION J) to the COR and Contracting Officer.

The Contractor shall collect and maintain current and accurate accounting of collected conference fees and conference expenses. The Contractor shall immediately notify the COR and Contracting Officer, in writing, if it appears the total registration fees collected will exceed the estimated total cost of the conference. If the registration fees collected are in excess of the total actual conference expenditures, the contractor shall return the excess funds to the Contracting Officer to be deposited as miscellaneous receipts into the U.S. Treasury.

If the registration fees collected are in excess of the uniform assumptions provided by the Contracting Officer, the Contracting Officer, shall, as necessary, modify the contract price to reflect the decrease in conference costs. If the registration fees collected are less than the uniform assumptions provided by the Contracting Officer, the Contracting Officer shall, as necessary, modify the contract price to reflect the increase in conference costs.

Although Contractors may bill for allowable conference costs as they are incurred, they may not submit a final invoice for the total costs of the conference until the "Post-Conference Expense Offset Worksheet" has been approved by the COR.

ARTICLE H.46. GUIDELINES FOR INCLUSION OF WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES IN NIH-SUPPORTED CONFERENCES (APPLICABLE AT THE TASK ORDER LEVEL)

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

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

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

See the policy announcement for additional details and definitions at:
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html

ARTICLE H.47. USE OF FUNDS FOR PROMOTIONAL ITEMS (APPLICABLE AT THE TASK ORDER LEVEL)

The Contractor shall not use contract funds to purchase promotional items. Promotional items include, but are not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees. This includes items or tokens given to individuals as these are considered personal gifts for which contract funds may not be expended.

ARTICLE H.48. SPECIAL CONTRACT REQUIREMENTS FME/EHS

NOTE TO OFFERORS: IN ADDITION TO REQUIREMENTS SET FORTH ELSEWHERE IN SECTION H., THESE SPECIAL REQUIREMENTS ARE APPLICABLE TO FACILITIES' MAINTENANCE AND ENGINEERING (FME) AND ENVIRONMENT, HEALTH AND SAFETY (EHS) ONLY.

ARTICLE H.48.1. NCI RIGHTS

a. INSPECTIONS/INVESTIGATIONS

1. The COR-FME/COR-EHS may, in any reasonable manner, observe and inspect the contractor's safety and accident prevention procedures for all activities and personnel. This specifically includes, but it not limited to, the right to attend all safety meetings.
2. Upon request, the COR-FME/COR-EHS shall receive copies of any safety inspection reports completed by the contractor or anyone performing work for, on behalf of or under the auspices of the contractor.
3. The COR-FME/EHS may, in any reasonable manner, observe or participate in any accident investigation conducted by the contractor or anyone performing work for, on behalf of or under the auspices of the contractor. The NCI may also, at its sole discretion and in any reasonable manner, undertake its own accident investigation.

b. CORRECTIVE ACTIONS/STOP WORK

1. The COR-FME/COR-EHS shall have the right to direct the contractor to correct unsafe working conditions, including taking corrective action when unsafe working conditions are observed (i.e. lack of good

housekeeping practices, use of equipment in obviously poor condition, failure to adhere to statutory OSHA regulations, etc.).

2. The COR-FME/COR-EHS shall have the right to require the removal, from the work site, any person, property or equipment that, in the NCI's opinion, is deemed unsafe.
3. The COR-FME/COR-EHS shall have the right to instruct the contractor to immediately cease any action and/or stop work (or any action thereof) when any conditions exist that, in the NCI's opinion, constitutes an imminent danger or could result in serious harm.
4. The COR-FME/COR-EHS shall have the right to suspend the work pending the completion of any accident/ incident investigation, whether undertaken by contractor, the NCI or others.
5. The contractor is responsible for costs, expenses and other obligations paid or incurred, as a result of the contractor or subcontractor's noncompliance with federal, state, or local safety regulations; or failure to comply with terms and conditions of this contract.

c. NCI'S ACTION/INACTION DOES NOT RELIEVE CONTRACTOR

Nothing the NCI may do, or fail to do, with respect to safety in the performance of the work shall relieve the contractor of its responsibility to comply strictly with this Contract and all standards referenced herein.

ARTICLE H.48.2. UTILITY SHUTDOWNS

All outages or modifications to the fire protection systems must be in accordance with Environment, Health and Safety Procedures. Contractors shall not cut, disconnect, switch, open, or alter position of valves, or otherwise interrupt any utility systems, piping systems, electric services, etc. without advanced coordination with COR-FME/COR-EHS and all impacted parties.

ARTICLE H.48.3. WORK BY THE GOVERNMENT

The Government reserves the right to undertake performance by Government forces or other Contractors, the same type or similar work as contracted for herein, as the Government deems necessary or desirable, and to do so will not breach or otherwise violate this contract.

1. General. The Government has awarded and will award other contracts for specialized work, which is outside the scope of this contract. These contracts will involve additional work at or near the site of the work under this contract. The contractor shall carefully adapt its schedule and performance of work under this contract to accommodate the work of the Other Government Contractors (OGCs), and shall take coordinating direction from the COR-FME. The OGCs will be placed under similar contracting conditions regarding coordination. The Contractor shall make every reasonable effort to avoid interference with the performance of work by the OGCs, as scheduled by the OGCs or by the Government.
2. Notification of Obstructive conditions. If any part of the Contractor's work is impeded by unscheduled occupation or obstruction of Contractor work areas by OGCs, the Contractor shall promptly report such conditions in writing to the COR-FME.
3. Preparation of and access to OGC Worksites. The Contractor shall be responsible to make ready applicable areas to allow for scheduled activities by each of the OGCs in accordance with the project schedule.
4. Notification of Scheduling Conflicts. If the Contractor becomes aware of potential scheduling conflicts with activities by OGCs, the Contractor shall promptly notify the COR-FME in writing.

ARTICLE H.48.4. SUPPORT OF NIH REPLACED, RENOVATED, IMPROVED EQUIPMENT OR FACILITIES

Within the term of this contract, NIH may replace, renovate, or improve equipment, systems, facilities, components, and fixtures by means not associated with this contract. The Contractor shall provide maintenance support for replaced, renovated, improved, and repaired systems facilities, components, and fixtures.

ARTICLE H.48.5. EQUIPMENT DEVIATIONS

Equipment deviations of greater or larger power, dimensions, capacity, and ratings may be furnished, provided such proposed equipment is approved in writing by the COR-FME; and, feeders, circuit breakers, conduit, motors, bases, structural support, and equipment spaces are increased by the contractor and other adjustments required to accommodate proper installment and use are made by the Contractor at no additional cost to the Government.

ARTICLE H.48.6. EQUIPMENT AND FIXTURE REPLACEMENT REQUIREMENT

When the Contractor completes work on a facility, system, or piece of equipment, that facility, or equipment shall be free of missing components or defects that would prevent it from functioning as originally intended and/or designed.

Corrective or repair and/or replacement work shall include operational checks and cleanup of the job site. When equipment and/or fixtures are replaced or repaired the contractor shall perform specific inspections, procedures, and preservation required by the manufacturer and shall verify all systems and components are operating as designed. Except where approved by the COR-FME, replacements shall match the existing in dimensions, finish, color, and design.

ARTICLE H.48.7. SUBCONTRACTOR MACHINERY AND STORAGE

Any subcontractor equipment allowed to be stored or to remain overnight on NCI property shall be kept only in designated areas and shall be the Contractor's total responsibility. The Government will not accept responsibility for loss or damage to any property of the subcontractor.

ARTICLE H.48.8. FURNISHED PARTS AND INDUSTRIAL CODES

The Contractor shall provide new or factory reconditioned parts and components when providing maintenance, repair, and alteration services as described herein. Lack of availability of parts, material, or equipment will not relieve the Contractor from the requirement to complete work within the time limits and quality standards stated herein. All replacement units, parts, components and materials to be used in the maintenance, repair, and alteration of facilities and equipment shall be compatible with the existing equipment on which it is to be used, shall be of equal or better quality than original equipment specifications, shall comply with all applicable Government, commercial, or industrial standards and regulations.

All parts shall be used in accordance with original design and manufacture intent, and shall be of acceptable industrial grade and quality. If the original manufacturer has updated the quality of parts for current production, parts supplied under this contract shall equal to or exceed the updated quality.

The Contractor shall maintain copies of all applicable manufacturer operation and maintenance (O&M) manuals, pamphlets, and any other documentation related to the products provided.

NOTE TO OFFERORS: PLEASE REFER TO SECTION J, ATTACHMENT 24 ENTITLED, "PROPOSED SPECIAL CONTRACT REQUIREMENTS" FOR ADDITIONAL DRAFT ARTICLES.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

The complete listing of these clauses may be accessed at:
https://oamp.od.nih.gov/DGS/reference-material-prospective-offerors-and-contractors

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

(APPLICABLE TO EDUCATIONAL INSTITUTIONS ONLY FOR COST REIMBURSEMENT TASK ORDERS)

This contract incorporates the following clauses 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. Also, the full text of a clause may be accessed electronically as follows: FAR Clauses at: http://www.acquisition.gov/far/. HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Nov 2013	Definitions (Over the Simplified Acquisition Threshold)
52.203-3	Apr 1984	Gratuities (Over the Simplified Acquisition Threshold)
52.203-5	May 2014	Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)
52.203-7	May 2014	Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)
52.203-17	Apr 2014	ontractor Employee Whistleblower Rights and Requirements to Inform mployees of Whistleblower Rights (Over the Simplified Acquisition Threshold)
52.203-99	Feb 2015	Prohibition on Contracting with Entities That Require Certain Internal Confidentiality Agreements (DEVIATION)
52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)
52.204-10	Oct 2015	Reporting Executive Compensation and First-Tier Subcontract Awards ($30,000 or more)
52.204-13	Jul 2013	System for Award Management Maintenance
52.209-6	Oct 2015	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $35,000)
52.215-2	Oct 2010	Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery

		Act funds.], Alternate II (Apr 1998)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data (Over $750,000)
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data (Over $750,000)
52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold)
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions (Over $750,000)
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
52.215-23	Oct 2009	Limitations on Pass-Through Charges (Over the Simplified Acquisition Threshold)
52.216-7	Jun 2013	Allowable Cost and Payment, Alternate II (Aug 2012)
52.216-11	Apr 1984	Cost Contract - No Fee
52.219-8	Oct 2014	Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)
52.219-9	Oct 2015	Small Business Subcontracting Plan (Over $700,000, $1.5 million for Construction)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $700,000, $1.5 million for Construction)
52.222-2	Jul 1990	Payment for Overtime Premium (Over the Simplified Acquisition Threshold) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-26	Apr 2015	Equal Opportunity
52.222-35	Oct 2015	Equal Opportunity for Veterans ($150,000 or more)
52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
52.222-37	Feb 2016	Employment Reports on Veterans ($150,000 or more)
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)
52.222-50	Mar 2015	Combating Trafficking in Persons
52.222-54	Oct 2015	Employment Eligibility Verification (Over the Simplified Acquisition Threshold)
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
52.225-1	May 2014	Buy American - Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Dec 2007	Rights in Data - General, Alternate IV (Dec 2007)
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jul 2013	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over the Simplified Acquisition Threshold)

52.244-2	Oct 2010	Subcontracts (Over the Simplified Acquisition Threshold), Alternate I (June 2007)
52.244-5	Dec 1996	Competition in Subcontracting (Over the Simplified Acquisition Threshold)
52.244-6	Feb 2016	Subcontracts for Commercial Items
52.245-1	Apr 2012	Government Property, Alternate II (April 2012)
52.245-9	Apr 2012	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over the Simplified Acquisition Threshold)
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.203-70	Dec 2015	Anti-Lobbying
352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
352.227-70	Dec 2015	Publications and Publicity
352.233-71	Dec 2015	Litigation and Claims
352.237-75	Dec 2015	Key Personnel

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT W_EDUCATIONAL INSTITUTION- Rev. 02/2016].

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

(APPLICABLE TO NON-PROFIT INSTITUTIONS ONLY FOR COST REIMBURSEMENT TASK ORDERS ONLY)

This contract incorporates the following clauses 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. Also, the full text of a clause may be accessed electronically as follows: FAR Clauses at: http://www.acquisition.gov/far/. HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

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

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52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)
52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)
52.203-99	Feb 2015	Prohibition on Contracting with Entities That Require Certain Internal Confidentiality Agreements (DEVIATION)
52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)

52.204-10	Oct 2015	Reporting Executive Compensation and First-Tier Subcontract Awards ($30,000 or more)
52.204-13	Jul 2013	System for Award Management Maintenance
52.209-6	Oct 2015	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $35,000)
52.215-2	Oct 2010	Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.], Alternate II (Apr 1998)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data (Over $750,000)
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data (Over $750,000)
52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold)
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions (Over $750,000)
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
52.215-23	Oct 2009	Limitations on Pass-Through Charges (Over the Simplified Acquisition Threshold)
52.216-7	Jun 2013	Allowable Cost and Payment, Alternate IV (Aug 2012)
52.216-11	Apr 1984	Cost Contract - No Fee
52.219-8	Oct 2014	Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)
52.219-9	Oct 2015	Small Business Subcontracting Plan (Over $700,000, $1.5 million for Construction)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $700,000, $1.5 million for Construction)
52.222-2	Jul 1990	Payment for Overtime Premium (Over the Simplified Acquisition Threshold) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-26	Apr 2015	Equal Opportunity
52.222-35	Oct 2015	Equal Opportunity for Veterans ($150,000 or more)
52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
52.222-37	Feb 2016	Employment Reports on Veterans ($150,000 or more)
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)
52.222-50	Mar 2015	Combating Trafficking in Persons
52.222-54	Oct 2015	Employment Eligibility Verification (Over the Simplified Acquisition Threshold)
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
52.225-1	May 2014	Buy American - Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Dec 2007	Rights in Data - General, Alternate IV (Dec 2007)
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jul 2013	Prompt Payment, Alternate I (Feb 2002)

52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2014	Penalties for Unallowable Costs (Over $700,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over the Simplified Acquisition Threshold)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Oct 2010	Subcontracts (Over the Simplified Acquisition Threshold), Alternate I (June 2007)
52.244-5	Dec 1996	Competition in Subcontracting (Over the Simplified Acquisition Threshold)
52.244-6	Feb 2016	Subcontracts for Commercial Items
52.245-1	Apr 2012	Government Property, Alternate II (April 2012)
52.245-9	Apr 2012	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over the Simplified Acquisition Threshold)
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.203-70	Dec 2015	Anti-Lobbying
352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
352.227-70	Dec 2015	Publications and Publicity
352.233-71	Dec 2015	Litigation and Claims
352.237-75	Dec 2015	Key Personnel

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT W_NON-PROFIT- Rev. 02/2016].

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

(APPLICABLE TO COST-REIMBURSEMENT TASK ORDERS ONLY)

This contract incorporates the following clauses 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. Also, the full text of a clause may be accessed electronically as follows: FAR Clauses at: http://www.acquisition.gov/far/. HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Nov 2013	Definitions (Over the Simplified Acquisition Threshold)
52.203-3	Apr 1984	Gratuities (Over the Simplified Acquisition Threshold)
52.203-5	May 2014	Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)
52.203-7	May 2014	Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity

		(Over the Simplified Acquisition Threshold)
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)
52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)
52.203-99	Feb 2015	Prohibition on Contracting with Entities That Require Certain Internal Confidentiality Agreements (DEVIATION)
52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)
52.204-10	Oct 2015	Reporting Executive Compensation and First-Tier Subcontract Awards ($30,000 or more)
52.204-13	Jul 2013	System for Award Management Maintenance
52.209-6	Oct 2015	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $35,000)
52.215-2	Oct 2010	Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.]
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data (Over $750,000)
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data (Over $750,000)
52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold)
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions (Over $750,000)
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
52.215-23	Oct 2009	Limitations on Pass-Through Charges (Over the Simplified Acquisition Threshold)
52.216-7	Jun 2013	Allowable Cost and Payment
52.216-8	Jun 2011	Fixed Fee
52.219-8	Oct 2014	Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)
52.219-9	Oct 2015	Small Business Subcontracting Plan (Over $700,000, $1.5 million for Construction)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $700,000, $1.5 million for Construction)
52.222-2	Jul 1990	Payment for Overtime Premium (Over the Simplified Acquisition Threshold) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-26	Apr 2015	Equal Opportunity
52.222-35	Oct 2015	Equal Opportunity for Veterans ($150,000 or more)
52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
52.222-37	Feb 2016	Employment Reports on Veterans ($150,000 or more)
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)
52.222-50	Mar 2015	Combating Trafficking in Persons
52.222-54	Oct 2015	Employment Eligibility Verification (Over the Simplified Acquisition Threshold)
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving

52.225-1	May 2014	Buy American - Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	May 2014	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest (Over the Simplified Acquisition Threshold)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jul 2013	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2014	Penalties for Unallowable Costs (Over $700,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over the Simplified Acquisition Threshold)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Oct 2010	Subcontracts (Over the Simplified Acquisition Threshold), Alternate I (June 2007)
52.244-5	Dec 1996	Competition in Subcontracting (Over the Simplified Acquisition Threshold)
52.244-6	Feb 2016	Subcontracts for Commercial Items
52.245-1	Apr 2012	Government Property
52.245-9	Apr 2012	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over the Simplified Acquisition Threshold)
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.203-70	Dec 2015	Anti-Lobbying
352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
352.227-70	Dec 2015	Publications and Publicity
352.233-71	Dec 2015	Litigation and Claims
352.237-75	Dec 2015	Key Personnel

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT- Rev. 02/2016].

ARTICLE I.1.D. GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE RESEARCH AND DEVELOPMENT CONTRACT

(APPLICABLE TO FIXED PRICED TASK ORDERS ONLY)

This contract incorporates the following clauses 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. Also, the full text of a clause may

be accessed electronically as follows: FAR Clauses at: http://www.acquisition.gov/far/. HHSAR Clauses at: http://www.hhs.gov/policies/hhsar/subpart352.html.

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Nov 2013	Definitions (Over the Simplified Acquisition Threshold)
52.203-3	Apr 1984	Gratuities (Over the Simplified Acquisition Threshold)
52.203-5	May 2014	Covenant Against Contingent Fees (Over the Simplified Acquisition Threshold)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over the Simplified Acquisition Threshold)
52.203-7	May 2014	Anti-Kickback Procedures (Over the Simplified Acquisition Threshold)
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity (Over the Simplified Acquisition Threshold)
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions (Over $150,000)
52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirements to Inform Employees of Whistleblower Rights (Over the Simplified Acquisition Threshold)
52.203-99	Feb 2015	Prohibition on Contracting with Entities That Require Certain Internal Confidentiality Agreements (DEVIATION)
52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper(Over the Simplified Acquisition Threshold)
52.204-10	Oct 2015	Reporting Executive Compensation and First-Tier Subcontract Awards ($30,000 or more)
52.204-13	Jul 2013	System for Award Management Maintenance
52.209-6	Oct 2015	Protecting the Government's Interest When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $35,000)
52.215-2	Oct 2010	Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with on-Recovery Act funds.]
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data (Over $750,000)
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data (Over $750,000)
52.215-14	Oct 2010	Integrity of Unit Prices (Over the Simplified Acquisition Threshold)
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions (Over $750,000)
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
52.219-8	Oct 2014	Utilization of Small Business Concerns (Over the Simplified Acquisition Threshold)
52.219-9	Oct 2015	Small Business Subcontracting Plan (Over $700,000, $1.5 million for Construction)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $700,000, $1.5 million for Construction)
52.222-3	Jun 2003	Convict Labor
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-26	Apr 2015	Equal Opportunity

52.222-35	Oct 2015	Equal Opportunity for Veterans ($150,000 or more)
52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
52.222-37	Feb 2016	Employment Reports on Veterans ($150,000 or more)
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)
52.222-50	Mar 2015	Combating Trafficking in Persons
52.222-54	Oct 2015	Employment Eligibility Verification (Over the Simplified Acquisition Threshold)
52.223-6	May 2001	Drug-Free Workplace
52.223-18	Aug 2011	Encouraging Contractor Policies to Ban Text Messaging While Driving
52.225-1	May 2014	Buy American - Supplies
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	May 2014	Rights in Data - General
52.229-3	Feb 2013	Federal, State and Local Taxes (Over the Simplified Acquisition Threshold)
52.232-2	Apr 1984	Payments under Fixed-Price Research and Development Contracts
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest (Over the Simplified Acquisition Threshold)
52.232-23	May 2014	Assignment of Claims
52.232-25	Jul 2013	Prompt Payment
52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
52.233-1	May 2014	Disputes
52.233-3	Aug 1996	Protest After Award
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-13	Jul 1995	Bankruptcy (Over the Simplified Acquisition Threshold)
52.243-1	Aug 1987	Changes - Fixed Price, Alternate V (Apr 1984)
52.244-6	Feb 2016	Subcontracts for Commercial Items
52.246-23	Feb 1997	Limitation of Liability (Over the Simplified Acquisition Threshold)
52.249-2	Apr 2012	Termination for the Convenience of the Government (Fixed-Price)
52.249-9	Apr 1984	Default (Fixed-Price Research and Development)(Over the Simplified Acquisition Threshold)
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.203-70	Dec 2015	Anti-Lobbying
352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
352.227-70	Dec 2015	Publications and Publicity
352.237-75	Dec 2015	Key Personnel

[End of GENERAL CLAUSES FOR A NEGOTIATED FIXED-PRICE RESEARCH AND DEVELOPMENT CONTRACT-Rev. 02/2016].

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 substitutions will be made part of the resultant contract:

a. ***Alternate II*** *(April 1998) of FAR Clause* ***52.215-2, Audit and Records--Negotiation*** *(October 2010) is added.*

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

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

d. FAR Clause **52.216-8, Fixed Fee** (June 2011) is deleted in its entirety and FAR Clause **52.216-10, Incentive Fee** (June 2011) is substituted therefor.

e. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (October 2015) is added.

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

g. FAR Clause **52.229-3, Federal, State and Local Taxes** (February 2013), is deleted in its entirety, and FAR Clause **52.229-6, Taxes--Foreign Fixed-Price Contracts** (February 2013) is substituted therefor. **(APPLICABLE TO FIXED PRICE TASK ORDERS IN A FOREIGN COUNTRY ONLY)**

h. FAR Clause **52.232-17, Interest** (May 2014) as applicable.

i. 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 Task Orders are 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.]**

j. **Alternate I** (February 2002), of FAR Clause **52.232-25, Prompt Payment** (July 2013) is deleted.

k. **Alternate I** (April 1984) of FAR Clause **52.243-1, Changes, Fixed Price** (August 1987), is hereby deleted in its entirety and **Alternate II** (April 1984) of FAR Clause **52.243-1, Changes, Fixed Price** (August 1987), is substituted therefor. **(APPLICABLE TO FIXED PRICE TASK ORDERS ONLY)**

l. FAR Clause **52.249-9, Default (Fixed-Price Research and Development)** (April 1984) is deleted in its entirety and FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)** (September 1996), is substituted therefore. **(APPLICABLE TO EDUCATIONAL AND NONPROFIT INSTITUTIONS ONLY)**

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

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

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

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

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

3. FAR Clause **52.204-9, Personal Identity Verification of Contractor Personnel** (January 2011).

4. FAR Clause **52.207-5, Option to Purchase Equipment** (February 1995).

5. FAR Clause **52.208-8, Required Sources for Helium and Helium Usage Data** (April 2014).

6. FAR Clause **52.208-9, Contractor Use of Mandatory Sources of Supply or Services** (May 2014).

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

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

9. FAR Clause **52.216-11, Cost Contract--No Fee** (April 1984). **(AS APPLICABLE)**

10. FAR Clause **52.216-15, Predetermined Indirect Cost Rates** (April 1998).

11. FAR Clause **52.217-6, Option for Increased Quantity** (March 1989).
    (APPLICABLE AT THE TASK ORDER LEVEL)

    "....The Contracting Officer may exercise the option by written notice to the Contractor within TBD ...."

12. FAR Clause **52.217-7, Option for Increased Quantity - Separately Priced Line Item** (March 1989).
    (APPLICABLE AT THE TASK ORDER LEVEL)

"....The Contracting Officer may exercise the option by written notice to the Contractor within TBD ...."

13. FAR Clause **52.217-8, Option to Extend Services** (November 1999).
(APPLICABLE AT THE TASK ORDER LEVEL)

    "..The Contracting Officer may exercise the option by written notice to the Contractor within TBD .

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

    "(c) Waiver of evaluation preference.....
    [ ] Offeror elects to waive the evaluation preference."

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

16. FAR Clause **52.222-4, Contract Work Hours and Safety Standards - Overtime Compensation - General** (May 2014).

17. FAR Clause **52.222-29, Notification of Visa Denial** (April 2015).

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

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

20. FAR Clause **52.223-5, Pollution Prevention and Right-to-Know Information** (May 2011).

    Alternate I (May 2011) is applicable to this contract.

    Alternate II (May 2011) is applicable to this contract.

21. FAR Clause **52.223-10, Waste Reduction Program** (May 2011).

22. FAR Clause **52.223-12, Refrigeration Equipment and Air Conditioners** (May 1995).

23. FAR Clause **52.223-13 Acquisition of EPEAT®-Registered Imaging Equipment** (June 2014)

    Alternate I (Oct 2015) is not applicable to this contract.

24. FAR Clause **52.223-14 Acquisition of EPEAT®-Registered Televisions** (June 2014)

    Alternate I (June 2014) is not applicable to this contract.

25. FAR Clause **52.223-15, Energy Efficiency in Energy-Consuming Products** (December 2007).

26. FAR Clause **52.223-16, Acquisition of EPEAT®-Registered Personal Computer Products** (October 2015).

    Alternate I (June 2014) is not applicable to this contract.

27. FAR Clause **52.223-17, Affirmative Procurement of EPA-designated Items in Service and Construction Contracts** (May 2008).

28. FAR Clause **52.223-19, Compliance with Environmental Management Systems** (May 2011).

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

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

31. FAR Clause **52.225-8, Duty-Free Entry** (October 2010).

32. FAR Clause **52.227-13, Patent Rights--Ownership by the Government** (December 2007).

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

34. FAR Clause **52.227-17, Rights in Data--Special Works** (December 2007).

35. FAR Clause **52.227-18, Rights in Data--Existing Works** (December 2007).

36. FAR Clause **52.227-19, Commercial Computer Software License** (December 2007).

37. FAR Clause **52.228-5, Insurance - Work on a Government Installation** (January 1997).

38. FAR Clause **52.228-7, Insurance - Liability to Third Persons** (MAR 1996).

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

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

41. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (October 2015). **(APPLICABLE TO EDUCATIONAL INSTITUTIONS ONLY)**

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

43. FAR Clause **52.236-13, Accident Prevention** (November 1991), with **Alternate I** (November 1991).

44. FAR Clause **52.237-2, Protection of Government Buildings, Equipment and Vegetation** (April 1984).

45. FAR Clause **52.237-3, Continuity of Services** (January 1991).

46. FAR Clause **52.237-11, Accepting and Dispensing of $1 Coin** (September 2008).

47. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

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

49. FAR Clause **52.242-4, Certification of Final Indirect Costs** (January 1997).

50. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984). **(APPLICABLE TO EDUCATIONAL INSTITUTIONS ONLY)**

51. FAR Clause **52.244-2, Subcontracts** (October 2010). **(APPLICABLE TO FIXED PRICE TASK ORDERS ONLY)**

52. FAR Clause **52.245-1, Government Property** (April 2012).

53. **Alternate II** (April 2012), FAR Clause **52.245-1, Government Property** (April 2012). **(APPLICABLE TO EDUCATIONAL AND NON-PROFIT INSTITUTIONS ONLY)**

54. FAR Clause **52.245-9, Use and Charges** (April 2012).

55. FAR Clause **52.246-25 Limitation of Liability-Services** (February 1997).

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

57. FAR Clause **52.247-64, Preference for Privately Owned U.S. Flag Commercial Vessels** (February 2006).

58. FAR Clause **52.247-68, Report of Shipment (REPSHIP)** (February 2006).

59. FAR Clause **52.249-5, Termination for Convenience of the Government** (Educational and Other Nonprofit Institutions) (September 1996). **(APPLICABLE TO EDUCATIONAL AND NONPROFIT INSTITUTIONS ONLY)**

60. FAR Clauses **52.249-6, Termination** (Cost-Reimbursement) (May 2004). **(APPLICABLE TO COST REIMBURSEMENT TASK ORDERS)**

61. FAR Clause **52.249-14, Excusable Delays** (April 1984). **(APPLICABLE TO COST REIMBURSEMENT TASK ORDERS)**

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

NOTE TO OFFERORS: THE FOLLOWING DEVIATIONS REFLECT DETERMINATIONS OF EXCEPTIONAL CIRCUMSTANCES UNDER THE CURRENT CONTRACT AND ARE PROVIDED FOR REFERENCE.

63. FAR Clause **52.227-11 (Deviation) Patent Rights--Ownership by the Contractor** (DEC 2007) [Patent Rights-Use of Third-party Technology and Information by OTS Subcontractors] is provided in the Virtual Library located on the FNLCR Acquisition Portal at: http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition.

64. FAR Clause **52.227-11 (Deviation) Patent Rights--Ownership by the Contractor** (DEC 2007) [Patent Rights-NCI Full-length cDNA Initiative] is provided in the Virtual Library located on the FNLCR Acquisition Portal at: http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition.

65. FAR Clause **52.227-11 (Deviation) Patent Rights --Ownership by the Contractor** (DEC 2007) [Patent Rights-NCI Initiative for Chemical Genetics (ICG)] (formerly called the Molecular Targets Laboratories (MTL) Initiative) is provided in the Virtual Library located on the FNLCR Acquisition Portal at: http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition.

66. FAR Clause **52.227-14 (Deviation) Rights in Data-General** (DEC 2007) [Rights in Data-NCI Full-length cDNA Initiative] is provided in the Virtual Library located on the FNLCR Acquisition Portal at: http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition.

67. FAR Clause **52.227-14 (Deviation) Rights in Data-General** (DEC 2007) [Initiative for Chemical Genetics (ICG)] (formerly called the Molecular Targets Laboratories (MTL) Initiative) is provided in the Virtual Library located on the FNLCR Acquisition Portal at: http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition.

68. FAR Clause **52.227-17 (Deviation) Rights in Data--Special Works** (DEC 2007) [Rights in Data-Use of Third-party Technology and Information] is provided in the Virtual Library located on the FNLCR Acquisition Portal at: http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition.

69. FAR Clause **52.227-11 (Deviation) Patent Rights--Ownership by the Contractor** (DEC 2007) [OTS Contractor CRADAs] is provided in the Virtual Library located on the FNLCR Acquisition Portal at: http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition.

70. FAR Clause **52.227-13 (Deviation) Patent Rights--Ownership by the Government** (DEC 2007) [Patent Rights-OTS Prime Contractor] (As amended MAR 2012) is provided in the Virtual Library located on the FNLCR Acquisition Portal at: http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition.

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

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

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

3. HHSAR Clause **352.211-3, Paperwork Reduction Act** (December 2015)

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

5. HHSAR Clause **352.224-71, Confidential Information** (December 2015).

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

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

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

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

7. HHSAR Clause **352.237-71, Crime Control Act of 1990--Reporting of Child Abuse** (December 2015).

8. FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).

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

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

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

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

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

This contract incorporates the following clauses in full text.

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

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

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

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

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

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

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

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

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

i. *Past performance reviews required by subpart 42.15;*

ii. *Information that was entered prior to April 15, 2011; or*

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

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

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

2. *The Contractor will also have an opportunity to post comments regarding information that has been posted by the Government. The comments will be retained as long as the associated information is retained, i.e., for a total period of 6 years. Contractor comments will remain a part of the record unless the Contractor revises them.*

3. *As required by section 3010 of Pub. L. 111-212, all information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available.*

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

(End of clause)

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

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

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

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

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

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

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

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

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

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

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

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

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

a. This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

b. Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the

supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the
"maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."

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

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

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

a. The Government may extend the term of this contract by written notice to the Contractor within ten (10) days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least sixty (60) days before the contract expires. The preliminary notice does not commit the Government to an extension.

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

c. The total duration of this contract, including the exercise of any options under this clause, shall not exceed twenty (20) years.

6. FAR Clause **52.223-7, Notice of Radioactive Materials** (January 1997)

a. The Contractor shall notify the Contracting Officer or designee, in writing, ten (10) days prior to completion of any servicing required by this contract of, items containing either (1) radioactive material requiring specific licensing under the regulations issued pursuant to the Atomic Energy Act of 1954, as amended, as set forth in Title 10 of the Code of Federal Regulations, in effect on the date of this contract, or (2) other radioactive material not requiring specific licensing in which the specific activity is greater than 0.002 microcuries per gram or the activity per item equals or exceeds 0.01 microcuries. Such notice shall specify the part or parts of the items which contain radioactive materials, a description of the materials, the name and activity of the isotope, the manufacturer of the materials, and any other information known to the Contractor which will put users of the items on notice as to the hazards involved (OMB No. 9000-0107).

b. If there has been no change affecting the quantity of activity, or the characteristics and composition of the radioactive material from deliveries under this contract or prior contracts, the Contractor may request that the Contracting Officer or designee waive the notice requirement in paragraph (a) of this clause. Any such request shall-

i. Be submitted in writing;

ii. State that the quantity of activity, characteristics, and composition of the radioactive material have not changed; and

iii. Cite the contract number on which the prior notification was submitted and the contracting office to which it was submitted.

c. All items, parts, or subassemblies which contain radioactive materials in which the specific activity is greater than 0.002 microcuries per gram or activity per item equals or exceeds 0.01 microcuries, and all containers in which such items, parts or subassemblies are delivered to the Government shall be clearly marked and labeled as required by the latest revision of MIL-STD 129 in effect on the date of the contract.

d. This clause, including this paragraph (d), shall be inserted in all subcontracts for radioactive materials meeting the criteria in paragraph (a) of this clause.

7. FAR Clause **52.223-9, Estimate of Percentage of Recovered Material Content for EPA Designated Items** (May 2008)

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

Postconsumer material means a material or finished product that has served its intended use and has been discarded for disposal or recovery, having completed its life as a consumer item. Postconsumer material is a part of the broader category of "recovered material."

Recovered material means waste materials and by-products recovered or diverted from solid waste, but the term does not include those materials and by-products generated from, and commonly reused within, an original manufacturing process.

b. The Contractor, on completion of this contract, shall--

1. Estimate the percentage of the total recovered material content for EPA-designated item(s) delivered and/or used in contract performance, including, if applicable, the percentage of post-consumer material content; and

2. Submit this estimate to Contracting Officer and Contracting Officer's Representative .

8. FAR Clause **52.223-11, Ozone-Depleting Substances** (May 2001)

a. Definition. Ozone-depleting substance, as used in this clause, means any substance the Environmental Protection Agency designates in 40 CFR part 82 as--

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

2. Class II, including, but not limited to, hydrochlorofluorocarbons.

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

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

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

9. FAR Clause **52.226-6, Promoting Excess Food Donation to Nonprofit Organizations** (March 2009)

(a) *Definitions*. As used in this clause--

Apparently wholesome food means food that meets all quality and labeling standards imposed by Federal, State, and local laws and regulations even though the food may not be readily marketable due to appearance, age, freshness, grade, size, surplus, or other conditions.

Excess food means food that--

(1) Is not required to meet the needs of the executive agencies; and
(2) Would otherwise be discarded.

Food-insecure means inconsistent access to sufficient, safe, and nutritious food.
Nonprofit organization means any organization that is--

(1) Described in section 501(c) of the Internal Revenue Code of 1986; and
(2) Exempt from tax under section 501(a) of that Code.

(b) In accordance with the Federal Food Donation Act of 2008 (Pub. L. 110-247), the Contractor is encouraged, to the maximum extent practicable and safe, to donate excess, apparently wholesome
food to nonprofit organizations that provide assistance to food-insecure people in the United States.

(c) *Costs*. (1) The Contractor, including any subcontractors, shall assume the responsibility for all the costs and the logistical support to collect, transport, maintain the safety of, or distribute the excess, apparently wholesome food to the nonprofit organization(s) that provides assistance to food-insecure people.

(2) The Contractor will not be reimbursed for any costs incurred or associated with the donation of excess foods. Any costs incurred for excess food donations are unallowable.

(d) *Liability*. The Government and the Contractor, including any subcontractors, shall be exempt from civil and criminal liability to the extent provided under the Bill Emerson Good Samaritan Food Donation Act (42 U.S.C. 1791). Nothing in this clause shall be construed to supersede State or local health regulations (subsection (f) of 42 U.S.C. 1791).

(e) *Flowdown*. The Contractor shall insert this clause in all contracts, task orders, delivery orders, purchase orders, and other similar instruments greater than $25,000 with its subcontractors or suppliers, at any tier, who will perform, under this contract, the provision, service, or sale of food in the United States.

10. FAR Clause **52.247-67, Submission of Transportation Documents for Audit** (February 2006).

(a) The Contractor shall submit to the address identified below, for prepayment audit, transportation documents on which the United States will assume freight charges that were paid--

(1) By Contractor under a cost-reimbursement contract; and
(2) By a first-tier subcontractor under a cost-reimbursement subcontract thereunder.

(b) Cost-reimbursement Contractors shall only submit for audit those bills of lading with freight shipment charges exceeding $100. Bills under $100 shall be retained on-site by the Contractor and made available for on-site audits. This exception only applies to freight shipment bills and is not intended to apply to bills and invoices for any other transportation services.

(c) Contractors shall submit the above referenced transportation documents to--

Contracting Officer
National Cancer Institute Campus at Frederick
TBD

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

1. THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.

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

ARTICLE I.5. SERVICE CONTRACT LABOR STANDARDS
(APPLICABLE AT THE SUBCONTRACT LEVEL ONLY)

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 **52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts** (January 2014).

b. FAR Clause **52.222-17 Nondisplacement of Qualified Workers** (May 2014).

c. FAR Clause **52.222-41, Service Contract Labor Standards** (May 2014).

d. FAR Clause **52.222-42, Statement of Equivalent Rates For Federal Hires** (May 2014)

In compliance with the Contract Labor Standards statute and the regulations of the Secretary of Labor (29 CFR Part 4), this clause identifies the classes of service employees expected to be employed under the contract and states the wages and fringe benefits payable to each if they were employed by the contracting agency subject to the provisions of 5 U.S.C. 5341 or 5332.

THIS STATEMENT IS FOR INFORMATION ONLY: IT IS NOT A WAGE DETERMINATION

Employee Class	Monetary Wage-Fringe Benefit

(End of Clause)

e. FAR Clause **52.222-43, Fair Labor Standards Act and Service Contract Labor Standards--Price Adjustment (Multiple Year And Option Contracts)** (May 2014).

f. FAR Clause **52.222-49, Service Contract Labor Standards--Place Of Performance Unknown** (May 2014)

"(a) ....., wage determinations have been requested for the following: _____ [insert places or areas]. The Contracting Officer will request wage determinations for additional places or areas of performance if asked to do so in writing by _____ [insert time and date]....."

g. FAR 52.222-55 **Minimum Wages Under Executive Order 13658** (December 2015)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (R&D)	http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition
Attachment 2:	Proposal Intent Response Sheet	http://ncioa.cancer.gov/oa-internet/forms/intent.jsp
Attachment 3:	FFRDC Statement of Work	http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition
Attachment 4:	Transition Task Order Statement of Work	http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition
Attachment 5:	Sample Task Order 1 Statement of Work	http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition
Attachment 6:	Sample Task Order 2 Statement of Work	http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition
Attachment 7:	Award Fee Plan	http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition
Attachment 8:	Government Furnished Property	http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition
Attachment 9:	Section K - Representations, Certifications, and Other Statements of Offerors	https://oamp.od.nih.gov/sites/default/files/DGS/FORMS/sectionk_508.pdf

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 10:	Additional Technical Proposal Instructions	http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition
Attachment 11:	Planned Enrollment Report, PHS-398/2590 (Rev. 08/12)	http://grants.nih.gov/grants/funding/phs398/PlannedEnrollmentReport.pdf
Attachment 12:	Technical Proposal Cost Summary	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf
Attachment 13:	Summary of Related Activities	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf
Attachment 14:	Protection of Human Subject Assurance Identification/IRB Certification/Declaration	http://www.hhs.gov/ohrp/assurances/forms/of310.pdf

Attachment No.	Title	Location
	of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310)	
Attachment 15:	Contract Proposal Vertebrate Animal Section (VAS) Worksheet	http://grants.nih.gov/grants/olaw/VAScontracts.pdf
Attachment 16:	HHS Section 508 Product Assessment Template	http://www.hhs.gov/web/508/contracting/technology/vendors.html

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 17:	Additional Business Proposal Instructions	http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition
Attachment 18:	Proposal Summary and Data Record, NIH-2043	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf
Attachment 19:	Small Business Subcontracting Plan	http://www.hhs.gov/asfr/ogapa/osbdu/smallbusiness/subcontractplan.html
Attachment 20:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/buscost.htm http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx
Attachment 21:	Offeror's Points of Contact	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf
Attachment 22:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://www.gsa.gov/portal/forms/download/116430

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 23:	Proposed Advance Understandings	http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition
Attachment 24:	Proposed Special Contract Requirements	http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition
Attachment 25:	FFRDC Policy 101	http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/documents/Acquisition
Attachment 26:	Environment, Health and Safety Procedures	https://ncifrederick.cancer.gov/ehs/procedures/default.aspx
Attachment 27:	Invoice Instructions for NIH Fixed Price Contracts NIH(RC)-2	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc2_508.pdf
Attachment 28:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc4_508.pdf
Attachment 29:	Privacy Act System of Records	http://oma.od.nih.gov/public/MS/privacy/PAfiles/read02systems.htm
Attachment 30:	Safety and Health, HHSAR Clause 352.223-70	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Safety-Health-hhsar-1-06.pdf

Attachment No.	Title	Location
Attachment 31:	Research Patient Care Costs, NIH(RC)-11	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc11.pdf
Attachment 32:	Cumulative Inclusion Enrollment Report	http://grants.nih.gov/grants/funding/phs398/CumulativeInclusionEnrollmentReport.pdf
Attachment 33:	Government Property Schedule	To be determined during negotiations.
Attachment 34:	Commitment to Protect Non-Public Information Contractor Agreement	https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf
Attachment 35:	Roster of Employees Requiring Suitability Investigations	https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx
Attachment 36:	Employee Separation Checklist	https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf
Attachment 37:	Conference Expense Offset Worksheets	Contractor Pre-Conference Expense Offset Worksheet, 1 page. Located at: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Pre-Conf-worksheet.pdf Post Conference Expense Offset Worksheet, 2 pages. Located at: http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Post-Conf-worksheet.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

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

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

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

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

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

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

(End of Clause)

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. **GENERAL INFORMATION**

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

a. Definitions. As used in this provision--

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

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

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

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

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

i. The solicitation number;

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

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

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

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

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

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

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

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

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

(3) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

(e) Restriction on disclosure and use of data.

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

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

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

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

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

(f) Contract award.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) A summary of the rationale for award.

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

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

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

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

b. **REQUEST FOR INFORMATION OR SOLICITATION FOR PLANNING PURPOSES** [FAR 52.215-3 (October 1997)]

(a) The Government does not intend to award a contract on the basis of this solicitation or to otherwise pay for the information solicited except as an allowable cost under other contracts as provided in subsection 31.205-18, Bid and proposal costs, of the Federal Acquisition Regulation.

(b) Although "proposal" and "offeror" are used in this Request for Information, your response will be treated as information only. It shall not be used as a proposal.

(c) This solicitation is issued for the purpose of: Comment and feedback from interested parties

(End of provision)

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 541712.
2. The small business size standard is 1,000 employees.

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

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 June 2017.
2. It is anticipated that the award from this solicitation will be a single award Indefinite Delivery Indefinite Quantity (IDIQ) contract with Cost Plus Award Fee and Fixed Price Task Orders subject to either Completion or Level of Effort with an Ordering Period of twenty (20) years if all Options are exercised, and that incremental funding may be used at the Task Order Level (See Section L.2.c. Business Proposal Instructions).
3. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information.

e. **COST PLUS AWARD FEE ACQUISITION**

The 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 Award Fee Plan, 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 Award Fee Plan is included in this SOLICITATION and located SECTION J.

f. **LEVEL OF EFFORT**

The Government's requirement for the work set forth in the Statement of Work of this solicitation is TBD direct labor years. It is estimated that the labor hours are constituted as specified below and will be expended across all issued task orders approximately as follows:

LABOR YEARS

	Labor Categories					
Contract Year	**Key Personnel**	**Administrative**	**Information Technology**	**Life Sciences**	**Biotechnology/ Regulatory**	**Totals**
Year 1	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 2	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 3	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 4	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 5	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Option Period 1						
Year 6	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 7	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 8	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 9	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 10	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Option Period 2						
Year 11	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 12	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 13	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 14	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 15	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Option Period 3						
Year 16	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 17	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 18	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 19	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**
Year 20	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**	**TBD**

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. **PROMOTING EFFICIENT SPENDING**

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

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

Any contract awarded as a result of this solicitation will:

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

i. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contracting Officer at: FNLCR_ACQinfo@nih.gov. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

j. **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.

k. **REFERENCE MATERIALS**

A "Virtual Library" containing reference materials pertinent to this acquisition is available on the FNLCR Acquisition Portal at: http://ncioa.cancer.gov/oa-internet/fnlcr/index.html#/home. Failure of offerors to examine the reference materials prior to proposal preparation and submission will be at the offeror's risk.

l. **PREPARATION COSTS**

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

m. **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
National Cancer Institute
TBD

(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)

n. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70 (December 2015)

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, the Government may consider a proposal received after the date specified for receipt if it appears to offer significant cost or technical value to the Government and it was

received before proposals were distributed for evaluation, or within 5 calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

o. **AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."**

Copies of the "Federal ADP and Telecommunications Standards Index" can be purchased from the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402.

p. **USE OF NON-GOVERNMENT PERSONNEL FOR TECHNICAL PROPOSAL EVALUATION**

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

2. **INSTRUCTIONS TO OFFERORS**

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

The following instructions will establish the acceptable minimum requirements for the format and contents of proposals. Special attention is directed to the requirements for technical and business proposals to be submitted in accordance with these instructions.

1. **Contract Type and General Clauses**

It is contemplated that a single award Indefinite Delivery Indefinite Quantity (IDIQ) contract with Cost Plus Award Fee and Fixed Price Task Orders subject to either Completion or Level of Effort will be awarded. 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: Volume I, "Technical Proposal" and Volume II, "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. **Page and Formatting Limitations**

Volume I, Technical Proposal shall not exceed one hundred ten (110) double-sided pages OR two hundred twenty (220) single-sided pages exclusive of cover sheet, table of contents, and any attachments. However, the total Volume I, Technical proposal shall not exceed one hundred twenty-five (125) double-sided pages OR two hundred fifty (250) single-sided pages inclusive of cover sheet, table of contents, and any attachments. Resumes/ Curricula Vitae (CVs) have no specified page limitations and do not count toward the technical proposal page limitations above. Offerors should consider that a concise and well formulated proposal is usually more effective than a voluminous proposal that lacks effective distillation. Volume II, Business Proposal is mandatory and must include all listed components; however, no page limit is specified for this volume. Pages in excess of the limitation will be deleted and will be neither read nor evaluated.

All pages shall be formatted for printing on 8-1/2 by 11-inch paper with Calibri or like font, with font size not smaller than 12 point. Font sizes of 8 or 10 point may be used for figures, tables, and charts. Document files must be in .pdf, .xls, or .xlsx formats. If constant spacing is used, 15 cpi (characters per inch) or fewer shall be used, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be no less than ½ inch around, exclusive of headers and footers.

6. **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.

7. **Evaluation of Proposals**

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

8. **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.

9. **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.

10. **Standards for Privacy of Individually Identifiable Health Information**

    The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply.

    Decisions about the applicability and implementation of the Privacy Rule reside with the Contractor and his/her institution. The OCR Web site (http://www.hhs.gov/ocr/) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html.

11. **Non-discrimination for Conscience, HHSAR 352.270-9 (December 2015)**

a. Section 301(d) of the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act, as amended, provides that an organization, including a faith-based organization, that is otherwise eligible to receive assistance under section 104A of the Foreign Assistance Act of 1961, under the United States Leadership Against HIV/AIDS, Tuberculosis, and Malaria Act of 2003, under the Tom Lantos and Henry J. Hyde United States Global Leadership Against HIV/AIDS, Tuberculosis, and Malaria Reauthorization Act of 2008, or under any amendment to the foregoing Acts for HIV/AIDS prevention, treatment, or care-

   i. Shall not be required, as a condition of receiving such assistance, to-

      i. Endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS; or

      ii. Endorse, utilize, make a referral to, become integrated with, or otherwise participate in any program or activity to which the organization has a religious or moral objection.

   ii. Shall not be discriminated against under the provisions of law in subparagraph (a) for refusing to meet any requirement described in paragraph (a)(1) in this solicitation.

b. Accordingly, an offeror who believes this solicitation contains work requirements that would require it to endorse or utilize a multisectoral or comprehensive approach to combating HIV/AIDS, or to endorse, utilize, make referral to, become integrated with, or otherwise participate in a program or activity to which it has a religious or moral objection, shall identify those work requirements it has excluded in its technical proposal.

c. The Government acknowledges that an offeror has specific rights, as cited in paragraph (b) of this provision, to exclude certain work requirements in this solicitation from its proposal. However, the Government reserves the right to not make an award to an offeror whose proposal does not comply with the salient work requirements of the solicitation. Any exercise of that Government right will be made by the Head of the Contracting Activity.

(End of provision)

12. **Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)**

Under the provisions of the Rights in Data General clause (52.227-14), contractors must seek permission to establish a copyright for software and associated data generated under a contract. As a general rule, permission is normally granted provided, a paid-up, world-wide, irrevocable, nonexclusive license to the Government is provided. This is to advise offerors that for this project, the Government intends to assert additional copyright permissions under this contract. The scope of the Government's interest in the copyright will be determined during negotiations.

13. **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.

14. **Selection of Offerors**

a. To conduct the evaluation, the Government will convene a panel to peer review Technical Proposals. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The panel may suggest that the Contracting Officer request clarifying information from an offeror.

b. The business portion of each contract proposal found to be technical acceptable will be subjected to a cost and price analysis, cost realism, management analysis, etc.

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

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

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

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

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

   While it is NCI's policy to conduct discussions with all offerors in the competitive range, NCI reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All

aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR Part 315.

e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.

f. The NCI reserves the right to make a single award, multiple awards, or no award at all to the SOLICITATION. In addition, the SOLICITATION may be amended or canceled as necessary to meet NCI requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

15. **Institutional Responsibility Regarding Investigator Conflicts of Interest**

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

16. **ROTC Access and Federal Military Recruiting on Campus (APPLICABLE TO EDUCATIONAL INSTITUTIONS ONLY)**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

17. **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.

18. **52.203-98 Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements--Representation (DEVIATION)**

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

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

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

19. **Past Performance Information**

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

A list of the no more than five (5) contracts/task orders/delivery orders currently being performed or completed during the past three (3) years that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as greater than $10,000,000.

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. Task Order/Delivery Order Number (as applicable)
4. Contract Type
5. Total Contract Value
6. Description of Requirement
7. Contracting Officer's Name and Telephone Number
8. Program Manager's/Contracting Officer's Representative's Name and Telephone Number
9. 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.

20. **Prohibition on Contractor Involvement with Terrorist Activities**

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

21. **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).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

B. **Standard for Security Configurations**

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

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

b. The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS. The following security configuration requirements apply:
The Contractor shall comply with the current OMB, NIST, DHS, HHS, NIH and NCI standards.

c. The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with FDCC Scanner capability to ensure its products operate correctly with FDCC configurations and do not alter FDCC settings - see http://scap.nist.gov/validation. The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest FDCC major version and subsequent major versions.

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

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

f. The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (http://csrc.nist.gov/publications/fips/fips201-1/FIPS-201-1-chng1.pdf), Homeland Security Presidential Directive 12 (HSPD-12) card readers with the purchase of servers, desktops, and laptops; and (2) comply with FAR Subpart 4.13, Personal Identity Verification.

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

C. **Standard for Encryption language**

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

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

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

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

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

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

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

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

1. Protecting Federal information and Federal information systems in order to ensure their -

a. Integrity, which means guarding against improper information modification or destruction, and includes ensuring information non-repudiation and authenticity;

b. Confidentiality, which means preserving authorized restrictions on access and disclosure, including means for protecting personal privacy and proprietary information; and

c. Availability, which means ensuring timely and reliable access to and use of information.

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

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

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

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

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

   i. Office of Management and Budget (OMB) Circular A-130, Management of Federal Information Resources, Appendix III, Security of Federal Automation Information Resources.

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

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

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

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

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

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

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

i. Annual testing of the system contingency plan; and

ii. The performance of security control testing and evaluation.

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

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

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

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

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

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

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

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

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

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

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

E. Additional NIH Requirements

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

a. Information Type:

[X] Administrative, Management and Support Information:

Sections 3.2 Facility Operations and 3.3 Business Operations and Management of the FFRDC SOW

[X] Mission Based Information:

Section 3.1 Research and Research Support Programs, Projects, and Activities of the FFRDC SOW

b. Security Categories and Levels:

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

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

2. INFORMATION SECURITY TRAINING

The contractor shall comply with the below training:

a. Mandatory Training

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

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

b. Role-based Training

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

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

c. Rules of Behavior

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

3. **PERSONNEL SECURITY RESPONSIBILITIES**

The contractor shall comply with the below personnel security responsibilities:

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

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

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

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

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

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

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

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

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

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

5. **VULNERABILITY SCANNING REQUIREMENTS**

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

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

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

    a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

    b. Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of the Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and standards/communications-and-it/about-the-section-508-standards.

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

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

    (End of provision)

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

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

    This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full

text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

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

b. Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).

c. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).

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

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

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

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

h. Identification of Uncompensated Overtime, FAR Clause 52.237-10, (March 2015).

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

Offerors should provide a detailed proposal indicating how each area of the FFRDC SOW is to be accomplished. The technical approach should be in sufficient detail to fully explain the proposed technical approach or method. The technical approach should reflect a clear understanding of the nature of the work being undertaken.

Offerors should refer to Attachment 10 "Additional Technical Proposal Instructions" for additional information.

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**

See Section J, Attachment 10 Additional Technical Proposal Instructions.

a. **Personnel**

See Section J, Attachment 10 Additional Technical Proposal Instructions.

1. Single Principal Investigator/Project Director

   See Section J, Attachment 10 Additional Technical Proposal Instructions.

2. Additional Personnel

   See Section J, Attachment 10 Additional Technical Proposal Instructions.

3. Resumes/Curricula Vitae (CVs)

   See Section J, Attachment 10 Additional Technical Proposal Instructions.

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. Other factors you feel are important and support your proposed research.

3. **Technical Evaluation**

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

4. **Human Subjects**

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

a. **Notice to Offerors of Requirements, Protection of Human Subjects, HHSAR 352.270-4(a) (December 2015)**

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

   b. The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable public information through intervention or interaction with the individual, or identifiable private information. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information

derived from individually identifiable human subjects. 45 CFR part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.

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

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

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

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

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

Alternate I (DEC 2015).

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

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

prior to the deadline for proposal submission. If the offeror cannot obtain an FWA before the proposal submission date, the proposal shall indicate the steps/actions the offeror will take to obtain OHRP approval within(Contracting Officer must insert a time period in which the FWA must be obtained). Upon obtaining FWA approval, submit the approval notice to the Contracting Officer.

b. **Instructions to Offerors Regarding Protection of Human Subjects**

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

a. Risks to the subjects

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

b. Adequacy of Protection Against Risks

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

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

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

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

d. Importance of the Knowledge to be Gained

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

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

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

c. **Required Education in the Protection of Human Research Participants**

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

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for

the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

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

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

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

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

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

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

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

Information Required for ALL Clinical Research Proposals

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

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

The proposal must include the following information:

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

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

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

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

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

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference).
*The definition of an " **NIH-Defined Phase III clinical trial**" can also be found at this website.)

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

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

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

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

  OR

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

  OR

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

Use the form entitled, "Planned Enrollment Report," when preparing your response to the solicitation requirements for inclusion of women and minorities. (See Section J-List of Documents, Exhibits and Other Attachments of the RFP)
Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

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

e. **Inclusion of Children in Research Involving Human Subjects**

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

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

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

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

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

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

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

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

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

- Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
- Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

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

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

Research Involving Prisoners as Subjects

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

b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

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

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

1. The sole purposes are:
    a. to describe the prevalence or incidence of a disease by identifying all cases, or
    b. to study potential risk factor associations for a disease, and
2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2 7) and determined and documented that:

a. the research presents no more than minimal risk, and

b. no more than inconvenience to the prisoner subjects, and

c. prisoners are not a particular focus of the research.

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

f. **Research Involving Recombinant or Synthetic Nucleic Acid Molecules (Including Human Gene Transfer Research)**

All research projects (both NIH-funded and non-NIH-funded) involving recombinant or synthetic nucleic acid molecules that are conducted at or sponsored by an entity in the U.S. that receives any support for recombinant or synthetic nucleic acid research from NIH shall be conducted in accordance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*) (see http://oba.od.nih.gov/rdna/nih_guidelines_oba.html). All NIH-funded projects abroad that include recombinant or synthetic nucleic acid molecules must also comply with the *NIH Guidelines*. In addition to biosafety and containment requirements, the NIH Guidelines delineate points to consider in the development and conduct of human gene transfer clinical trials, including ethical principles and safety reporting requirements (see Appendix M of the NIH Guidelines). Further information about compliance with the NIH Guidelines can be found on the NIH Office of Biotechnology Activities (OBA) web site at: http://oba.od.nih.gov/rdna_ibc/ibc.html.

Prior to beginning any clinical trial involving the transfer of recombinant or synthetic nucleic acid molecules to humans, the trial must be registered with the NIH OBA and reviewed by the NIH Recombinant DNA Advisory Committee (RAC). If this contract involves a human gene transfer trial raising unique and/or novel issues, the RAC may recommend that the trial also be discussed by the RAC in a public forum. Approval of an Institutional Biosafety Committee (IBC) and the Institutional Review Board (IRB) are necessary before the Contracting Officer's Representative (COR) and Contracting Officer (CO) may approve the protocol prior to the start of the research. The IBC approval may not occur before the NIH RAC has concluded its review of the protocol.

For human gene transfer research, Appendix M-I-C-4 of the *NIH Guidelines* requires any serious adverse events (SAEs) that are both unexpected and possibly associated with the human gene transfer product to be reported to NIH OBA and an IBC within 15 days, or within 7 days if the event was life-threatening or resulted in a death. A copy of the report must also be filed with the COR and CO (see: http://osp.od.nih.gov/sites/default/files/NIH_Guidelines_0.pdf). SAE reports must also be submitted within their mandated time frames to the IRB, Food and Drug Administration (FDA), and, if applicable, the Health and Human Services (HHS) Office for Human Research Protections (OHRP). In addition, annual reports must be submitted to NIH OBA covering certain information about human gene transfer protocols. Further information about the content of these reports can be found in Appendix M-I-C-3 of the *NIH Guidelines*. Additional information on the requirements that pertain to human gene transfer can be found in a series of Frequently Asked Questions at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/biosafety-guidance/faq.

Failure to comply with the *NIH Guidelines* may result in suspension, limitation, or termination of the contract for any work related to recombinant or synthetic nucleic acid research or a requirement for the CO to approve any or all recombinant or synthetic nucleic acid molecule projects under this contract. This includes the requirement for the institution to have an IBC registered with NIH OBA that complies with the requirements of the *NIH Guidelines*. Further information about compliance with the NIH Guidelines

can be found on the NIH Office of Biotechnology Activities (OBA) web site at: http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines.

g. **Human Embryonic Germ Cell (HEGC) Research**

1. Guidelines

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

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

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

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

The TBD has determined that human embryonic germ cells are required to be used for the conduct of this research. The offeror must confirm in its proposal that it plans to use human embryonic germ cells as a part of its research. If the offeror receives a contract award, the Contractor may not perform any research using human embryonic germ cells until the Human Pluripotent Stem Cell Review Group (HPSCRG) has reviewed and approved the documentation furnished as prescribed in the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) and the Contracting Officer has notified the Contractor of the approval in writing.

Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.b of the NIH Guidelines at:
(http://stemcells.nih.gov/staticresources/news/newsArchives/fr25au00-136.asp).
Offerors should also review the March 19, 2002, DHHS Office of Human Research Protection's document titled "Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell Derived Test Articles," at:
(http://stemcells.nih.gov/StaticResources/news/newsArchives/stemcell.pdf)

The resultant contract will be divided into discrete phases or option periods. During Option Period(s)/Phase(s) (TBD) of the contract, the Contractor shall submit the original and two copies of the required documentation and assurances that address the areas covered in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," at:
(http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html)

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

If the HPSCRG disapproves the documentation presented by the Contractor, the Contracting Officer may elect to either terminate the contract in accordance with the Termination for Convenience clause of the contract OR determine not to exercise subsequent option(s) as appropriate based the terms of the specific contract. Otherwise, when the HPSCRG approves the documentation, the Contracting Officer will notify the Contractor in writing that research using the human embryonic germ cells may commence.

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

h. **Human Embryonic Stem Cell (hESC) Research**

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

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

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

i. **Data and Safety Monitoring in Clinical Trials**

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

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

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

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

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

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

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

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

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

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

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

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

j. **HIV Antiretroviral Treatment Trials**

The NIH is committed to conducting HIV/AIDS research in an effort to improve the health of people living with this disease, particularly people in countries most affected by the epidemic. It is important that individuals who volunteer to participate in NIH funded HIV antiretroviral trials be given the option to continue to receive antiretroviral treatment following their completion of the trial. In order to accomplish this, the Contractor must work with the host countries' authorities and other stakeholders to identify sources available, if any, in the country for the provision of such treatment. It is noted that NIH cannot provide this treatment following the completion of the research. See NIH Guide Notice, " Guidance for Addressing the Provision of Antiretroviral Treatment for Trial Participants Following Their Completion of NIH Funded HIV Antiretroviral Treatment Trials in Developing Countries," located at:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-038.html.

The offeror's proposal must address a plan that describes the following:

- A description of available sources, if any (e.g., name of source, location, contact person of facility/organization) for the provision of antiretroviral treatment and care following the completion of the trial;
- A summary of the offeror's interaction with the providers;
- Documents, if any, from available sources/ providers regarding plans for implementation;
- A description of how this information will be conveyed to the trial participants.

If there are no sources for antiretroviral treatment in or available to the country in which the treatment trials will take place, the offeror must provide:

1. A statement confirming that at the time of the offer, no sources of antiretroviral treatment could be identified;
2. A description of how this information will be conveyed to the trial participants;
3. A commitment to continue to explore potential sources as the trial proceeds.

This plan or the documentation provided regarding the lack of available sources of antiretroviral treatment will be evaluated by the Contracting Officer's Representative (COR) as a part of the overall review of the proposal. While an offeror's documentation of the lack of available sources for antiretroviral treatment will not, of itself, constitute denial of a contract award, priority for contract awards may be given to those offerors who identify sources for the provision of antiretroviral treatment following the completion of the trial.

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

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

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

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

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

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

- Where the Contractor is the IND/IDE holder, the Contractor will be considered the Sponsor, therefore the "Responsible Party."
- Where there is no IND/IDE holder or where the Government is the IND/IDE holder, the Government will generally be considered the "Sponsor" and may designate the contractor's Principal Investigator (PI) as the "Responsible Party."
- For Multi-Center trials where there is no IND/IDE holder or where the Government is the IND/IDE holder, the "Responsible Party" will be designated at one site (generally the lead clinical site) and all other sites will be responsible for providing necessary data to the "Responsible Party" for reporting in the database.

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

5. **Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, HHSAR 352.270-5(a)** (December 2015)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health
(NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (Email: olaw@od.nih.gov; Phone: 301-496-7163).

(End of provision)

The PHS Policy is available on the internet at: http://www.grants.nih.gov/grants/olaw/olaw.htm.

6. **Research Involving Live Vertebrate Animals**

It is intended that live vertebrate animals will be used during performance of this contract. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (authority derived from

the Health Research Extension Act of 1985) specifies that certain information is required from offerors in contract proposals submitted to the NIH that will use live vertebrate animals.

The following five points must be addressed in a separate section of the Technical Proposal titled "Vertebrate Animal Section" (VAS):

a. Detailed description of the proposed use of the animals, including species, strains, ages, sex and number to be used.

b. Justification for the use of animals, choice of species, and numbers to be used.

c. Information on the veterinary care of the animals.

d. Description of procedures for minimizing discomfort, distress, pain and injury.

e. Method of euthanasia and the reasons for the selection.

A concise (no more than 1-2 pages), complete description addressing these five points must be provided. The description must be cohesive and include sufficient information to allow evaluation by reviewers and NIH staff. For more discussion regarding the five points in the VAS, see NIH Guide Notice NOT-OD-10-049 at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html.

The Contract Proposal VAS Worksheet is provided as an Attachment in SECTION J of this solicitation to assist in the preparation of the VAS as part of the Technical Proposal. It can be accessed at: http://grants.nih.gov/grants/olaw/VAScontracts.pdf.

7. **Obtaining and Disseminating Biomedical Research Resources**

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

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

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

http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf

a. **Sharing Research Data**

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

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

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

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

b. **Sharing of Model Organisms for Biomedical Research**

The NIH Research Tools Policy (http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf) also referred to as NIH Principles and Guidelines for Sharing of Biomedical Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042 at:
(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html), dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066 at:
(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html),
the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Offerors must include in their technical proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR provide appropriate reasons why such sharing is restricted or not possible. A reasonable time frame for periodic disposition of material and associated data must be specified in the proposal. In addition, the plan must address if, or how, offerors will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following:

- Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) at:
  http://www.ott.nih.gov/mta-policy; for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (http://www.autm.net/UBMTA/8847.htm)
- How will inappropriate "reach-through" requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?
- How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

Offerors may request funds in their cost proposal to defray reasonable costs associated with sharing materials or data or transfer of model organisms and associated data to appropriate repositories.

c. **Data Sharing Policy for Genome-Wide Association Studies**

NIH is interested in advancing genome-wide association studies (GWAS) to identify common genetic factors that influence health and disease through a centralized GWAS data repository. For the purposes of this policy, a genome-wide association study is defined as any study of genetic variation across the entire human genome that is designed to identify genetic associations with observable traits (such as blood pressure or weight), or the presence or absence of a disease or condition.

All offerors proposing a genome-wide association study are expected to provide a plan for submission of GWAS data to the NIH-designated GWAS data repository, or provide an appropriate explanation why submission to the repository is not possible. Contractors submitting GWAS data are expected to:

- Provide descriptive information about their studies;
- Submit coded genotypic and phenotypic data to the NIH GWAS data repository; and
- Submit a certification that the institution or organization has reviewed and approved submission to the NIH, noting any limitations on data use based on the relevant informed consents and providing assurance that all data are submitted to the NIH in accord with applicable laws and regulations and that the identities of research participants will not be disclosed to the NIH GWAS data repository and an IRB and/or Privacy Board, as applicable, has reviewed and verified that:
    - The submission of data to the NIH GWAS data repository and subsequent sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained;
    - The investigator's plan for de-identifying datasets is consistent with the standards outlined above;
    - It has considered the risks to individuals, their families, and groups or populations associated with data submitted to the GWAS data repository; and
    - The genotype and phenotype data to be submitted were collected in a manner consistent with 45 C.F.R. Part 46.

Contractors requesting access to GWAS data in the NIH repository are expected to:

- Submit a data access request, including a brief description of the proposed research and a Data Use Certification that is co-signed by the designated Institutional Official(s) at their sponsoring institution;
- Use the data only for the approved research project described in the data access request;
- Protect data confidentiality;
- Not attempt to use the requested datasets to re-identify or contact individual study participants;
- Retain control of the data and not distribute it to any entity or individual not covered in the data access request;
- Ensure that data security measures are in place;
- Notify the appropriate Data Access Committee of policy violations; and

- Submit annual progress reports detailing significant research findings.

Additionally, Contractors requesting access to the data are also expected to abide by the dbGaP Approved User Code of Conduct (https://dbgap.ncbi.nlm.nih.gov/aa/GWAS_Code_of_Conduct.html).

Data repository management (submission and access) is governed by the Policy for Sharing of Data Obtained in NIH Supported or Conducted Genome-Wide Association Studies, NIH Guide NOT-OD-07-088 located at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-088.html. For additional information see: http://gwas.nih.gov/.

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

   The following Section 508 accessibility standards apply to the content or communications material identified in this Statement of Work Performance Work Statement:
   36 CFR Part 1194.21 ¿ 26.

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

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

   (End of Provision)

c. **BUSINESS PROPOSAL INSTRUCTIONS**
Offerors should refer to Attachment 17 Additional Business Proposal Instructions for additional information.

1. **Basic Cost/Price Information**

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

2. **Proposal Cover Sheet**

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

   1. Solicitation, contract, and/or modification number;
   2. Name and address of Offeror;
   3. Name and telephone number of point of contact;

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

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

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

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

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

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

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

   a. **Direct Labor**

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

   b. **Materials**

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

   c. **Subcontracted Items**

      Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over

$750,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

d. **Raw Materials**

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

e. **Purchased Parts**

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

f. **Fringe Benefits**

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

g. **Indirect Costs**

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

h. **Special Equipment**

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

i. **Travel**

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

j. **Other Costs**

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

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

(a) Exceptions from certified cost or pricing data.

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

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

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

(b) Requirements for certified cost or pricing data. If the offeror is not granted an exception from the requirement to submit certified cost or pricing data, the following applies:

(1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.
(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

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

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

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

5. **Salary Rate Limitation**

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

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

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

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

6. **Small Business Subcontracting Plan**

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

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

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

   c. The offeror understands that:

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

      2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small

Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

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

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

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

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

d. Each plan must contain the following:

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

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

3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

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

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

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

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

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

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

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

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

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

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

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

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

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

   b. The program consists of--

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

      2. Protege firms--firms that:
         (i) Seek developmental assistance;
         (ii) Qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned small businesses; and
         (iii) Have a Mentor-Protege agreement approved by HHS' OSDBU; and

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

(End of provision)

8. **HUBZone Small Business Concerns**

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

9. **Total Compensation Plan**

   a. **Instructions**

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

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

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

   b. **Evaluation**

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

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

      2. **Cost (Professional Compensation)**

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

3. **Other (Labor Relations)**

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

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

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

10. **Other Administrative Data**

a. **Property**

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

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

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

2. Government Property

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

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

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

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

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

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

3. Government-Furnished Property

   A Listing of Government Furnished Property is provided in Section J - Solicitation Attachments of this solicitation

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. **Royalties**

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

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

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

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

(End of Provision)

d. **Financial Capacity**

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

e. **Adequate Accounting System**

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

NOTE TO OFFERORS: THE SUCCESSFUL OFFEROR WILL ASSUME THE EXISTING ACCOUNTING SYSTEM FROM THE INCUMBENT.

f. **Incremental Funding (APPLICABLE AT THE TASK ORDER LEVEL)**

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

Incremental Funding, HHSAR 352.232-70 (December 2015)

The Government intends to negotiate and award a cost-reimbursement contract using incremental funding as described in the clauses at FAR 52.232-22, "Limitation of Funds." The initial obligation of funds under the contract is expected to cover 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)

11. **Subcontractors**

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

a. Willingness to perform as a subcontractor for specific duties (list duties).
b. What priority the work will be given and how it will relate to other work.
c. The amount of time and facilities available to this project.
d. Information on their cognizant field audit offices.
e. How rights to publications and patents are to be handled.
f. A complete cost proposal in the same format as the offeror's cost proposal.

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

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

13. **Travel Costs/Travel Policy**

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

b. **Travel Policy**
One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

NOTE TO OFFERORS: FOR EDUCATIONAL INSTITUTIONS PLEASE REFER TO OMB CIRCULAR A-21 COST PRINCIPLES FOR EDUCATIONAL INSTITUTIONS.

14. **Certification of Visas for Non-U.S. Citizens**

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

SECTION M - EVALUATION FACTORS FOR AWARD

1. **GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against the evaluation factors contained herein. The factors in order of importance are: technical, past performance, and cost. Although technical factors are of paramount consideration in the award of the contract, past performance and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost. The Government intends to make an award to that offeror whose proposal provides the best overall value to the Government.

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

To conduct the evaluation the Government will convene a panel to peer review Technical Proposals. In addition, the Contracting Officer, together with other relevant Government technical and business evaluators, will evaluate the Business Proposals.

2. **COST/PRICE EVALUATION**

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

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

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

3. **HUMAN SUBJECT EVALUATION**

This research project involves human subjects. NIH Policy requires:

a. **Protection of Human Subjects from Research Risks**

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

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

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion

of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

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

b. **Women and Minorities**

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

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

  OR

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

  OR

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

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

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

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

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

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

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

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

c. **Children**

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

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your

proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

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

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

d. **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers will rely on the Statement of Work and Section L in the solicitation, as well as any further technical evaluation factors in this Section M, as applicable, for the solicitation's specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will consider the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

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

e. **HIV Antiviral Treatment Trials**

The offeror's proposal must address a plan to have host countries authorities and/or other stakeholders identify sources available, if any, to provide antiretroviral treatment to HIV affected populations that have participated in the contract funded HIV antiretroviral treatment trial, OR

describe why the offeror believes that there are no such sources available. The information provided must be in accordance with Section L.2.b. Technical Proposal Instructions.

The Project Officer (PO) and/or the Contracting Officer's Representative (COR) will evaluate the documentation provided. While an offeror's documentation of the lack of available sources for antiretroviral treatment will not, of itself, constitute denial of a contract award, priority for contract awards may be given to those offerors who identify sources for the provision of antiretroviral treatment following the completion of the trial.

4. **LIVE VERTEBRATE ANIMALS EVALUATION**

The offerors proposal must include, as a separate section of the Technical Proposal titled "Vertebrate Animal Section," (VAS) a complete, concise (no more than 1-2 pages) description addressing the following five points. (See NIH Guide Notice NOT-OD-10-049 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-049.html):

a. Detailed description of the proposed use of the animals, including species, strains, ages, sex and number to be used.

b. Justification for the use of animals, choice of species, and numbers to be used.

c. Information on the veterinary care of the animals.

d. Description of procedures for minimizing discomfort, distress, pain and injury.

e. Method of euthanasia and the reasons for the selection.

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

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

5. **EVALUATION OF OPTIONS**

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

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

6. **EVALUATION OF DATA SHARING PLAN**

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

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

(FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

7. **EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH**

The offeror's proposal must address the plans for sharing model organisms, OR state appropriate reasons why such sharing is restricted or not possible. Offerors must also address as part of the sharing plan if, or how, they will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. The discussion areas regarding intellectual property outlined in Section L should be addressed.

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

8. **EVALUATION OF PLAN FOR SUBMISSION OF GENOME-WIDE ASSOCIATION STUDY (GWAS) DATA**

The Offeror's plan for the submission of genome-wide association study (GWAS) data to the NIH-designated GWAS data repository will be assessed for appropriateness and adequacy. Proposals submitted for GWAS in which the data submission expectation cannot be met will be considered for award on a case-by-case basis.

9. **TECHNICAL EVALUATION FACTORS**

A. **TECHNICAL APPROACH (40%)**
Demonstrated understanding of technical, scientific, and operational challenges and issues associated with accomplishing all of the requirements of the FFRDC Statement of Work, meeting delivery schedules and knowledge and familiarity with the regulations and standards identified in the FFRDC Statement of Work and FFRDC Statement of Work Exhibit A, as well as for Sample Task Orders 1 and 2. Sample Task Orders 1 and 2 will be used for evaluation purposes only.

1. Biomedical Scientific Approach (30%)

a. Suitability of the proposed scientific approach for planning and conducting the work and soundness and feasibility of methodology, including demonstrated effective communication and management, and the successful ability to perform and complete tasks relevant to the scientific areas described in the Statement of Work to address the following scientific areas: 1) Basic Research; 2) Preclinical Product Development; 3) cGMP; 4) Domestic and International Clinical Trials Support (regulatory, monitoring, medical staff, clinical laboratory support); 5) Genomics, Proteomics, Metabolomics and related "omics" Technologies, Bioinformatics, Biocomputing, and large data set sciences; 6) Laboratory Animal Sciences (animal husbandry and support services e.g. - histology, pathology, small animal imaging, diagnostics, generation of genetically engineered rodents); 7) Repositories; and, 8) Information Systems, Information Technologies, and Data Science.

b. Appropriateness of the proposed approach to the continuous improvement of existing technologies and development of new and novel technologies to address new and emerging research requirements in a timely manner.

c. Demonstrated capability, understanding and ability to communicate the overall technical challenges and possible resolutions involved in providing the requirements in the SOW in a biomedical R&D environment.

d. Appropriateness of the proposed technical approach for the execution of multiple projects and studies in diverse, complex biomedical scientific research and research-support service areas.

e. Appropriateness of the proposed strategy for identifying, transitioning from, or discontinuing outdated /non-productive research projects, antiquated technologies, non-essential services or services/technologies that can be provided through other sources.

f. Feasibility of the proposed strategy to implement an in-house program facilitating independent research proposals and collaborations to execute projects and requirements at the FNLCR.

g. Feasibility of proposed continuous quality assurance system, approach to quality assurance including development, implementation, and continuous monitoring for a quality control program for all task areas of the SOW.

h. Adequacy of proposed technical approach to Sample Task Orders 1 and 2.

2. Leadership Approach (10%)

a. Suitability of the proposed approach to ensure successful execution of all organizational planning and management functions, including: strategy planning/management, organizational change management, communications management, conflict resolution, innovation management, and process improvement.

b. Appropriateness of the proposed approach to labor allocation adjustments to facilitate shifts in scientific priorities to support new projects, urgent requirements, or changes to existing projects.

c. Adequacy of proposed strategy for evaluation and determination of work as in-house versus outsourced efforts.

d. Soundness of the approach to delineating reporting structure, lines of authority, areas of responsibility, communication approach and documented commitment of time and effort.

e. Appropriateness and feasibility of the proposed approach that would be used by senior leadership to ensure continuous effective and efficient development of innovative practices to manage the FNLCR's scientifically and operationally complex projects.

f. Adequacy of proposed leadership approach to Sample Task Orders 1 and 2.

B. **KEY PERSONNEL AND LEADERSHIP TEAM (25%)**

1. Suitability of qualifications, knowledge, experience, scientific expertise, education, and availability to successfully perform the Statement of Work.

2. Documented expertise in working on, managing, and coordinating the technical (biomedical science, business, management, and facilities) efforts and functions as described in the Statement of Work.

3. Demonstrated experience with service-oriented biomedical research extending from providing a menu of services to intellectual collaboration in solving complex biological problems.

4. Demonstrated experience in academic, commercial and/or government biomedical scientific research environments as well as the business components of research.

5. Demonstrated experience in a scientific environment to cohesively and successfully lead interdisciplinary and cross-functional teams, including supervising and coordinating the efforts of personnel required to perform projects of a similar scope, nature, and complexity and managing on-going and new novel scientific efforts.

6. Suitability of expertise in communications, resource allocation and prioritization of complex projects that include multiple scientific components, various sizes and complexities, multiple stakeholders, as well as international components.

7. Suitability and feasibility of the proposed cross-functional team that collectively possess the knowledge in all functional areas (biomedical science, business, management and facilities) and the ability to successfully accomplish the work specified in the Statement of Work.
8. Suitability of proposed subcontractors or partners, including training, experience, qualifications, availability, and specific area of expertise to be contributed to projects.
9. Suitability of the proposed key personnel and leadership team for Sample Task Orders 1 and 2.

C. **ORGANIZATIONAL EXPERIENCE AND MANAGEMENT (25%)**

1. Demonstrated experience in project management in a complex research environment and the ability to ensure the effective initiation, implementation, conduct, completion and communication regarding contract activities, and to monitor, track, and report on Contractor costs and performance.
2. Demonstrated experience in responding quickly to and communicating changes in priorities and to supply appropriate levels of support to new projects, urgent requirements, or changes to existing projects or unforeseen advances in scientific development by the biomedical research enterprise.
3. Suitability of experience in appropriate use of subcontractors to supplement areas of expertise and in the development and execution of projects/partnerships and subcontracts/agreements at the FNLCR with other NIH institutes, other government agencies, academic institutions and corporate entities.
4. Demonstrated proficiency in managing and communicating tasks within the prime institution and across multiple collaborating and/or subcontracting institutions.
5. Demonstrated understanding of staffing considerations, resource planning methodologies, and succession planning for Key Personnel staff required to effectively manage and execute work for a contract of this size and scope.
6. Appropriateness of recruitment and retention strategies for personnel in highly competitive fields and emerging scientific disciplines.
7. Suitability of proposed employee evaluation strategy, as well as strategy for staffing adjustments, additions or removals when programs encounter problems.
8. Demonstrated corporate experience with evolving financial management systems development and robust financial management and monitoring, including cost effective methods and cost controls in a similar environment.
9. Adequacy of proposed organizational management approach to Sample Task Orders 1 and 2.

D. **FACILITIES OPERATION (10%)**

1. Demonstrated experience, knowledge and familiarity with the regulations and standards; quality performance in facilities management, and ability to perform and complete tasks relevant to the work described in the FFRDC Statement of Work and FFRDC Statement of Work Exhibit 1.
2. Suitability of the approach for management and operation of the types of facilities and spaces that support the FNLCR (including but not limited to comparable facilities such as laboratories, research facilities, freezer storage, animal, infrastructure, support, administrative space), as well as contractor-leased facilities.
3. Demonstrated experience in successfully managing R&D and R&D support infrastructure consisting of multiple buildings of varying age and condition across multiple locations, as well as, in maintaining and operating existing biomedical research facilities during planning, design and renovation phases.
4. Demonstrated experience performing preventative maintenance activities including successfully optimizing maintenance frequency and minimizing facility downtime, as well as, executing the modification, repair, calibration, and installation of special-purpose research equipment.

5. Demonstrated experience in planning and executing renovations for biomedical research and administrative facilities utilizing contemporary project management and risk management practices.
6. Demonstrated experience and success in developing and implementing a facility plan to include a communication strategy that addresses the repair needs (both large and small) of the facilities; timely resolution to simultaneous repairs that may be minor, major and emergency repairs to facility utility systems or structures.
7. Demonstrated experience developing and implementing an emergency management/preparedness program for biomedical facilities to include: emergency planning, preparedness, response, communications and readiness assurance procedures.
8. Appropriateness of approach to facility operations which includes an approach to quickly adapt to new or changing facility priorities through adjustments and effective communications to workload prioritization, redistribution of resources, and labor allocation adjustments.
9. Demonstrated knowledge of requirements for and experience with managing large volumes of Government-Issued, Contractor-Held property, including accounting for: control, use, preservation, protection, repair, and maintenance.
10. Adequacy of proposed approach to facilities operations in Sample Task Orders 1 and 2.

TOTAL 100%

E. **Transition (Acceptable/Unacceptable)**

The Transition Task Order Cost Proposal will be used for evaluation, cost analysis, cost realism and the basis for award of the first task order. The offeror shall demonstrate in their Transition Task Order proposal a smooth transfer of responsibility from the incumbent contractor. This criterion would be rated as either: acceptable or unacceptable. (Note: the incumbent contractor will only submit a Transition Task Order proposal for Task Area 2 of the Transition Task Order SOW and will be rated as "neutral" for Task Area 1 of the Transition Task Order SOW.) If your Transition Task Order proposal is considered "Unacceptable," and the Government includes your proposal in the competitive range, you will be afforded the opportunity to further discuss, clarify or modify your Transition Task Order proposal during discussions and in your Final Proposal Revision (FPR). If your Transition Task Order proposal is still considered "Unacceptable" by the Government after discussions, your proposal may not be considered further for award.

1. Soundness of approach to working with the incumbent to ensure the seamless transition of all aspects of the SOW, securing all documentation, records, data, approaches, strategies, points of contact and systems including: business and financial records and data; scientific and other technical records and data; all business, financial, and technical systems; and system infrastructure.
2. Demonstrated experience transitioning a large, multi-project contract in biomedical research environment.
3. Appropriateness of identified transition activities to be undertaken and feasibility of milestones for transition activities.
4. Appropriateness of the proposed strategy for transition management including the communication approach.
5. Applicability and appropriateness of corporate or external support including areas of support, roles, responsibilities, and other resources, if any are proposed.
6. Adequacy and appropriateness of quantity and mix of staff to be assigned to execute and manage the transition activities thereunder.
7. Strategy for risk mitigation and resolution of any identified or anticipated risks during the transition and strategy for anticipating and addressing unexpected issues that arise.

8. Demonstrated approach to workforce evaluation and restructure including, methodology for evaluation of existing position for appropriateness/necessity, evaluation of existing FNLCR staff for quality and expertise in consultation with stakeholders, and a plan for execution of workforce restructure based on evaluation.

9. Demonstrated approach to the evaluation of resources for appropriateness and necessity, including, but not limited to: equipment, property, leases, subcontracts, consultants, and all other agreements.

10. Demonstrated approach to the evaluation and proposed modification of operations for appropriateness, efficiency, and necessity, including but not limited to: operating practices and activities, standard operating procedures, policies, processes, and systems.

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

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

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

11. **PAST PERFORMANCE FACTOR**

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.

12. **SUBCONTRACTING PROGRAM EVALUATION FACTORS**

The offeror's proposed Small Business Subcontracting Plan will be evaluated to determine whether it represents the maximum practicable opportunity for subcontracting. Because the offeror's record of previous performance in

carrying out the intent of the subcontracting program will be considered as a significant sub-factor, each offeror is encouraged to submit subcontracting plans and documentation that demonstrates their prior corporate support for small, small disadvantaged, women-owned small, HUBZone small, veteran-owned small, and service-disabled veteran-owned small business suppliers.

If offers are received from both large and small businesses, the small business offerors shall receive the maximum possible number of points for this factor.

13. **SUSTAINABLE ACQUISITION PLAN**

The Offeror's proposal must demonstrate compliance with FAR 23.1, "Sustainable Acquisition Policy" and the interim rule entitled "Sustainable Acquisition" at http://www.gpo.gov/fdsys/pkg/FR-2011-05-31/pdf/2011-12851.pdf (FAR case 2010-001, FAC 2005-52). If the proposal does not include a Sustainable Acquisition Plan that addresses the environmental products and services to be utilized under the resulting contract, or if the Plan is considered to be "poor" and the Government includes your proposal in the competitive range, the Offeror will be afforded the opportunity to further discuss, clarify, or modify the Plan during discussions and in their Final Proposal Revision (FPR). The Government is seeking to determine whether the Offeror has demonstrated a commitment to advance sustainable products and services.

The following evaluation criterion will be used in review of the Sustainable Acquisition Plan:

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