SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Requisition or other Purchase Authority: Public Law 92.218, as amended		
2. **Request for Proposal (RFP) Number:** 75N91021R00004	3. **Issue Date:** 11/20/2020	4. **Set Aside:** [X] No [ ] Yes See Part IV Section L
5. Title : Preclinical Toxicology Of Large Molecule Drugs Developed For Cancer And Other Indications		
6. ISSUED BY: National Institutes of Health National Cancer Institute Office of Acquisitions Treatment and Support Branch 8490 Progress Drive, Suite 400 Frederick, MD 21702		7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "eCPS Proposal Delivery Instructions," until **4:00 PM Eastern Daylight Time (EDT)** on **January 4, 2021**. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043. The deadline for receipt of questions is **December 18, 2020** at **4:00 PM EDT** per the instructions in Section L.1 General Instructions.		
9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "eCPS Proposal Delivery Instructions." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Clause 52.215-1, and HHSAR Clause 352.215-70, “Late Proposals and Revisions” LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
10. Offeror must be registered in the System for Award Management (SAM) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at https://beta.sam.gov		
11. FOR INFORMATION CALL: Randall Tiqui PHONE: 301-624-1242 e-MAIL: randall.tiqui@nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
Submit all questions in writing to randall.tiqui@nih.gov. Responses to questions will be provided in Amendments to the Solicitation. Questions received after the deadlines (stated above in Box 8) may not be addressed. Offerors are asked to return the proposal intent form (Attachment 2) by December 18, 2020 if they intend to submit a response to this RFP.		Randall Tiqui Contracting Officer, TSB, OA National Cancer Institute

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PART I - THE SCHEDULE

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

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objective of this contract is to acquire for the direct benefit of the Government toxicological data allowing essential characterization of the toxicological properties of potential investigational new drugs (large molecules/biologics) for the treatment of Cancer and other diseases. The data will serve as the basis of the Government's or the Principal Investigator's filing for an IND (investigational new drug) application to institute human clinical trials

ARTICLE B.2. PRICES/COSTS

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

ARTICLE B.3. ESTIMATED COST - OPTION

1. The estimated cost of the Base Period of this contract is $**TBD**.
2. The fixed fee for the Base Period of this contract is $**TBD**. The fixed fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the direct percent of total effort expended. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.
3. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is $**TBD**.
    a. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost ($)	**Fixed Fee ($)**	**Estimated Cost Plus Fixed Fee ($)**
Base Period (07/01/2021 – 06/30/2022):	TBD	TBD	TBD
Option Period 1 (07/01/2022 – 06/30/2023):	TBD	TBD	TBD
Option Period 2 (07/01/2023 – 06/30/2024):	TBD	TBD	TBD
Option Period 3 (07/01/2024 – 06/30/2025):	TBD	TBD	TBD

	Estimated Cost ($)	Fixed Fee ($)	Estimated Cost Plus Fixed Fee ($)
Option Period 4 (07/01/2025 – 06/30/2026):	TBD	TBD	TBD
Option Period 5 (07/01/2026 – 06/30/2027):	TBD	TBD	TBD
Option Period 6 (07/01/2027 – 06/30/2028):	TBD	TBD	TBD
Total Base Period and Options	TBD	TBD	TBD

ARTICLE B.4. ESTIMATED COST - INCREMENTALLY FUNDED CONTRACT

a. The total estimated cost to the Government for full performance of this contract, including all allowable direct and indirect costs, is $ **TBD**.

b. The following represents the schedule* by which the Government expects to allot funds to this contract:

CLIN, Task, Number, or Description	Start Date of Period or Increment of Performance	End Date of Period or Increment of Performance	Estimated Cost ($)	Fee ($) (as appropriate)	Estimated Cost Plus Fee ($) (as appropriate)
*TBD	*TBD	*TBD	*TBD	*TBD	*TBD
Total Base Period and Options					

*To be inserted after negotiation

c. Total funds currently obligated and available for payment under this contract are $**TBD**.

d. The Contracting Officer may issue unilateral modifications to obligate additional funds to the contract and make related changes to paragraphs b. and/or c., above.

e. Until this contract is fully funded, the requirements of the clause at FAR 52.232-22, Limitation of Funds, shall govern. Once the contract is fully funded, the requirements of the clause at FAR 52.232-20, Limitation of Cost, shall govern.

f. Payment of fee shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

The fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended.

ARTICLE B.5. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Conferences & Meetings, 2) Food for Meals, Light Refreshments & Beverages, 3) Promotional Items, 4) Acquisition, by purchase or lease, of any interest in real property; 5) Special rearrangement or alteration of facilities; 6) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 7) Travel Costs including Foreign Travel; 8) Consultant Costs; 9) Subcontract Costs; 10) Patient Care Costs; 11) Accountable Government Property; 12) Printing costs; and 13) Research Funding.

ARTICLE B.6. ADVANCE UNDERSTANDINGS

Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. DESCRIPTION - STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated 11/20/2020, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format via e-mail, as attachments to the following designated NCI Branch Distribution Mailbox: NCIbranchcinvoices@mail.nih.gov.

Each e-mail submission shall contain only one deliverable. If the attached file for the deliverable exceeds 50 MB, the Contractor shall divide the deliverable into files of 50 MB each. All deliverables shall be limited to five file attachments or less.

The subject line of the e-mail shall read as follows: **Deliverable**_ *Contract Number*_ *Vendor's Name*_ *Deliverable Description*_ *Due Date*.

Section 508 – **ICT Accessibility Requirements**

Section 508 of the Rehabilitation Act, as amended by the Workforce Investment Act of 1998 (P.L. 105-220) requires that when Federal agencies develop, procure, maintain, or use Information and Communication Technology (ICT), it shall be accessible to people with disabilities. Federal employees and members of the public who have disabilities must have access to, and use of, information and data that is comparable to people without disabilities.

Products, platforms and services delivered as part of this work statement that are ICT, or contain ICT, must conform to the Revised 508 Standards, which are located at 36 C.F.R. § 1194.1 & Apps. A, C & D, and available at https://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-ict-refresh/final-rule/text-of-the-standards-and-guidelines

Section 508 Conformance (as outlined in the attached Word document) of electronic documents shall be determined or confirmed by successful completion and submission of the relevant checklists and acceptance by NCI. Fillable versions of the GSA Section 508 Create Accessible Products may be downloaded at https://www.section508.gov/create and/or HHS's Making Files Accessible shall be provided to the selected offeror upon initiation of this contract. NCI retains the right to confirm the accessibility and Section 508-conformance of vendor submitted documents and to return them for remediation, at no cost to the National Cancer Institute but at the contractor's expense.

Any and all reports (including monthly and ad-hoc reports) shall be formatted for Section 508-conformance and accessibility for persons with disabilities. Instructions may be found at HHS Making Files Accessible and at GSA Section508.gov Create Accessible Digital Products. The respective checklists from either of these sites will be considered acceptable.

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

a. **Technical Progress Reports**

The Contractor shall include the following statement on all reports submitted under this contract: "**The data contained in this report is confidential and the property of the U.S. Government. It is not to be disclosed to a third party, used in an Investigational New Drug (IND) or used in any other publications without the express written permission of the Toxicology and Pharmacology Branch, Developmental Therapeutics Program, DCTD, NCI**"

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

   For proposal preparation purposes only, it is estimated that only electronic version(s) of reports will be required as follows:

   [X] Monthly
   [ ] Quarterly
   [ ] Semi-Annually
   [X] Annually
   [ ] Annually (with a requirement for a Draft Annual Report)
   [ ] Final - Upon final completion of the contract
   [X] Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

   A basic description of each report is provided below.

2. **Monthly Technical and Budget Progress Report**

   The Contractor shall provide Monthly Technical Progress Reports during performance under the contract. These reports shall include: 1) summary of progress on each protocol during the past month, 2) summary of deliverables that have been completed, and the completion date, and 3) summary of deliverables in progress on and whether or not these projects are on schedule, and whether any problems were encountered in the collection, handling or processing of data, including resolution of the problems.

   The Monthly Technical Progress Report shall be accompanied by a Monthly Budget Report in Excel that contains the following for each project: (1) a starting budget that is mutually agreed upon by the Contractor and the NCI COR, (2) a listing of each month's expenditures since the beginning of the project's start-up, (3) total expenditures on the project, (4) remaining funds to date, and (5) projected expenses to complete the project. The budget report contains detailed expenditures for labor and other study activities for the past month by individual project and a summary for the entire contract. Future activities and projected expenses by project are also included to provide the information necessary to monitor progress and make any required adjustments. They will also include for each project and for the contract as a whole; a budgetary summary of monthly expenditures incurred since the beginning of the project's start-up; total expenditures on the project; projected expenses to complete each study; and remaining funds to date. Current hours used by the Contractor's staff will also be identified by project. It will also include the expenditures incurred and problems encountered.

   The reporting period shall consist of each calendar month. The first report shall cover the period consisting of the first full calendar month following the effective date of the contract and any fractional part of the initial month. Reports shall be due on or before the 15th of each month following the end of each reporting period. A Monthly Report shall not be submitted when the Annual or Final Report is due.

3. **Annual Progress Report**

   The Contractor shall provide an Annual Progress Report during performance under the contract. These reports shall include: 1) summary of progress on each protocol during the past year, 2)

summary of deliverables that have been completed, and the completion date, and 3) summary of deliverables in progress and whether or not these projects are on schedule, and whether any problems were encountered in the collection, handling or processing of data, including resolution of the problems. The reporting period is a 12 month period. An Annual Progress Report shall be due on or before the expiration date of the contract. If an Option Period is exercised, this report shall be due 15 calendar days after each reporting period.

4. **Draft Study Report**

The Contractor shall prepare a QA-audited Draft Study Report **for each GLP-compliant study** performed under this contract, in accordance with 21 CFR PART 58, Subpart J. Under certain circumstances, QA-audited Draft Study Reports will be required for non-GLP-compliant studies. Data generated from GLP-compliant studies, and in certain circumstances, from some non-GLP-compliant studies, shall also be submitted in a validated SEND format, per FDA's requirement.

A Draft Study Report for non-GLP-compliant and GLP-compliant studies shall be submitted to the COR for review and comment within 45 and 60 business days, respectively, after the end of in-life phase of the study. These reports shall contain all summarized and raw data, and shall contain all information necessary for regulatory FDA submission.

a. Draft Study Reports shall be organized and formatted into the following specific sections:

i. Table of Contents
ii. Summary
iii. Key Personnel
iv. Introduction
v. Purpose and Objectives
vi. Experimental Design
vii. Materials and Methods
viii. Regulatory Compliance
ix. Results
x. Discussion and Conclusions
xi. Quality Assurance Statement
xii. Tables
xiii. Figures
xiv. Appendices
xv. High Resolution, illustrative photographs or digital images of drug lesions
xvi. Description of Statistical Analysis used
xvii. Document and state that the study was conducted under Good Laboratory Practice

b. The PDF file shall contain a bookmarked Table of Contents.

c. Comments or needed corrections/clarifications will be returned by the COR within 30 calendar days of receipt of the Draft Study Report.

5. **Final Study Report**

The Contractor shall prepare a QA-audited Final Study Report **for each GLP-compliant study** performed under this contract, in accordance with 21 CFR PART 58, Subpart J. Under certain circumstances, QA-audited Final Study Reports will be required for non-GLP-compliant studies. Data generated from GLP-compliant studies, and in certain circumstances, from some non-GLP-compliant studies, shall also be submitted in a validated SEND format, per FDA's requirement.

A Final Study Report shall be submitted to the COR within 15 business days upon receipt of the COR's comments. The Contractor shall implement and/or address all COR comments in the Final Study Report. This report shall contain all summarized and individual animal data and shall contain all information necessary for regulatory FDA submission.

a. Final Reports shall be organized and formatted into the following specific sections:

i. Table of Contents
ii. Summary
iii. Key Personnel
iv. Introduction
v. Purpose and Objectives
vi. Experimental Design
vii. Materials and Methods
viii. Regulatory Compliance
ix. Results
x. Discussion and Conclusions
xi. Quality Assurance Statement
xii. Tables
xiii. Figures
xiv. Appendices
xv. High Resolution, illustrative photographs or digital images of drug lesions
xvi. Description of Statistical Analysis used
xvii. Document and state that the study was conducted under Good Laboratory Practice

b. The PDF file shall contain a bookmarked Table of Contents.

c. The Contractor shall also prepare Final Study Reports with study data generated in the electronic Common Technical Document (eCTD) format. Final tabular data and raw data will also be transmitted to the NCI electronically as requested in the project. Data from each study will also be provided to the NCI in Excel and SEND-compliant formats. The latter requirement is currently an FDA requirement for toxicology studies; however, if this requirement is expanded to other studies conducted under this contract (e.g. pharmacology), data from these studies conducted

under this contract will also be submitted to the NCI in SEND-compliant format. The Excel datasets and SEND formatted data shall be submitted at the same time as the PDF format of the Final Study Report.

6. **Draft Transition-Out Plan**

   A Draft Transition-Out plan shall be submitted 3 months prior to the end of this contract. The plan shall clearly describe transition of authority, duties, activities, equipment and function for the services to a new contract awarded to perform these services. Comments or needed corrections/clarifications will be returned by the COR within 30 calendar days of receipt of the Draft Transition-Out Plan.

7. **Final Transition-Out Plan**

   A Final Transition-Out Plan shall be submitted within 30 days upon receipt of the COR's comments. The Contractor shall implement and/or address all COR comments in the Final Transition-Out Plan. The plan shall clearly describe transition of authority, duties, activities, equipment and function for the services to a new contract awarded to perform these services.

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 https://beta.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**.

2. INFORMATION AND/OR PHYSICAL SECURITY

A. **Security Assessment and Authorization (SA&A)-** A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) shall work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s) within three (3) months after contract award. The Contractor shall conduct the SA&A requirements in accordance with HHS IS2P, NIST SP 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach (latest revision).
For an existing ATO, Contracting Officer Representative must make a determination if the existing ATO provides appropriate safeguards or if an additional ATO is required for the performance of the contract and state as such.

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

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

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

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

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

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

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

C. **Contingency Plan and Contingency Plan Test -** due 60 days after contract award. The Contingency Plan must be developed in accordance with NIST SP 800-34, Contingency Planning Guide for Federal Information Systems, and be consistent with HHS and NIH policies. Upon acceptance by the System Owner, the Contractor, in coordination with the System Owner, shall test the Contingency Plan and prepare a Contingency Plan

Test Report that includes the test results, lessons learned and any action items that need to be addressed. Thereafter, the Contractor shall update and test the Contingency Plan at least annually.

- **E-Authentication Questionnaire -** The contractor (and/or any subcontractor) shall collaborate with government personnel to ensure that an E-Authentication Threshold Analysis (E-auth TA) is completed to determine if a full E-Authentication Risk Assessment (E-auth RA) is necessary. System documentation developed for a system using E-auth TA/E-auth RA methods shall follow OMB 04-04 and NIST SP 800-63, Rev. 2, Electronic Authentication Guidelines.
  Based on the level of assurance determined by the E-Auth, the Contractor (and/or subcontractor) must ensure appropriate authentication to the system, including remote authentication, is in-place in accordance with the assurance level determined by the E-Auth (when required) in accordance with HHS policies.

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

[ ] 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).

1. **HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12**

Roster-

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

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

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

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

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

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

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

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

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

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

E. CONTRACT INITIATION AND EXPIRATION

1. **General Security Requirements-** The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the contractor shall follow the HHS EPLC framework and methodology or and in accordance with the HHS Contract Closeout Guide (2012). HHS EA requirements may be located here: https://www.hhs.gov/ocio/ea/documents/proplans.html

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

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

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

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

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

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

G. **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 a separate cover on monthly basis.

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

a. At any tier handling or accessing information, consent to and allow the Government, or an independent third party working at the Government's direction, without notice at any time during a weekday during regular business hours contractor local time, to access contractor and subcontractor installations, facilities, infrastructure, data centers, equipment (including but not limited to all servers, computing devices, and portable media), operations, documentation (whether in electronic, paper, or other forms), databases, and personnel which are used in performance of the contract.
The Government includes but is not limited to the U.S. Department of Justice, U.S. Government Accountability Office, and the HHS Office of the Inspector General (OIG). The purpose of the access is to facilitate performance inspections and reviews, security and compliance audits, and law enforcement investigations. For security audits, the audit may include but not be limited to such items as buffer overflows, open ports, unnecessary services, lack of user input filtering, cross site scripting vulnerabilities, SQL injection vulnerabilities, and any other known vulnerabilities.

b. At any tier handling or accessing protected information, fully cooperate with all audits, inspections, investigations, forensic analysis, or other reviews or requirements needed to carry out requirements presented in applicable law or policy. Beyond providing access, full cooperation also includes, but is not limited to, disclosure to investigators of information sufficient to identify the nature and extent of any criminal or fraudulent activity and the individuals responsible for that activity. It includes timely and complete production of requested data, metadata, information, and records relevant to any inspection, audit, investigation, or review, and making employees of the contractor available for interview by inspectors, auditors, and investigators upon request. Full cooperation also includes allowing the Government to make reproductions or copies of information and equipment, including, if necessary, collecting a machine or system image capture.

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

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

3. **Multiple Principal Investigators Leadership Plan**

The Contractor shall submit a revised/updated Leadership Plan in the event of a change in any of the Principal Investigators named in the Key Personnel Article in SECTION G of this contract. The revised plan is subject to review and approval by the Contracting Officer.

4. **Service Contract Report (SCR)**

   In accordance with FAR clause 52.204-14, Service Contract Reporting Requirements (Oct 2016), the Contractor shall enter and submit the following Service Contract Report data elements into System for Award Management (SAM), with a copy to the Contracting Officer annually, by October 31st for services performed under this contract during the preceding Government fiscal year (October 1 - September 30). SCR data elements:

   a. Contract Number;

   b. The total dollar amount invoiced for services performed during the previous Government fiscal year under the contract;

   c. Total number of Contractor direct labor hours expended on the services performed during the previous Government fiscal year; and

   d. Data reported by first-tier subcontractors that have provided services under this contract, as applicable.

      i. First-tier subcontract number (including subcontractor name and unique entity identifier)

      ii. The number of first-tier subcontractor direct-labor hours expended on the services performed during the previous Government fiscal year

5. **Email file Transfer Service (SEFT)**

   All sensitive data/information involved in performance of this contract that may be provided to the Contractors by the Government and/or generated by Contractors during performance of the contract shall be transmitted in a secure manner (e.g. using Secure Email and File Transfer Service (SEFT). The SEFT service will be provided by the NCI to the Contractors to utilize in transmitting any sensitive data in performance of this contract.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

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

The first annual utilization report shall be due on or before anniversary date of the contract. Thereafter, reports shall be due on or before the 15 Calendar day following the reporting period. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
National Cancer Institute, Office of Acquisitions, TSB
8490 Progress Dr., Suite 400
Frederick, MD 21701

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

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

ARTICLE D.1. PACKAGING

All deliverables shall be marked in accordance with the Government specifications and industry standards. The Contractor shall package and ship specified animal fluids and tissues to NCI-designated laboratories. All applicable USDOT regulations for packaging and shipment of hazardous materials shall be followed.

ARTICLE D.2. MARKING

All deliverables shall be marked in accordance with the Government specifications and industry standards. The Contractor shall package and ship specified animal fluids and tissues to NCI-designated laboratories. All applicable USDOT regulations for packaging and shipment of hazardous materials shall be followed.

ARTICLE D.3. SHIPPING

All deliverables shall be marked in accordance with the Government specifications and industry standards. The Contractor shall package and ship specified animal fluids and tissues to NCI-designated laboratories. All applicable USDOT regulations for packaging and shipment of hazardous materials shall be followed.

SECTION E - INSPECTION AND ACCEPTANCE

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

b. For the purpose of this SECTION, the Contracting Officer Representative (COR) is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:

Developmental Therapeutics Program
Division of Cancer Treatment and Diagnosis
National Cancer Institute
9609 Medical Center D
Rockville, MD 20850

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

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

FAR Clause **52.246-3, Inspection of Supplies - Cost-Reimbursement** (May 2001).

FAR Clause **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).

FAR Clause **52.246-9, Inspection of Research and Development (Short Form)** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

1. The period of performance of this contract shall be from July 1, 2021 through June 30, 2022.
2. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Period
Option Period 1	July 1, 2022 - June 30, 2023
Option Period 2	July 1, 2023 - June 30, 2024
Option Period 3	July 1, 2024 - June 30, 2025
Option Period 4	July 1, 2025 - June 30, 2026
Option Period 5	July 1, 2026 - June 30, 2027
Option Period 6	July 1, 2027 - June 30, 2028

ARTICLE F.2. DELIVERIES

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

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

Item	Description	Quantity	Delivery Schedule
(1)	Monthly Technical and Budget Progress Report	One (1) PDF format to the COR, CO & NCI Branch C.	Due 15 calendar days after the end of each reporting period, unless an annual report is due during the reporting period.
(2)	Annual Progress Report	One (1) PDF format to the COR, CO & NCI Branch C.	Due 15 calendars days after the end of each reporting period, and on or before completion date of the contract.
(3)	Draft Study Report	One (1) PDF format to the COR, CO & NCI Branch C.	Due between 45-60 days after the end of in-life phase.
(4)	Final Study Report	One (1) PDF format to the COR, CO & NCI Branch C.	Due 15 days after comments by the COR on Draft Study Report submitted to Contractor
(5)	Draft Transition-Out Plan	One (1) PDF format to the COR, CO & NCI Branch C.	Due 3 months prior to completion date of the contract.
(6)	Final Transition-Out Plan	One (1) PDF format to the COR, CO & NCI Branch C.	Due 30 days after comments by the COR on Draft Transition-Out Plan submitted to Contractor
(7)	Financial Conflict of Interest	One (1) PDF format to the COR, CO & NCI Branch C.	Due as conflict arises.

Item	Description	Quantity	Delivery Schedule
(8)	Report of USDA-Designated Biobased Products	One (1) PDF format to the COR, CO & NCI Branch C.	Due October 31st of each year and on the completion date of the contract.
(9)	SA&A Package Deliverables	One (1) PDF format to the COR, CO & NCI Branch C.	Due within 30 days of contract award.
(10)	System Security Plan (SSP)	One (1) PDF format to the COR, CO & NCI Branch C.	Due within 30 days of contract award and at least annually thereafter.
(11)	Security Assessment Plan / Report (SAP/SAR)	One (1) PDF format to the COR, CO & NCI Branch C.	Due within 30 days of contract award.
(12)	Independent Assessment	One (1) PDF format to the COR, CO & NCI Branch C.	Due within 90 days of contract award.
(13)	Plan of Actions and Milestones (POA&M)	One (1) PDF format to the COR, CO & NCI Branch C.	Due within 30 days of contract award and updated at least quarterly thereafter.
(14)	Contingency Plan and Contingency Plan Test	One (1) PDF format to the COR, CO, & NCI Branch C.	Due within 60 days of contract award and the Contingency Plan updated at least annually thereafter.
(15)	Plan to obtain FedRAMP compliant ATO	One (1) PDF format to the COR, CO & NCI Branch C.	Due within 30 days of contract award (Applicable only if offeror will use clouse servicesi n performance of the contract)
(16)	Annual Utilization Report	One (1) PDF format to the COR, CO, & NCI Branch C.	Due 12 months after contract award and annually thereafter.
(17)	Final Invention Statement	One (1) PDF format to the CO & NCI Branch C.	Due on or before the contract completion date.
(18)	Invention Disclosure Report	One (1) PDF format to the CO, DEITR & NCI Branch C.	Due on or before the contract completion date.
(19)	Contractor- Employee Non-Disclosure Agreement(s)	One (1) PDF format to the COR, CO & NCI Branch C.	Due prior to performing any work on behalf of HHS.
(20)	Encryption Validation documentation (FIPS 140-2)	One (1) PDF format to the COR, CO & NCI Branch C.	Due within 15 days of validation.
(21)	Encryption Keys	One (1) PDF format to the COR, CO & NCI Branch C.	Due upon request of the COR and at the conclusion of the contract.
(22)	Rules of Behavior	One (1) PDF format to the COR, CO & NCI Branch C.	Due at the beginning of the contract and at least annual thereafter.
(23)	Multiple Principal Investigators Leadership Plan (if applicable)	One (1) PDF format to the CO, COR & NCI Branch C.	Due as needed.
(24)	NIH Contractor Employee Separation Checklist	One (1) PDF format to the CO, COR & NCI Branch C	Due when an employee terminates work under this contract within 2 days of the

Item	Description	Quantity	Delivery Schedule
			employee's exit from the contract. All documentation shall be made available to the CO and/or COR upon request.
(25)	Roster of Suitability	One (1) PDF format to the CO, COR & NCI Branch C	The roster shall be submitted to the CO and/or COR within 14 calendar days after the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 7 calendar days of the change. THe COR will notify the Contractor of the appropriate level of investigation required for each staff member.
(26)	Individual Subcontracting Report	Submit to the eSRS System (see Article H.17)	Due on April 30th & October 30th each year during the period of performance, and upon completion date of the contract.
(27)	Summary Subcontracting Report	Submit to the eSRS System (see Article H.17)	Due on October 30th each year during the period of performance of the contract.
(28)	Service Contract Report	Submit to https://beta.SAM.gov and One (1) PDF format to the CO, COR & NCI Branch C.	Due on October 31st each year during the performance of the contract.

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

Addressee	Deliverable Item No	Quantity
Contracting Officer's Representative (COR)	1-15, 19-25	1 electronic copy
Contracting Officer (CO)	1-25, 28	1 electronic copy
NCI Branch C Invoice Inbox ncibranchcinvoices@mail.nih.gov	1-25, 28	1 electronic copy
Division of Extramural Inventions and Technology Resources (DEITR) OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980 Bethesda, MD 20892-7980 http://www.iedison.gov	18	1 electronic copy
Electronic Subcontract Reporting System (eSRS) Entered into www.eSRS.gov	26-27	1 electronic copy
Service Contract Report Entered in https://beta.SAM.gov	28	1 electronic copy

ARTICLE F.3. LEVEL OF EFFORT

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

Labor Hours

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Professional	TBD	TBD	TBD	TBD	TBD	TBD	TBD
Other Professional	TBD	TBD	TBD	TBD	TBD	TBD	TBD
Support	TBD	TBD	TBD	TBD	TBD	TBD	TBD
Totals	TBD	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 Hours specified herein are furnished. These terms and conditions do not supersede the requirements of either the "Limitation of Cost" or "Limitation of Funds" clause.

c. In the event fewer Hours than the minimum specified number of direct labor Hours in the total categories are used by the Contractor in accomplishing the prescribed work and the Government has not invoked its rights under FAR Clause 52.249-6, TERMINATION (Cost-Reimbursement) incorporated in this contract, these parties agree that the fee will be adjusted based solely upon the quantity of Hours by which the number of direct labor Hours furnished is less than the number of direct labor Hours specified in this ARTICLE. The resulting adjustment shall be evidenced by a contract modification.

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: https://www.acquisition.gov/?q=browsefar.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989)

Alternate I (April 1984) is applicable to this contract.

52.247-35, F.o.b. Destination Within Consignees Premises (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

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

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

TBD

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

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

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

The Government may unilaterally change its COR designation.

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

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

(End of Clause)

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

Name	Title
TBD	TBD

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

a. Invoice Submission/Contract Financing Request and Contract Financial Reporting, NIH(RC)-4for 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.

Note: Attachment 19- Electronic Invoicing Instructions, is the most recent invoicing instructions (which supercedes any reference to hard copy submissions).

Central Point of Distribution: ncibranchcinvoices@mail.nih.gov

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

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

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

        invoicing@nih.gov

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

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

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

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

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

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

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

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

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

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

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

f. The Contract Title is:

PRECLINICAL TOXICOLOGY OF LARGE MOLECULE DRUGS DEVELOPED FOR CANCER AND OTHER INDICATIONS

g. Contract Line Items as follows:

Line Item #	Line Item Description
TBD	TBD

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

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

a. Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such

payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

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

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

(End of Clause)

ARTICLE G.5. INDIRECT COST RATES

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

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

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

ARTICLE G.6. GOVERNMENT PROPERTY

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

ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

1. Contractor Performance Evaluations

   Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually as follows on the anniversary date of the contract.

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

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

2. Electronic Access to Contractor Performance Evaluations

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

   http://www.cpars.gov

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

ARTICLE H.2. HUMAN MATERIALS

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

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

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

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

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

ARTICLE H.4. 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://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines). 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 the NIH Office of Science Policy 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 Science Policy website available at: http://osp.od.nih.gov/.

ARTICLE H.5. NIH POLICY ON ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

Contractors shall adhere to the NIH policy of enhancing reproducibility through rigor and transparency by addressing each of the four areas of the policy in performance of the Statement of Work and in publications, as applicable: 1) Scientific Premise; 2) Scientific Rigor; 3) Consideration of Relevant Biological Variables, including Sex; and 4) Authentication of Key Biological and/or Chemical Resources. This policy applies to all NIH funded research and development, from basic through advanced clinical studies. See NIH Guide Notice, NOT-OD-15-103, "Enhancing Reproducibility through Rigor and Transparency" and NOT-OD-15-102, "Consideration of Sex as a Biological Variable in NIH-funded Research" for more information. In addition, publications are expected to follow the guidance at http://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research, whether preclinical or otherwise, as appropriate. More information is available at http://grants.nih.gov/reproducibility/index.htm, including FAQs and a General Policy Overview.

ARTICLE H.6. 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.7. 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.8. 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.9. MULTIPLE PRINCIPAL INVESTIGATORS

The NIH awarded this contract as a multiple Principal Investigators project. The Key Personnel Article in SECTION G of this contract designates the Contact Principal Investigator and all other Principal Investigators.

Contracts designating multiple Principal Investigators require a current Leadership Plan with updates as needed. The Contractor's Leadership Plan, dated _TBD__, (and as modified thereafter, in accordance with the Reporting Requirements Article in SECTION C of this contract), is hereby incorporated by reference.

ARTICLE H.10. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015)

1. 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.
2. 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.
3. 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 and 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.
4. 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).

(End of clause)

ARTICLE H.11. 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.12. INTRODUCTION OF RODENTS AND RODENT PRODUCTS

No rodent or rodent product shall be delivered into the NIH, NCI environment (NIH) directly, or through collaborative research or holding facilities under contract to NCI 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, NCI 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.13. 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.14. 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.15. GUN CONTROL

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

ARTICLE H.16. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-8, Option to Extend Services and FAR Clause 52.217-9, Option to Extend the Term of the Contract set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 30 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST PLUS FIXED FEE Article in SECTION B of this contract.

ARTICLE H.17. 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:

randall.tiqui@nih.gov
Contracting Officer

ARTICLE H.18. HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS

All sensitive data/information involved in performance of this contract that may be provided to Contractors by the Government and/or generated by Contractors during performance of the contract shall be transmitted in a secure manner (e.g. using Secure Email and File Transfer Service (SEFT). The SEFT service will be provided by NCI to the Contractors to utilize in transmitting any sensitive data in performance of this contract.

ARTICLE H.18.1. INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

A. Baseline Security Requirements

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

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

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

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

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

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

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

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

d. Comply with the Privacy Act requirements.

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

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

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

[X] No PII [ ] Yes PII

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

PII Confidentiality Impact Level has been determined to be: [ ] Low [ ] Moderate [ ] High [X] Not Applicable

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

a. Marked appropriately;

b. Disclosed to authorized personnel on a Need-To-Know basis;

c. Protected in accordance with NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations applicable baseline if handled by a Contractor system operated on behalf of the agency, or NIST SP 800-171, Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations if handled by internal Contractor system; and

d. Returned to HHS control, destroyed when no longer needed, or held until otherwise directed. Destruction of information and/or data shall be accomplished in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

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

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

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

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

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

c. 44 U.S.C. Chapter 35, Subchapter I (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.

7. **Internet Protocol Version 6 (IPv6)-** All procurements using Internet Protocol shall comply with OMB Memorandum M-05-22, Transition Planning for Internet Protocol Version 6 (IPv6).

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

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

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

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

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

c. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and NIH-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).

d. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative within ***15 days*** of the validation .

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

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

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

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

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

B. **TRAINING**

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

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

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

C. **RULES OF BEHAVIOR**

1. The Contractor (and/or any subcontractor) shall ensure that all employees performing on the contract comply with the HHS Information Technology General Rules of Behavior, and 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

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

D. **INCIDENT RESPONSE**

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

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

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

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

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

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

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

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

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

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

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

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

E. POSITION SENSITIVITY DESIGNATIONS

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

[ ] 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).

F. HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

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

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

Roster-

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

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

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

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

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

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

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

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

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

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

G. **CONTRACT INITIATION AND EXPIRATION**

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

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

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

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

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

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

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

H. **RECORDS MANAGEMENT AND RETENTION**

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

ARTICLE H.18.2. GOVERNMENT INFORMATION PROCESSED ON GOCO OR COCO SYSTEMS

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

1. **Federal Policies-** The Contractor (and/or any subcontractor) shall comply with applicable federal laws that include, but are not limited to, the HHS Information Security and Privacy Policy (IS2P), Federal Information Security Modernization Act (FISMA) of 2014, (44 U.S.C. 101); National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53, Security and Privacy Controls for Federal Information Systems and Organizations; Office of Management and Budget (OMB) Circular A-130, Managing Information as a Strategic Resource; and other applicable federal laws, regulations, NIST guidance, and Departmental policies.
2. **Security Assessment and Authorization (SA&A)-** A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) shall work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s) within three (3) months after contract award. The Contractor shall conduct the SA&A requirements in accordance with HHS IS2P, NIST SP 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach (latest revision).

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

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

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

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

planning adequate, cost-effective security protection for a system. The Contractor shall update the SSP at least annually thereafter.

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

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

Thereafter, the Contractor, in coordination with the NIH shall conduct/assist in the assessment of the security controls and update the SAR at least annually.

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

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

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

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

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

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

- **Annual Assessment/Pen Test -** Assess the system security and privacy controls (or ensure an assessment of the controls is conducted) at least annually to determine the implemented security and privacy controls are operating as intended and producing the desired results (this may involve penetration testing conducted by

the agency or independent third-party. In addition, review all relevant SA&A documentation (SSP, POA&M, Contingency Plan, etc.) and provide updates by specified due date provided by the Contracting Officer's Representative.

- **Asset Management -** Using any available Security Content Automation Protocol (SCAP)-compliant automated tools for active/passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing HHS-owned information/data. It is anticipated that this inventory information will be required to be produced at least 60 days after contract award. IT asset inventory information shall include IP address, machine name, operating system level, security patch level, and SCAP-compliant format information. The contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.
- **Configuration Management -** Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.
- **Configuration Management -** Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.
- **Vulnerability Management -** Use SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process government information. Contractors shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS policy. Automated tools shall be compliant with NIST-specified SCAP standards for vulnerability identification and management. The contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP-compliant automated tools and report to the agency at least within 30 days of the contract award.
- **Patching and Vulnerability Remediation -** Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeframes.
- **Secure Coding -** Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
- **Boundary Protection -** The contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).

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

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

The Government includes but is not limited to the U.S. Department of Justice, U.S. Government Accountability Office, and the HHS Office of the Inspector General (OIG). The purpose of the access is to facilitate performance inspections and reviews, security and compliance audits, and law enforcement investigations. For security audits, the audit may include but not be limited to such items as buffer overflows, open ports, unnecessary services, lack of user input filtering, cross site scripting vulnerabilities, SQL injection vulnerabilities, and any other known vulnerabilities.

b. At any tier handling or accessing protected information, fully cooperate with all audits, inspections, investigations, forensic analysis, or other reviews or requirements needed to carry out requirements presented in applicable law or policy. Beyond providing access, full cooperation also includes, but is not limited to, disclosure to investigators of information sufficient to identify the nature and extent of any criminal or fraudulent activity and the individuals responsible for that activity. It includes timely and complete production of requested data, metadata, information, and records relevant to any inspection, audit, investigation, or review, and making employees of the contractor available for interview by inspectors, auditors, and investigators upon request. Full cooperation also includes allowing the Government to make reproductions or copies of information and equipment, including, if necessary, collecting a machine or system image capture.

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

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

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

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

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

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

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

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

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

- Configuring its systems to allow for periodic HHS vulnerability and security configuration assessment scanning; and
- Using Security Content Automation Protocol (SCAP)-validated tools with USGCB Scanner capabilities to scan its systems at least on a monthly basis and report the results of these scans to the CO and/or COR, Project Officer, and any other applicable designated POC.

ARTICLE H.18.3. CLOUD SERVICES- (APPLICABLE ONLY IF THE OFFEROR WILL USE CLOUD SERVICES IN PERFORMANCE OF THE CONTRACT)

A. **HHS FedRAMP Privacy and Security Requirements**

The Contractor (and/or any subcontractor) shall be responsible for the following privacy and security requirements:

a. **FedRAMP Compliant ATO.** Comply with FedRAMP Security Assessment and Authorization (SA&A) requirements and ensure the information system/service under this contract has a valid FedRAMP compliant (approved) authority to operate (ATO) in accordance with Federal Information Processing Standard (FIPS) Publication 199 defined security categorization. If a FedRAMP compliant ATO has not been granted, the Contractor shall submit a plan to obtain a FedRAMP compliant ATO by 30 days of the contract award.

b. A security control assessment must be conducted by a FedRAMP third-party assessment organization (3PAO) for the initial ATO and annually thereafter or whenever there is a significant change to the system's security posture in accordance with the FedRAMP Continuous Monitoring Plan.

2. **Data Jurisdiction-** The contractor shall store all information within the security authorization boundary, data at rest or data backup, within the continental United States (CONUS) if so required as stated in section C.

3. **Service Level Agreements-** Add when applicable/Mark as Not Applicable TBD The Contractor shall understand the terms of the service agreements that define the legal relationships between cloud customers and cloud providers and work with NIH to develop and maintain an SLA.

4. **Interconnection Agreements/Memorandum of Agreements-** Add when applicable/Mark as Not Applicable TBD The Contractor shall establish and maintain Interconnection Agreements and or Memorandum of Agreements/Understanding in accordance with HHS/NIH policies.

B. **Protection of Information in a Cloud Environment**

1. If contractor (and/or any subcontractor) personnel must remove any information from the primary work area, they shall protect it to the same extent they would the proprietary data and/or company trade secrets and in accordance with HHS/NIH policies.

2. HHS will retain unrestricted rights to federal data handled under this contract. Specifically, HHS retains ownership of any user created/loaded data and applications collected, maintained, used, or operated on behalf of HHS and hosted on contractor's infrastructure, as well as maintains the right to request full copies of these at any time. If requested, data must be available to HHS within one (1) business day from request date or within the timeframe specified otherwise. In addition, the data shall be provided at no additional cost to HHS.

3. The Contractor (and/or any subcontractor) shall ensure that the facilities that house the network infrastructure are physically and logically secure in accordance with FedRAMP requirements and HHS policies.

4. The contractor shall support a system of records in accordance with NARA-approved records schedule(s) and protection requirements for federal agencies to manage their electronic records in accordance with 36 CFR § 1236.20 & 1236.22 (ref. a), including but not limited to the following:

a. Maintenance of links between records and metadata, and

b. Categorization of records to manage retention and disposal, either through transfer of permanent records to NARA or deletion of temporary records in accordance with NARA-approved retention schedules.

5. The disposition of all HHS data shall be at the written direction of HHS/NIH. This may include documents returned to HHS control; destroyed; or held as specified until otherwise directed. Items returned to the Government shall be hand carried or sent by certified mail to the COR.

6. If the system involves the design, development, or operation of a system of records on individuals, the Contractor shall comply with the Privacy Act requirements.

C. **Security Assessment and Authorization (SA&A) Process**

1. The Contractor (and/or any subcontractor) shall comply with HHS and FedRAMP requirements as mandated by federal laws, regulations, and HHS policies, including making available any documentation, physical access, and logical access needed to support the SA&A requirement. The level of effort for the SA&A is based on the system's FIPS 199 security categorization and HHS/NIH security policies.

a. In addition to the FedRAMP compliant ATO, the contractor shall complete and maintain an agency SA&A package to obtain agency ATO prior to system deployment/service implementation. The agency ATO must be approved by the NIH authorizing official (AO) prior to implementation of system and/or service being acquired.

b. CSP systems categorized as Federal Information Processing Standards (FIPS) 199 high must leverage a FedRAMP accredited third-party assessment organization (3PAO); moderate impact CSP systems must make a best effort to use a FedRAMP accredited 3PAO. CSP systems categorized as FIPS 199 low impact may leverage a non-accredited, independent assessor.

c. For all acquired cloud services, the SA&A package must contain the following documentation: SSP, SAR, POA&M, Authorization Letter, CP and CPT report, E-Authorization (if applicable), PTA/PIA (if applicable), Interconnection/Data Use Agreements (if applicable), Authorization Letter, Configuration Management Plan (if applicable), Configuration Baseline, Following the initial ATO, the Contractor must review and maintain the ATO in accordance with HHS/NIH policies.

2. HHS reserves the right to perform penetration testing (pen testing) on all systems operated on behalf of agency. If HHS exercises this right, the Contractor (and/or any subcontractor) shall allow HHS employees (and/or designated third parties) to conduct Security Assessment activities to include control reviews in accordance with HHS requirements. Review activities include, but are not limited to, scanning operating systems, web applications, wireless scanning; network device scanning to include routers, switches, and firewall, and IDS/ IPS; databases and other applicable systems, including general support structure, that support the processing, transportation, storage, or security of Government information for vulnerabilities.

3. The Contractor must identify any gaps between required FedRAMP Security Control Baseline/Continuous Monitoring controls and the contractor's implementation status as documented in the Security Assessment Report and related Continuous Monitoring artifacts. In addition, all gaps shall be documented and tracked by the contractor for mitigation in a Plan of Action and Milestones (POA&M) document. Depending on the severity of the risks, HHS may require remediation at the contractor's expense, before HHS issues an ATO.

4. The Contractor (and/or any subcontractor) shall mitigate security risks for which they are responsible, including those identified during SA&A and continuous monitoring activities. All vulnerabilities and other risk findings shall be remediated by the prescribed timelines from discovery: (1) critical vulnerabilities no later than thirty (30) days and (2) high, medium and low vulnerabilities no later than sixty (60) days. In the event a vulnerability or other risk finding cannot be mitigated within the prescribed timelines above, they shall be added to the designated POA&M and mitigated within the newly designated timelines 30 days. HHS will determine the risk rating of vulnerabilities using FedRAMP baselines.

5. Revocation of a Cloud Service. HHS/NIH staff division have the right to take action in response to the CSP's lack of compliance and/or increased level of risk. In the event the CSP fails to meet HHS and FedRAMP security and privacy requirements and/or there is an incident involving sensitive information, HHS and/or NIH may suspend or revoke an existing agency ATO (either in part or in whole) and/or cease operations. If an ATO

is suspended or revoked in accordance with this provision, the CO and/or COR may direct the CSP to take additional security measures to secure sensitive information. These measures may include restricting access to sensitive information on the Contractor information system under this contract. Restricting access may include disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls.

D. **Reporting and Continuous Monitoring**

1. Following the initial ATOs, the Contractor (and/or any subcontractor) must perform the minimum ongoing continuous monitoring activities specified below, submit required deliverables by the specified due dates, and meet with the system/service owner and other relevant stakeholders to discuss the ongoing continuous monitoring activities, findings, and other relevant matters. The CSP will work with the agency to schedule ongoing continuous monitoring activities.

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

- **Annual Assessment/Pen Test -** Assess the system security and privacy controls (or ensure an assessment of the controls is conducted) at least annually to determine the implemented security and privacy controls are operating as intended and producing the desired results (this may involve penetration testing conducted by the agency or independent third-party. In addition, review all relevant SA&A documentation (SSP, POA&M, Contingency Plan, etc.) and provide updates by specified due date provided by the Contracting Officer's Representative.
- **Asset Management -** Using any available Security Content Automation Protocol (SCAP)-compliant automated tools for active/passive scans, provide an inventory of all information technology (IT) assets for hardware and software, (computers, servers, routers, databases, operating systems, etc.) that are processing HHS-owned information/data. It is anticipated that this inventory information will be required to be produced at least 60 days after contract award. IT asset inventory information shall include IP address, machine name, operating system level, security patch level, and SCAP-compliant format information. The contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools.
- **Configuration Management -** Use available SCAP-compliant automated tools, per NIST IR 7511, for authenticated scans to provide visibility into the security configuration compliance status of all IT assets, (computers, servers, routers, databases, operating systems, application, etc.) that store and process government information. Compliance will be measured using IT assets and standard HHS and government configuration baselines at least within 60 days. The contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.
- **Vulnerability Management -** Use SCAP-compliant automated tools for authenticated scans to scan information system(s) and detect any security vulnerabilities in all assets (computers, servers, routers, Web applications, databases, operating systems, etc.) that store and process government information. Contractors shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with HHS policy. Automated tools shall be compliant with NIST-specified SCAP standards for vulnerability identification and management. The contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP-compliant automated tools and report to the agency at least within 30 days of the contract award.
- **Patching and Vulnerability Remediation -** Install vendor released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeframes.

- **Secure Coding -** Follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
- **Boundary Protection -** The contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities is routed through a Trusted Internet Connection (TIC).
- A security control assessment must be conducted by a FedRAMP third-party assessment organization (3PAO) for the initial ATO and annually thereafter or whenever there is a significant change to the system's security posture in accordance with the FedRAMP Continuous Monitoring Plan.

2. At a minimum, the Contractor must provide the following artifacts/deliverables on a monthly basis as directed by the Contracting Officer/Contracting Officer's Representative.

a. Operating system, database, Web application, and network vulnerability scan results;

b. Updated POA&Ms;

c. Any updated authorization package documentation as required by the annual attestation/assessment/review or as requested by the NIH System Owner or AO; and

d. Any configuration changes to the system and/or system components or CSP's cloud environment, that may impact HHS/NIH's security posture. Changes to the configuration of the system, its components, or environment that may impact the security posture of the system under this contract must be approved by the agency.

E. **Configuration Baseline**

1. The contractor shall certify that applications are fully functional and operate correctly as intended on systems using the US Government Configuration Baseline (USGCB), DISA Security Technical Implementation Guides (STIGs), Center for Information Security (CIS) Security Benchmarks or any other HHS-identified configuration baseline. The standard installation, operation, maintenance, updates, and/or patching of software shall not alter the configuration settings from the approved HHS/NIH.

- The Contractor shall configure its computers that contain HHS data with the latest applicable United States Government Configuration Baseline (USGCB) and/or other approved HHS IT Security Configurations. (See: https://usgcb.nist.gov/). Note: Approved security configurations include, but are not limited to, those published by the Department, the NIH , and the National Institute of Standards and Technology (NIST) . NIH may have security configurations that are more stringent than the minimum baseline set by the Department or NIST. When incorporating such security configuration requirements in solicitations and contracts, the NIH CISO and/or Information System Security Officer (ISSO) shall be consulted to determine the appropriate configuration reference for a particular system or services acquisition.)
- The Contractor shall apply approved security configurations to information technology (IT) that is used to process information on behalf of HHS and must adhere to all NIH configuration standards and policies (See: https://ocio.nih.gov/InfoSecurity/Policy/Pages/CM.aspx.
- The Contractor shall ensure IT applications operated on behalf of HHS are fully functional and operate correctly on systems configured in accordance with the above configuration requirements. The Contractor shall use Security Content Automation Protocol (SCAP)-validated tools with USGCB Scanner capability to ensure its products operate correctly with USGCB configurations and do not alter USCGB settings - (See: http://scap.nist.gov/validation) . The Contractor shall test applicable product versions with all relevant and current updates and patches installed. The Contractor shall ensure currently supported versions of information technology products met the latest USGCB major version and subsequent major versions.
- The Contractor shall ensure IT applications designed for end users run in the standard user context without requiring elevated administrative privileges.

- The Contractor shall ensure hardware and software installation, operation, maintenance, update, and patching will not alter the configuration settings or requirements specified above.
- The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (See: 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.
- The Contractor shall ensure that its subcontractors (at all tiers) which perform work under this contract comply with the requirements contained in this clause.

2. The contractor shall use Security Content Automation Protocol (SCAP) validated tools with configuration baseline scanner capability to certify their products operate correctly with HHS and NIST defined configurations and do not alter these settings.

F. **Incident Reporting**

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams within 24 hours, whether the response is positive or negative.
FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cyber security and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.
A privacy breach is a type of incident and is defined by Federal Information Security Modernization Act (FISMA) as the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally identifiable information for an other than authorized purpose. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines a breach as "a suspected or confirmed incident involving PII" .
In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) shall:

1. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.
2. NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send NIH approved notifications to affected individuals within ***5 business days*** of the incident.
3. 3. Report all suspected and confirmed information security and privacy incidents and breaches to the NIH Incident Response Team (IRT) IRT@nih.gov **,** COR, CO, the NIH Office of the SOP (or his or her designee), and other stakeholders, including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable NIH and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contract information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor shall:

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

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

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

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

5. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation.
6. The Contractor (and/or any subcontractor) shall provide an Incident and Breach Response Plan (IRP) in accordance with HHS/NIH, OMB, and US-CERT requirements and obtain approval from the NIH. In addition, the Contractor must follow the incident response and US-CERT reporting guidance contained in the FedRAMP Incident Communications.
7. The Contractor (and/or any subcontractor) must implement a program of inspection to safeguard against threats and hazards to the security, confidentiality, integrity, and availability of federal data, afford HHS access to its facilities, installations, technical capabilities, operations, documentation, records, and databases within 72 hours of notification. The program of inspection shall include, but is not limited to:

a. Conduct authenticated and unauthenticated operating system/network/database/Web application vulnerability scans. Automated scans can be performed by HHS/NIH personnel, or agents acting on behalf of HHS/NIH, using agency-operated equipment and/or specified tools. The Contractor may choose to run its own automated scans or audits, provided the scanning tools and configuration settings are compliant with NIST Security Content Automation Protocol (SCAP) standards and have been approved by the agency. The agency may request the Contractor's scanning results and, at the agency discretion, accept those in lieu of agency performed vulnerability scans.

b. In the event an incident involving sensitive information occurs, cooperate on all required activities determined by the agency to ensure an effective incident or breach response and provide all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. In addition, the Contractor must follow the agency reporting procedures and document the steps it takes to contain and eradicate the incident, recover from the incident, and provide a post-incident report that includes at a minimum the following:

- Company and point of contact name;
- Contract information;
- Impact classifications/threat vector;
- Type of information compromised;
- A summary of lessons learned; and
- Explanation of the mitigation steps of exploited vulnerabilities to prevent similar incidents in the future.

G. **Media Transport**

1. The Contractor and its employees shall be accountable and document all activities associated with the transport of government information, devices, and media transported outside controlled areas and/or facilities. These include information stored on digital and non-digital media (e.g., CD-ROM, tapes, etc.), mobile/portable devices (e.g., USB flash drives, external hard drives, and SD cards).
2. All information, devices and media must be encrypted with HHS-approved encryption mechanisms to protect the confidentiality, integrity, and availability of all government information transported outside of controlled facilities.

H. **Boundary Protection: Trusted Internet Connections (TIC)**

1. The contractor shall ensure that government information, other than unrestricted information, being transmitted from federal government entities to external entities using cloud services is inspected by Trusted Internet Connection (TIC) processes.

2. The contractor shall route all external connections through a TIC.
3. **Non-Repudiation-** The contractor shall provide a system that implements FIPS 140-2 validated encryption that provides for origin authentication, data integrity, and signer non-repudiation.

ARTICLE H.19. 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 under the contract which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify and mark such Confidential Information from time to time during the performance of the contract. Failure to mutually agree to the confidential nature of such Confidential Information shall be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that Confidential 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 handling and 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 by the Contractor to any third party who is not involved in the contract without the prior written consent of the authorized Contracting Officer on the behalf of the owning institution or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material-associated information or any information provided solely for the contract, or if such information in question is subject to the Privacy Act or is deemed 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 of such information.

f. Contracting Officer determinations in (e) shall reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply when causing conflicts with any relevant Federal, State, or local laws.

The following information is covered by this article:

All data provided to the Contractor and/or developed by the Contractor under this contract shall be treated confidentially. Under no circumstances are chemicals, drugs, their structures, or any other information associated with these agents, chemicals or drugs, including the data developed under this contract, to be released or divulged without prior written approval by the Contracting Officer.

ARTICLE H.20. 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.21. Publication and Publicity

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

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

No data or results generated under this contract may be transferred to any third party or disclosed or published by the Contractor without the explicit written permission of the NCI. In the event the data or results will be or are being used to support an Investigational New Drug Application (IND) or other regulatory filing, Contractor understands that permission to publish may be denied or withheld until after such regulatory filings and the studies thereunder are completed.

All manuscripts shall be submitted by the Contractor to NCI for review and comment at least forty-five (45) days prior to submission for publication. When applicable, such Manuscripts will also be forwarded to NCI Collaborators for review.

- For manuscripts arising from utilizing any data or materials or Study Agent subject to a NCI CTEP collaborative agreement shall be submitted by the Contractor to NCI Regulatory Affairs Branch (RAB) [NCICTEPpubs@mail.nih.gov] for review and comment at least forty-five (45) days prior to publication submission. When applicable, such manuscripts will also be forwarded by RAB to CTEP Collaborators for review pursuant to such collaborative agreement.

- All abstracts or other forms of public disclosures arising from utilizing any data or materials or Study Agent subject to a CTEP collaborative agreement shall be submitted by the Contractor to RAB [NCICTEPpubs@mail.nih.gov] for forwarding to the CTEP Collaborator for review and comment preferably no less than five (5) days prior to publication submission, but prior to presentation or publication, to allow for preservation of any possible U.S. or foreign patent rights by CTEP Collaborators.

- For publications reviewed and approved pursuant to a CTEP-sponsored clinical study, such publications may be delayed until after the publication of such clinical study's primary endpoint.

a. **Advanced Copies of Press Releases**

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

ARTICLE H.22. 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.23. INTELLECTUAL PROPERTY OPTION TO COLLABORATOR

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.
NCI may collaborate with an outside entity (“Collaborator”) who has proprietary rights to original materials, compounds and/or data, based on which work 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, and the following terms regarding Intellectual Property Rights will be applicable.

Contractor agrees to promptly notify the NCI 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 Contract that either use the Collaborator's study agent (“Study Agent”) or are related to the use and/or composition of Collaborator’s proprietary materials and/or incorporate Collaborator’s proprietary information (hereinafter "Contractor Inventions"). The NCI will then inform the Collaborator in writing of such Contractor Inventions.

Contractor agrees to grant to Collaborator: (1) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for internal 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 the relevant Collaborator and Contractor.
The 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),* but are arising out of any unauthorized use of the Collaborator's Study Agent or any Study Agent-related proprietary materials and/or data shall be the property of the Collaborator (hereinafter "**Collaborator Inventions**"). Contractor will promptly notify the NCI in writing of any such Collaborator Inventions and, at Collaborator's request and expense, Contractor will cause to be assigned to Collaborator all rights, title and interest in 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 or proprietary materials and/or data 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 said agreement, 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.

However, for any Subject Invention made using certain materials, Study Agents, or compounds that are provided by a Collaborator under a NCI CTEP collaborative agreement (“CTEP Collaborator”), Contractor agrees to provide the rights of such Subject Invention described in the CTEP IP Option to such CTEP Collaborator. The rights described in the CTEP IP Option to Collaborator are described at: https://ctep.cancer.gov/branches/rab/intellectual_property_option_to_collaborators.htm, and also found in The Federal Register, Vol. 76, No. 48, pages 13404-13410 (2011) (https://www.gpo.gov/fdsys/pkg/FR-2011-03-11/pdf/FR-2011-03-11.pdf).

Protection of Proprietary Data

Consistent with Data rights clauses FAR 52.227-17 and FAR 52.227-16, data generated using a Study Agent proprietary to a Collaborator will be kept confidential and shared only with the NCI and such Collaborator. Only upon written permission of the Contracting Officer, The Contractor may disclose or publish research results subject to the other applicable terms of this contract.

ARTICLE H.24. 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.

ARTICLE H.25. SHARING RESEARCH DATA

The Contractor's data sharing plan, dated TBD is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

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

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.26. 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.27. CONSTITUTION DAY

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

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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

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

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

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

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT SERVICE CONTRACT

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

It is expected that the following substitution(s) will be made part of the resultant contract:

a. ***Alternate II*** *(August 2016) of FAR Clause* ***52.215-2, Audit and Records--Negotiation*** *(October 2010) is added.*

b. *FAR 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. **Alternate II** (November 2016) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (June 2020) is added.

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (June 2020).

2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (June 2020).

   ".....(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 **52.204-14**, **Service Contract Reporting Requirements** (October 2016).

4. FAR Clause **52.204-18 Commercial and Government Entity Code Maintenance** (August 2020)

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

6. FAR Clause **52.210-1, Market Research** (June 2020).

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

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

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

9. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (March 2020).

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

10. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (May 2020).

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

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

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

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

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

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

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

18. FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (October 2015).

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

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

21. FAR Clause **52.232-18, Availability of Funds** (April 1984).

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

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

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

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

26. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).

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

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

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

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

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

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

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

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

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

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

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

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

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

THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.

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

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

This contract incorporates the following clauses in full text.

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

1. FAR Clause 52.204-21, **Basic Safeguarding of Covered Contractor Information Systems** (June 2016)

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

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

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

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

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

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

b. Safeguarding requirements and procedures.

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

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

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

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

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

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

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

vii. Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

viii. Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

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

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

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

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

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

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

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

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

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

2. *FAR Clause* ***52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters*** *(October 2018)*

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 via https://beta.sam.gov.

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

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

(i)Government personnel and authorized users performing business on behalf of the Government; or

(ii)The Contractor, when viewing data on itself; and

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

(i)Past performance reviews required by subpart 42.15;

(ii)Information that was entered prior to April 15, 2011; or

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

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

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

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

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

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

(End of clause)

3. FAR Clause **52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment** (August 2020).

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

Backhaul means intermediate links between the core network, or backbone network, and the small subnetworks at the edge of the network (*e.g.*, connecting cell phones/towers to the core telephone network). Backhaul can be wireless (e.g., microwave) or wired (*e.g.*, fiber optic, coaxial cable, Ethernet).

Covered foreign country means The People's Republic of China.

Covered telecommunications equipment or services means–

(1) Telecommunications equipment produced by Huawei Technologies Company or ZTE Corporation (or any subsidiary or affiliate of such entities);

(2) For the purpose of public safety, security of Government facilities, physical security surveillance of critical infrastructure, and other national security purposes, video surveillance and telecommunications equipment produced by Hytera Communications Corporation, Hangzhou Hikvision Digital Technology Company, or Dahua Technology Company (or any subsidiary or affiliate of such entities);

(3) Telecommunications or video surveillance services provided by such entities or using such equipment; or

(4) Telecommunications or video surveillance equipment or services produced or provided by an entity that the Secretary of Defense, in consultation with the Director of National Intelligence or the Director of the Federal Bureau of Investigation, reasonably believes to be an entity owned or controlled by, or otherwise connected to, the government of a covered foreign country.

Critical technology means–

(1) Defense articles or defense services included on the United States Munitions List set forth in the International Traffic in Arms Regulations under subchapter M of chapter I of title 22, Code of Federal Regulations;

(2) Items included on the Commerce Control List set forth in Supplement No. 1 to part 774 of the Export Administration Regulations under subchapter C of chapter VII of title 15, Code of Federal Regulations, and controlled-

(i) Pursuant to multilateral regimes, including for reasons relating to national security, chemical and biological weapons proliferation, nuclear nonproliferation, or missile technology; or

(ii) For reasons relating to regional stability or surreptitious listening;

(3) Specially designed and prepared nuclear equipment, parts and components, materials, software, and technology covered by part 810 of title 10, Code of Federal Regulations (relating to assistance to foreign atomic energy activities);

(4) Nuclear facilities, equipment, and material covered by part 110 of title 10, Code of Federal Regulations (relating to export and import of nuclear equipment and material);

(5) Select agents and toxins covered by part 331 of title 7, Code of Federal Regulations, part 121 of title 9 of such Code, or part 73 of title 42 of such Code; or

(6) Emerging and foundational technologies controlled pursuant to section 1758 of the Export Control Reform Act of 2018 (50 U.S.C. 4817).

Interconnection arrangements means arrangements governing the physical connection of two or more networks to allow the use of another's network to hand off traffic where it is ultimately delivered (*e.g.*, connection of a customer of telephone provider A to a customer of telephone company B) or sharing data and other information resources.

Reasonable inquiry means an inquiry designed to uncover any information in the entity's possession about the identity of the producer or provider of covered telecommunications equipment or services used by the entity that excludes the need to include an internal or third-party audit.

Roaming means cellular communications services (*e.g.*, voice, video, data) received from a visited network when unable to connect to the facilities of the home network either because signal coverage is too weak or because traffic is too high.

Substantial or essential component means any component necessary for the proper function or performance of a piece of equipment, system, or service.

(b) *Prohibition*. (1) Section 889(a)(1)(A) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2019, from procuring or obtaining, or extending or renewing a contract to procure or obtain, any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system. The Contractor is prohibited from providing to the Government any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104.

(2) Section 889(a)(1)(B) of the John S. McCain National Defense Authorization Act for Fiscal Year 2019 (Pub. L. 115-232) prohibits the head of an executive agency on or after August 13, 2020, from entering into a contract, or extending or renewing a contract, with an entity that uses any equipment, system, or service that uses covered telecommunications equipment or services as a substantial or essential component of any system, or as critical technology as part of any system, unless an exception at paragraph (c) of this clause applies or the covered telecommunication equipment or services are covered by a waiver described in FAR 4.2104. This prohibition applies to the use of covered telecommunications equipment or services, regardless of whether that use is in performance of work under a Federal contract.

(c) *Exceptions.* This clause does not prohibit contractors from providing—

(1) A service that connects to the facilities of a third-party, such as backhaul, roaming, or interconnection arrangements; or

(2) Telecommunications equipment that cannot route or redirect user data traffic or permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(d) Reporting requirement. (1) In the event the Contractor identifies covered telecommunications equipment or services used as a substantial or essential component of any system, or as critical technology as part of any system, during contract performance, or the Contractor is notified of such by a subcontractor at any tier or by any other source, the Contractor shall report the information in paragraph (d)(2) of this clause to the Contracting Officer, unless elsewhere in this contract are established procedures for reporting the information; in the case of the Department of Defense, the Contractor shall report to the website at https://dibnet.dod.mil. For indefinite delivery contracts, the Contractor shall report to the Contracting Officer for the

indefinite delivery contract and the Contracting Officer(s) for any affected order or, in the case of the Department of Defense, identify both the indefinite delivery contract and any affected orders in the report provided at https://dibnet.dod.mil.

(2) The Contractor shall report the following information pursuant to paragraph (d)(1) of this clause

(i) Within one business day from the date of such identification or notification: the contract number; the order number(s), if applicable; supplier name; supplier unique entity identifier (if known); supplier Commercial and Government Entity (CAGE) code (if known); brand; model number (original equipment manufacturer number, manufacturer part number, or wholesaler number); item description; and any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (d)(2)(i) of this clause: any further available information about mitigation actions undertaken or recommended. In addition, the Contractor shall describe the efforts it undertook to prevent use or submission of covered telecommunications equipment or services, and any additional efforts that will be incorporated to prevent future use or submission of covered telecommunications equipment or services.

(e) *Subcontracts.* The Contractor shall insert the substance of this clause, including this paragraph (e) and excluding paragraph (b)(2), in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial items.

(End of clause)

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

    1. The Government may extend the term of this contract by written notice to the Contractor within 30 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.
    2. If the Government exercises this option, the extended contract shall be considered to include this option clause.
    3. The total duration of this contract, including the exercise of any options under this clause, shall not exceed 7 YEARS.

5. FAR Clause **52.244-6, Subcontracts for Commercial Items** (October 2020).

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

Commercial item and *commercially available off-the-shelf item* have the meanings contained in Federal Acquisition Regulation (FAR) 2.101.

Subcontract includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or non-developmental items as components of items to be supplied under this contract.

(c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

(i) 52.203-13, Contractor Code of Business Ethics and Conduct (Jun 2020) (41 U.S.C. 3509), if the subcontract exceeds the threshold specified in FAR 3.1004(a) on the date of subcontract award, and has a performance period of more than 120 days. In altering this clause to identify the appropriate parties, all disclosures of violation of the civil False Claims Act or of Federal criminal law shall be directed to the agency Office of the Inspector General, with a copy to the Contracting Officer.

(ii) 52.203-15, Whistleblower Protections Under the American Recovery and Reinvestment Act of 2009 (Jun 2010) (Section 1553 of Pub. L. 111-5), if the subcontract is funded under the Recovery Act.

(iii) 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements (Jan 2017).

(iv) 52.204-21, Basic Safeguarding of Covered Contractor Information Systems (Jun 2016), other than subcontracts for commercially available off-the-shelf items, if flow down is required in accordance with paragraph (c) of FAR clause 52.204-21.

(v) 52.204-23, Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities (Jul 2018) (Section 1634 of Pub. L. 115-91).

(vi) 52.204-25, Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment. (Aug 2020) (Section 889(a)(1)(A) of Pub. L. 115-232).

(vii) 52.219-8, Utilization of Small Business Concerns (Oct 2018) (15 U.S.C.637(d)(2) and (3)), if the subcontract offers further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds the applicable threshold specified in FAR 19.702(a) on the date of subcontract award, the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.

(viii) 52.222-21, *Prohibition*of Segregated Facilities (Apr 2015).

(ix) 52.222-26, Equal Opportunity (*Sept* 2015) (E.O.11246).

(x) 52.222-35, Equal Opportunity for Veterans (Jun 2020) (38 U.S.C.4212(a));

(xi) 52.222-36, Equal Opportunity for Workers with Disabilities (Jun 2020) (29 U.S.C.793).

(xii) 52.222-37, Employment Reports on Veterans (Jun 2020) (38 U.S.C.4212).

(xiii) 52.222-40, Notification of Employee Rights Under the National Labor Relations Act (Dec 2010) (E.O. 13496), if flow down is required in accordance with paragraph (f) of FAR clause 52.222-40.

(xiv) (A) 52.222-50, Combating Trafficking in Persons (Oct 2020) (22 U.S.C. chapter 78 and E.O. 13627).

(B) Alternate I (Mar 2015) of 52.222-50(22 U.S.C. chapter 78 and E.O. 13627).

(xv) 52.222-55, Minimum Wages under Executive Order 13658 (Dec 2015), if flow down is required in accordance with paragraph (k) of FAR clause 52.222-55.

(xvi) 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2017) (E.O. 13706), if flow down is required in accordance with paragraph (m) of FAR clause 52.222-62.

(xvii) (A) 52.224-3, Privacy Training (Jan 2017) (5 U.S.C. 552a) if flow down is required in accordance with 52.224-3(f).

(B) Alternate I (Jan 2017) of 52.224-3, if flow down is required in accordance with 52.224-3(f) and the agency specifies that only its agency-provided training is acceptable).

(xviii) 52.225-26, Contractors Performing Private Security Functions Outside the United States (Oct 2016) (Section 862, as amended, of the National Defense Authorization Act for Fiscal Year 2008; 10 U.S.C. 2302 Note).

(xix) 52.232-40, Providing Accelerated Payments to Small Business Subcontractors (Dec 2013), if flow down is required in accordance with paragraph (c) of FAR clause 52.232-40.

(xx) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (Feb 2006) (46 U.S.C. App.1241 and 10 U.S.C.2631), if flow down is required in accordance with paragraph (d) of FAR clause 52.247-64).

(2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

(End of clause)

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

   a. The Contractor shall notify the Contracting Officer or designee, in writing, 30 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.

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

c. **THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.**

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	eCPS Proposal and Delivery Instructions	See Attachment 1
Attachment 2:	Proposal Intent Response Sheet	See Attachment 2
Attachment 3:	Statement of Work	See Attachment 3
Attachment 4:	Sample Protocols	See Attachment 4
Attachment 5:	Section K - Representations, Certifications, and Other Statements of Offerors	See Attachment 5

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 6:	Technical Proposal Cost Summary	See Attachment 6
Attachment 7:	Summary of Related Activities	See Attachment 7
Attachment 8:	Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310)	See Attachment 8
Attachment 9:	Contract Proposal Vertebrate Animal Section (VAS) Worksheet	See Attachment 9
Attachment 10:	Additional Technical Proposal Instructions	See Attachment 10

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 11:	Proposal Summary and Data Record, NIH-2043	See Attachment 11
Attachment 12:	Small Business Subcontracting Plan	See Attachment 12 or fillable Word version at Small Business Subcontract Plan (Word)
Attachment 13:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee-and-labor-hours https://oamp.od.nih.gov/sites/default/files/DFASDocs/buscntrctprpslsprdsht08-2014_508.xlsx
Attachment 14:	Offeror's Points of Contact	See Attachment 14
Attachment 15:	Wage Rate Determination	RESERVED
Attachment 16:	Disclosure of Lobbying Activities, OMB Form SF-LLL	See Attachment 16

Attachment No.	Title	Location
Attachment 17:	Additional Business Proposal Instructions	See Attachment 17

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 18:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	See Attachment 18
Attachment 19:	Electronic Invoicing Instructions	See Attachment 19
Attachment 20:	Safety and Health, HHSAR Clause 352.223-70	See Attachment 20
Attachment 21:	Government Property Schedule	To be determined during negotiations.
Attachment 22:	Disclosure of Lobbying Activities, OMB Form SF-LLL	See Attachment 22
Attachment 23:	Commitment to Protect Non-Public Information Contractor Agreement	See Attachment 23
Attachment 24:	Roster of Employees Requiring Suitability Investigations	See Attachment 24
Attachment 25:	Employee Separation Checklist	See Attachment 25
Attachment 26:	FAR Clause 52.204-24- Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment	See Attachment 26

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 **Beta System for Award Management (SAM)** and complete the Representations and Certifications. The SAM website may be accessed at: https://beta.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 2017)]*

a. Definitions. As used in this provision--

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

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

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

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

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

i. The solicitation number;

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

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

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

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

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

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

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

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

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

(3) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

(e) Restriction on disclosure and use of data.

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

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

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

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

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

(f) Contract award.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(iv) A summary of the rationale for award.

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

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

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

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

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

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

b. **NAICS CODE AND SIZE STANDARD**

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

1. The North American Industry Classification System (NAICS) code for this acquisition is 541715.
2. The small business size standard is 1,000.

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

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

1. It is anticipated that one award will be made from this solicitation and that the award will be made on/about July 1, 2021.
2. It is anticipated that the award from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a Period of Performance of up to 7 years, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).
3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

d. **LEVEL OF EFFORT**

The Government's requirement for the work set forth in the Statement of Work of this solicitation is 5,426 direct labor hours, inclusive of subcontractors and consultants, for the Base Period and for each Option Period. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

Labor Hours

Labor Category	Base Period Year 1	Option Period 1* Year 2	Option Period 2* Year 3	Option Period 3* Year 4	Option Period 4* Year 5	Option Period 5* Year 6	Option Period 6* Year 7
Principal Investigator	72	72	72	72	72	72	72
Professional	754	754	754	754	754	754	754
Technical Support	3,700	3,700	3,700	3,700	3,700	3,700	3,700
Administrative	900	900	900	900	900	900	900

Labor Category	Base Period Year 1	Option Period 1* Year 2	Option Period 2* Year 3	Option Period 3* Year 4	Option Period 4* Year 5	Option Period 5* Year 6	Option Period 6* Year 7
TOTAL	5,426	5,426	5,426	5,426	5,426	5,426	5,426

*Contingent Upon Option Being Exercised

e. **COMMITMENT OF PUBLIC FUNDS**

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

f. **PROMOTING EFFICIENT SPENDING**

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

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

Any contract awarded as a result of this solicitation will:

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

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this SOLICITATIONS. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

h. **RELEASE OF INFORMATION**

Contract selection and award information will be disclosed to offerors in accordance with regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful offerors as they are eliminated from the competition, and to all offerors following award.

i. **PREPARATION COSTS**

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

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

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

Contracting Officer
Office of Acquisitions, TSB
National Cancer Institute
8490 Progress Drive, Room 4030
Frederick, MD, 21702

(b) The copy of any protest shall be received in the office designated above within one day of filing a protest with the GAO.

(End of Provision)

k. **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)

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

2. **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper, printed/copied double-sided, on at least 30 percent post consumer fiber paper, as required by FAR 4.302(b), and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the SOLICITATION should be placed in the following order:

I. COVER PAGE

Include RFP title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

PLEASE PROVIDE A RESPONSE TO THE STATEMENT OF WORK FOR THE LARGE MOLECULE TOXICOLOGY CONTRACT (SHOWN AS ATTACHMENT 3 IN SECTION J). PLEASE ALSO PROVIDE A RESPONSE TO ALL SAMPLE PROTOCOLS (SHOW AS ATTACHMENT 4).

III. BUSINESS PROPOSAL**A BUSINESS PROPOSAL MUST INCLUDE A CUMULATIVE COST SUMMARY FOR ALL SAMPLE PROTOCOLS (SHOWN IN ATTACHMENT 4). PLEASE ALSO PROVIDE SEPARATE COST SUMMARIES FOR EACH INDIVIDUAL PROTOCOL AS SUPPORTING DOCUMENTATION.**

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

3. **Proposal Summary and Data Record (NIH-2043)**

The Offeror must complete the Form NIH-2043, attached, with particular attention to the length of time the proposal is firm and the designation of those personnel authorized to conduct negotiations. (See SECTION J, Attachment entitled, PROPOSAL SUMMARY AND DATA RECORD).

4. **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

5. **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved

or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

6. **Evaluation of Proposals**

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

7. **Potential Award Without Discussions**

   The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

8. **Use of the Metric System of Measurement**

   It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

   The offeror is encouraged to prepare their proposal using either "Hard Metric," "Soft Metric," or "Dual Systems" of measurement. The following definitions are provided for your information:

   Hard Metric - - The replacement of a standard inch-pound size with an accepted metric size for a particular purpose. An example of size substitution might be: selling or packaging liquids by the liter instead of by the pint or quart (as for soft drinks), or instead of by the gallon (as for gasoline).

   Soft Metric - The result of a mathematical conversion of inch-pound measurements to metric equivalents for a particular purpose. The physical characteristics are not changed.

   Dual Systems - The use of both inch-pound and metric systems. For example, an item is designed, produced, and described in inch-pound values with soft metric values also shown for information or comparison purposes.

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

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

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

10. **Privacy Act - Treatment of Proposal Information**

    The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to

be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The NIH is requesting the information called for in this SOLICITATION pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract.

Failure to provide any or all of the requested information may result in a less than adequate review.

In addition, the Privacy Act of 1974 (P.L. 93-579, Section 7) requires that the following information be provided when individuals are requested to disclose their social security number.

Provision of the social security number is voluntary. Social security numbers are requested for the purpose of accurate and efficient identification, referral, review and management of NIH contracting programs. Authority for requesting this information is provided by Section 301 and Title IV of the PHS Act, as amended.

The information provided by you may be routinely disclosed for the following purposes:

- to the cognizant audit agency and the Government Accountability Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

11. **Selection of Offerors**

1. The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
2. The business portion of each contract proposal found to be technical acceptable will be subjected to a cost and price analysis, management analysis, etc.
3. 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.
4. 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.

5. 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.

6. 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.

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

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

13. **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

14. **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.

15. **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)

16. **Past Performance Information**

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

       A list of the last three (3) contracts completed during the past Five (5) years and ALL CONTRACTS currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as $650,000 and above.

       Include the following information for each contract or subcontract listed:

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

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

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

16. HHS SECURITY AND PRIVACY LANGUGAGE FOR INFORMATION AND IT PROCUREMENTS

17. HHS Security and Privacy Language for Information and Information Technology Procurements 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.

INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

A. **POSITION SENSITIVITY DESIGNATIONS**

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

[ ] 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).

1. **HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12**

The Contractor (and/or any subcontractor) and its employees shall comply with Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; FIPS 201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; and Executive Order 13467, Part 1 §1.2.
For additional information, see HSPD-12 policy at: https://www.dhs.gov/homeland-security-presidential-directive-12)

Roster-

a. The Contractor (and/or any subcontractor) shall submit a roster by name, position, e-mail address, phone number and responsibility, of all staff working under this acquisition where the Contractor will develop, have the ability to access, or host and/or maintain a government information system(s). The roster shall be submitted to the COR and/or CO within fourteen (14) calendar days after the effective date of this contract. Any revisions

to the roster as a result of staffing changes shall be submitted within seven (7) calendar days of the change. The COR will notify the Contractor of the appropriate level of investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at: https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx .

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

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

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

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

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

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

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

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

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

B. **Security Assessment and Authorization (SA&A)-** A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor (and/or any subcontractor) shall work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s) within three (3) months after contract award. The Contractor shall conduct the SA&A requirements in accordance with HHS IS2P, NIST SP 800-37, Guide for Applying the Risk Management Framework to Federal Information Systems: A Security Life Cycle Approach (latest revision).
For an existing ATO, Contracting Officer Representative must make a determination if the existing ATO provides appropriate safeguards or if an additional ATO is required for the performance of the contract and state as such. NIH acceptance of the ATO does not alleviate the Contractor's responsibility to ensure the system security and privacy controls are implemented and operating effectively.

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

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

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

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

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

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

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

- **E-Authentication Questionnaire -** The contractor (and/or any subcontractor) shall collaborate with government personnel to ensure that an E-Authentication Threshold Analysis (E-auth TA) is completed to determine if a full E-Authentication Risk Assessment (E-auth RA) is necessary. System documentation developed for a system using E-auth TA/E-auth RA methods shall follow OMB 04-04 and NIST SP 800-63, Rev. 2, Electronic Authentication Guidelines.
Based on the level of assurance determined by the E-Auth, the Contractor (and/or subcontractor) must ensure appropriate authentication to the system, including remote authentication, is in-place in accordance with the assurance level determined by the E-Auth (when required) in accordance with HHS policies.

E. **Reporting and Continuous Monitoring**

1. Following the initial ATOs, the Contractor (and/or any subcontractor) must perform the minimum ongoing continuous monitoring activities specified below, submit required deliverables by the specified due dates, and meet with the system/service owner and other relevant stakeholders to discuss the ongoing continuous monitoring activities, findings, and other relevant matters. The CSP will work with the agency to schedule ongoing continuous monitoring activities.

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

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

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

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

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

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

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

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

- A security control assessment must be conducted by a FedRAMP third-party assessment organization (3PAO) for the initial ATO and annually thereafter or whenever there is a significant change to the system's security posture in accordance with the FedRAMP Continuous Monitoring Plan.

2. At a minimum, the Contractor must provide the following artifacts/deliverables on a monthly basis as directed by the Contracting Officer/Contracting Officer's Representative.

a. Operating system, database, Web application, and network vulnerability scan results;

b. Updated POA&Ms;

c. Any updated authorization package documentation as required by the annual attestation/assessment/review or as requested by the NIH System Owner or AO; and

d. Any configuration changes to the system and/or system components or CSP's cloud environment, that may impact HHS/NIH's security posture. Changes to the configuration of the system, its components, or environment that may impact the security posture of the system under this contract must be approved by the agency.

F. **Configuration Baseline**

1. The contractor shall certify that applications are fully functional and operate correctly as intended on systems using the US Government Configuration Baseline (USGCB), DISA Security Technical Implementation Guides (STIGs), Center for Information Security (CIS) Security Benchmarks or any other HHS-identified configuration baseline. The standard installation, operation, maintenance, updates, and/or patching of software shall not alter the configuration settings from the approved HHS/NIH.

- The Contractor shall configure its computers that contain HHS data with the latest applicable United States Government Configuration Baseline (USGCB) and/or other approved HHS IT Security Configurations. (See: https://usgcb.nist.gov/). Note: Approved security configurations include, but are not limited to, those published by the Department, the NIH , and the National Institute of Standards and Technology (NIST) . NIH may have security configurations that are more stringent than the minimum baseline set by the Department or NIST. When incorporating such security configuration requirements in solicitations and contracts, the NIH CISO and/or Information System Security Officer (ISSO) shall be consulted to determine the appropriate configuration reference for a particular system or services acquisition.)

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

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

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

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

- The Contractor shall (1) include Federal Information Processing Standard (FIPS) 201-compliant (See: 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.

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

2. The contractor shall use Security Content Automation Protocol (SCAP) validated tools with configuration baseline scanner capability to certify their products operate correctly with HHS and NIST defined configurations and do not alter these settings.

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

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

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

c. Secure all devices (i.e.: desktops, laptops, mobile devices, etc.) that store and process government information and ensure devices meet HHS and NIH-specific encryption standard requirements. Maintain a complete and current inventory of all laptop computers, desktop computers, and other mobile devices and portable media that store or process sensitive government information (including PII).

d. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-2. The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer's Technical Representative within 15 days of the validation.

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

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

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

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

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

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

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

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

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

d. Comply with the Privacy Act requirements.

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

Confidentiality: [ ] Low [X] Moderate [ ] High

Integrity: [ ] Low [X] Moderate [ ] High

Availability: [X] Low [ ] Moderate [ ] High

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

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

[X] No PII [ ] Yes PII

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

PII Confidentiality Impact Level has been determined to be: [ ] Low [ ] Moderate [ ] High [X] Not Applicable

K. **CONTRACT INITIATION AND EXPIRATION**

1. **General Security Requirements-** The Contractor (and/or any subcontractor) shall comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the contractor shall follow the HHS EPLC framework and methodology or and in accordance with the HHS Contract Closeout Guide (2012). HHS EA requirements may be located here: https://www.hhs.gov/ocio/ea/documents/proplans.html

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

3. **Sanitization of Government Files and Information-** As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) shall provide all required documentation in accordance with the NIH Media Sanitization and Disposal Policy to the CO and/or COR to certify that, at the government's

direction, all electronic and paper records are appropriately disposed of and all devices and media are sanitized in accordance with NIST SP 800-88, Guidelines for Media Sanitization.

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

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

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

7. **TRAINING**

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

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

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

M. **RULES OF BEHAVIOR**

1. The Contractor (and/or any subcontractor) shall ensure that all employees performing on the contract comply with the HHS Information Technology General Rules of Behavior, and 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

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

N. **INCIDENT RESPONSE**

The Contractor (and/or any subcontractor) shall respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams within 24 hours, whether the response is positive or negative.
FISMA defines an incident as "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies.. The HHS Policy for IT Security and Privacy Incident Reporting and Response further defines incidents as events involving cyber security and privacy threats, such as viruses, malicious user activity, loss of, unauthorized disclosure or destruction of data, and so on.

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

1. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract so as to avoid a secondary sensitive information incident with FIPS 140-2 validated encryption.
2. NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor shall send NIH approved notifications to affected individuals individuals in accordance with https://ocio.nih.gov/InfoSecurity/IncidentResponse/Pages/ir_guidelines.aspx
3. Report all suspected and confirmed information security and privacy incidents and breaches to the NIH Incident Response Team (IRT) via email at IRT@mail.nih.gov, COR, CO, the NIH Office of the SOP (or his or her designee), and other stakeholders, including incidents involving PII, in any medium or form, including paper, oral, or electronic, as soon as possible and without unreasonable delay, no later than one (1) hour, and consistent with the applicable NIH and HHS policy and procedures, NIST standards and guidelines, as well as US-CERT notification guidelines. The types of information required in an incident report must include at a minimum: company and point of contact information, contract information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor shall:

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

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

c. encrypt sensitive information in attachments to email, media, etc.
Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.

4. Comply with OMB M-17-12, Preparing for and Responding to a Breach of Personally Identifiable Information HHS and NIH incident response policies when handling PII breaches.
5. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files, and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation within an hour of discovery.

O. **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 a separate cover on monthly basis.

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

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

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

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

44 U.S.C. Chapter 35, Subchapter I (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.

18. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

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

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

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

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

e. Identification of Uncompensated Overtime, FAR Clause 52.237-10, (March 2015).

b. **TECHNICAL PROPOSAL INSTRUCTIONS (Please also see Attachment 10 for additional technical proposal instructions)**

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

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

1. **Technical Discussions**

   As outlined in Section L – Instructions, Conditions, and Notices to Offerors, **OFFERORS SHALL SUBMIT A TECHNICAL PROPOSAL THAT ADDRESSES THE CONTRACT STATEMENT OF WORK (SOW), WITH A *SEPARATE* SECTION FOR EACH SAMPLE PROTOCOL.**

   A detailed work plan must be submitted indicating how each aspect of the Statement of Work and each Sample Protocol are to be accomplished. In addition, the technical discussion included in the technical proposal should respond to the items set forth below:

   a. **Statement of Work**

      1. Objectives

         State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and relation to comparable work in progress elsewhere. This should support the scope of the project as you perceive it.

      2. Approach

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

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

      3. Methods

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

      4. Schedule

         Provide a schedule for completion of the work and delivery of items specified in the statement of work. Performance or delivery schedules shall be indicated for phases or segments of work, as applicable, by contract year as well as for the overall contract. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, from the date of a stated event, as for example, receipt of a required approval by the Contracting Officer. Unless the request for proposal indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based

upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b. **Personnel**

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

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

THE RELEVANT PROVISIONS/CLAUSES (E.G., SERVICE CONTRACT LABOR STANDARDS) AND APPROPRIATE WAGE DETERMINATIONS, IF APPLICABLE, WILL BE ADDED TO ANY RESULTING CONTRACT AWARDED TO AN OFFEROR THAT PROPOSES TO UTILIZE PERSONNEL DEFINED AS “SERVICE EMPLOYEES” IN ACCORDANCE WITH FAR 22.001, UNLESS AN EXEMPTION APPLIES.

1. Single Principal Investigator/Project Director

   List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director in managing and coordinating the efforts of personnel including consultants and subcontractors, required to perform the functions described in the Statement of Work. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

2. Multiple Principal Investigators

   The NIH now provides offerors the opportunity to propose a multiple Principal Investigator (PI) model on research and development contracts. The multiple PI model is intended to supplement, and not replace, the traditional single PI model. The NIH chose this RFP as a candidate for the multiple PI model. Ultimately, the decision to submit a proposal using the multiple PI versus single PI is the decision of the investigators and their institutions. The decision should be consistent with and justified by the scientific goals of the project.

   It is essential that organizations consider all aspects of this approach before submitting a proposal. While there are some projects that clearly are appropriate for the multiple PI model, the "fit" of other projects may not be so clear. Offerors should base the selection of either the single PI or multiple PI option on the research proposed, to ensure optimal facilitation of the science. Projects suitable for the multiple PI model could include as few as two PIs who

are jointly responsible for the scientific and technical direction of the project. The multiple PI option is based on the proposed project, not on the number of performance sites or the number of participating institutions.

Multiple PIs under research contracts shall use the Subcontract Model. In this approach, offerors submit a single proposal, and a single award is made to the prime contractor. The prime contractor, when appropriate, will award subcontracts to fund the components of the project at the other institutions. The relationship between the contractor and subcontractors must be designed to support all components of the project.

To facilitate communication with the NIH, the offeror must designate a Contact PI at the time of proposal submission. The Contact PI must be employed at the prime contractor's organization. The designation of the Contact PI may rotate on an annual basis. However, this rotation is restricted to PIs located at the prime contractor's organization. The Contact PI is responsible for: relaying communications between all of the PIs and the NIH, and coordinating progress reports for the project. Being named Contact PI does not confer any special authority for the project.

Leadership Plan

Offerors proposing multiple PIs will need to submit a Leadership Plan as part of the Technical Proposal. The Leadership Plan shall describe the governance and organizational structure of the research project including communication plans, process for making decisions on scientific direction, allocation of resources, publications, intellectual property issues, and procedures for resolving conflicts. The Leadership Plan shall follow the Table of Contents provided below:

I. Rationale
   Include a discussion of how the project will be enhanced by the multiple PI approach.

II. Identification of all proposed PIs
   Identify the proposed PIs, their point of contact information and affiliated organizations, and the percentages of time proposed for this project. Identify the Contact PI and plans for rotation of that role, if any.

III. Roles and Responsibilities
   Identify both the scientific and administrative roles and responsibilities of all named PIs.

IV. Approach to Fiscal and Management Coordination
   Describe how the project will be performed and monitored from a fiscal and management perspective. Discuss organizational administrative coordination and support.

V. Project Direction and Resource Allocation
   Address how decisions will be made regarding scientific direction, and, how resources will be allocated and redistributed if needed during performance. Address plans for shared resources such as IT or other shared data considerations. If joint standard operating procedures will be developed, describe this process.

VI. Communication and Lines of Authority
   Address communication and lines of authority within and among PIs and within and among organizations.

VII. Data sharing, Intellectual Property, Publication, and other Proprietary Considerations
Data sharing plans, intellectual property considerations, publication agreements, and any other proprietary or confidential information sharing should be addressed in this section.

VIII. Conflict Resolution
Address how conflicts will be avoided, identified, and resolved.

IX. Other
Address any other information relative to the leadership approach to Multiple PI projects.

Offerors submitting single PI proposals do not need to submit a Leadership Plan.

3. Other Investigators

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

4. Additional Personnel

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

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

5. Resumes

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

2. **Other Considerations**

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

a. Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how the statement of work will be accomplished within this working relationship.

b. Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.

c. Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.

d. Other factors you feel are important and support your proposed research.

e. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

3. **Technical Evaluation**

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

4. **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.

5. **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 criteria must be addressed in a separate section of the Technical Proposal titled "Vertebrate Animal Section" (VAS):

1. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.

2. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).

3. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

4. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

A concise (no more than 1-2 pages), complete description addressing these criteria 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 VAS, see NIH Guide Notice NOT-OD-16-006 at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.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.

6. **Enhancing Reproducibility through Rigor and Transparency**

The offeror shall demonstrate compliance with the NIH Policy on enhancing Reproducibility through Rigor and Transparency as described in NIH Guide Notice NOT- OD-15-103. Specifically, the offeror shall describe in its technical proposal the information described below:

Compliance Factors

a. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.

b. Explain how relevant biological variables, including sex, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for proposals proposing to study only one sex. If your proposal involves human subjects, the sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion and justify the proposed proportions of individuals (such as males and females) in the sample. Refer to https://grants.nih.gov/grants/guide/notice-files/not-od-15-102.html for further consideration of NIH expectations about sex as a biological variable.

c. If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposal. Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.

Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals. If the Technical Proposal does not propose the use of key biological and/or chemical resources, a plan for authentication is not required, and the offeror should so state in its proposal.

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

c. **BUSINESS PROPOSAL INSTRUCTIONS**

1. **Basic Cost/Price Information**

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

2. **Proposal Cover Sheet**

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

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;

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

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

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

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

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

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

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

   a. **Direct Labor**

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

   b. **Materials**

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

   c. **Subcontracted Items**

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

d. **Raw Materials**

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

e. **Purchased Parts**

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

f. **Fringe Benefits**

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

g. **Indirect Costs**

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

h. **Special Equipment**

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

i. **Travel**

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

j. **Other Costs**

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

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

(a) Exceptions from certified cost or pricing data.

(1) In lieu of submitting certified cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following subparagraphs. The Contracting Officer may require additional supporting information, but only to the extent

necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) Requirements for certified cost or pricing data. If the offeror is not granted an exception from the requirement to submit certified cost or pricing data, the following applies:

(1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.
(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

5. **Salary Rate Limitation**

Offerors are advised that no NIH funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's

direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

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

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 $750,000 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 $750,000 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:

22.5% 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**

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

    (End of provision)

8. **HUBZone Small Business Concerns**

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

9. **Total Compensation Plan**

a. **Instructions**

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

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

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

b. **Evaluation**

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

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

2. **Cost (Professional Compensation)**

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

3. **Other (Labor Relations)**

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

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

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

10. **Other Administrative Data**

a. **Property**

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

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

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

2. Government Property

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

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

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

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

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

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

3. Government-Furnished Property

No Government Furnished Property is offered for this acquisition

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

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

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

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

(End of Provision)

c. **Financial Capacity**

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

d. **Adequate Accounting System**

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

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

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

- Complies with generally accepted accounting principles (GAAP).

- Provides for:
  - Proper segregation of direct costs from indirect costs.
  - Identification and accumulation of direct costs by contract.
  - A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
  - Accumulation of costs under general ledger control.
  - A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
  - A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
  - Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
  - Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions.
  - Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.
  - Segregation of preproduction costs from production costs, if applicable.
- Accounting system provides financial information:
  - Required by contract clause concerning limitation of cost (FAR 52.232-20) or limitation on payments (FAR 52.216-16).
  - Required to support requests for progress payments.
- Accounting system was designed, and records are maintained in such a manner that adequate, reliable data are developed for use in pricing follow-on acquisitions.
- Accounting system is currently in full operation.

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

e. **Incremental Funding**

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

Incremental Funding, HHSAR 352.232-70 (December 2015)

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

(End of provision)

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

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

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

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

(End of Provision)

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

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

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

11. **Qualifications of the Offeror**

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

a. **General Experience**

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

b. **Organizational Experience Related to the RFP**

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

c. **Performance History**

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

d. **Pertinent Contracts**

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

received. The same type of organizational experience and past performance data should be submitted.

e. **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

12. **Subcontractors**

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

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

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

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

d. Information on their cognizant field audit offices.

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

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

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

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

14. **Travel Costs/Travel Policy**

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

b. **Travel Policy**
One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

SECTION M - EVALUATION FACTORS FOR AWARD

1. **GENERAL**

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

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

2. **COST/PRICE EVALUATION**

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

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

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

3. **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 criteria. (See NIH Guide Notice NOT-OD-16-006 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html):

a. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.

b. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).

c. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

d. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

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 criteria 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 criteria, 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.

4. **MANDATORY QUALIFICATION CRITERIA**

Listed below are mandatory qualification criteria. THE OFFEROR SHALL INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS TECHNICAL PROPOSAL.

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

The Offeror shall document and provide evidence of the following in the technical proposal:

a. GLP Compliance**:** The laboratory facility must be in compliance with the Food and Drug Administration's (FDA) Good Laboratory Practice Regulations (GLP) as published in CFR Title 21, Part 58, and as updated. Some, but not all, toxicology studies submitted in support of an Investigational New Drug application to the FDA must be GLP-compliant. As such, the contractor must be able to conduct GLP-compliant studies since DTP/NCI anticipates needing several of these studies each year. Documentation shall be in the form the most recent FDA Establishment Inspection Report demonstrating that the facility is currently in compliance with FDA GLP regulations, i.e. is not currently disqualified.

b. Animal Care and Use: The Offeror shall establish and provide resources for an animal care and use program that is managed in compliance with applicable federal, state, and local laws and regulations, such as:

- Animal Welfare Regulations (9 CFR, 1985/1989)

  https://www.nal.usda.gov/awic/final-rules-animal-welfare-9-cfr-parts-1-2-and-3

- Guide for the Care and Use of Laboratory Animals 8th ed., National Research Council, 2011

  http://www.ncbi.nlm.nih.gov/books/NBK54050/

- Public Health Service Policy on Humane Care and Use of Laboratory Animals, revised 2015.

https://grants.nih.gov/grants/olaw/references/phspol.htm.

To demonstrate compliance with the above policies and guidance, Offerors shall submit with their Technical Proposal: 1) a copy of your organization's most recent letter from NIH's Office of Laboratory Animal Welfare (OLAW) documenting approval of a valid Animal Welfare Assurance, and 2) a copy of your organization's most recent USDA Animal Welfare Act registration certificate.

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 AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES**

If the offeror has proposed the use of key biological and/or chemical resources, the offeror's plan for authentication will be reviewed adequacy.

Any concerns associated with key biological and/or chemical resource authentication raised during the review process will need to be resolved prior to award.

7. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data, or, if data sharing is not possible, the offeror's documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

8. **TECHNICAL EVALUATION FACTORS**

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

A. **PERSONNEL- 30 Points**

- Adequacy of documented commitment of time and effort, and qualifications of the proposed Principal Investigator (PI).
- Documented experience of the PI to manage interdisciplinary teams in the conduct of Good Laboratory Practice (GLP) toxicology and pharmacology studies to qualify potential cancer therapeutic agents or other pharmacological agents for further testing and for clinical development.
- Appropriateness and adequacy of the education, training, experience, expertise, knowledge and effort of the proposed key personnel in managing and coordinating the efforts of personnel, including consultants and subcontractors, required to perform the functions described in the Statement of Work.
- Suitability of expertise of all proposed staff in the technical aspects of the Statement of Work, including pathology, clinical pathology, immunology, statistics, veterinary medicine, laboratory animal care, analytical chemistry, pharmacokinetics, and quality assurance.

- Documented evidence that there is a participating ACLAM certified veterinarian, or a veterinarian with the equivalent certification, on staff. Alternatively, documented evidence that there is an established, contractual relationship with an on-call consultant ACLAM veterinarian.
- Adequacy of proposed subcontractor(s), including training, experience, qualifications, availability, and specific area of expertise to be contributed to the projects. Note that it is expected that the Prime Contractor shall perform the majority of the work, as this will prevent *excessive pass-through charges by the Contractor* for indirect costs or profit/fees for managing subcontractors, as well as potentially prevent unnecessary delays. As such, a strong proposal is viewed as one in which the Offeror can perform most of the studies described in the Statement of Work on site.
- Demonstrated adequacy of experience and expertise of all proposed staff to perform the work described in the Statement of Work.

B. **TECHNICAL APPROACH AND AWARENESS- 30 Points**

- Demonstrated knowledge and familiarity with the regulatory requirements and general study design, conduct, data-gathering, and evaluations required to undertake the tasks in the Statement of Work.
- Documented utilization and adherence to quality assurance and control procedures in areas such as animal health and husbandry, compound formulation and administration, analytical chemistry, and clinical and anatomic pathology.
- Demonstrated adequacy of data gathering systems, validated computer systems, and Quality Assurance Unit.
- Demonstrated adequacy of proposed staffing plan and work schedule to complete the task within the period of award.
- Adequacy of the technical approach for the work outlined in the Statement of Work.
- Adequacy of proposed Safety and Health Plan.
- Adequacy of the technical approach for the work outlined in the Sample Protocols.

a. **DEMONSTRATION OF A STRONG SCIENTIFIC PREMISE FOR THE TECHNICAL PROPOSAL**

Sufficiency of proposed strategy to ensure a robust and unbiased approach, as appropriate for the work proposed. Adequacy of proposed plan to address relevant biological variables, including sex, for studies in vertebrate animals and/or human subjects.

C. **Organizational Experience- 20 Points**

- Demonstrated organizational experience in data collection and processing capabilities (computer systems), including statistical analysis, and quality assurance.
- Documented ability to collaborate with other individuals and organizations.
- Documented experience in appropriate use of subcontractors to supplement areas of expertise.
- Adequacy of plan to manage the infrastructures composed of one or more collaborating institutions.
- Adequacy of organizational chart that describes reporting structure of the organization.
- Documented track record of GLP-compliant study reports submitted as part of INDs.

D. **COMPLIANCE WITH FEDERAL REGULATION 21 CFR PART 58- 10 Points**

- Adequacy of documented evidence of GLP compliance.

E. **FACILITIES AND EQUIPMENT- 10Points**

- Suitability and availability of facilities and floor plans drawn to scale to accomplish tasks in each task area.
- Documented compliance with all other federal, state, and local regulations and statutes and appropriate accreditations and licensures.
- Evidence of your AAALAC accreditation.
- Documentation that you have a current established IACUC.
- Evidence of availability of appropriate equipment to accomplish each task, including but not limited to:
    - Cell culture facilities and associated equipment and techniques
    - Animal caging, cleaning, and husbandry
    - Compound formulation and administration
    - Analytical and clinical chemistry laboratories
    - Necropsy and histopathology laboratories
    - Data collection and computerization
    - Data/sample archive
    - Electrical and environmental back up provisions for critical components e.g. animal rooms, chemical test article and biological samples, etc.
- Adequacy of facility design and maintenance to meet chemical and biological control of potential teratogens, carcinogens, and radioactive material, in compliance with applicable safety and health standards and laws.
- Adequacy of facilities proposed to complete the work described in the Statement of Work.
- Adequacy of facilities to perform several studies of the same type at the same time (i.e., concurrently), in particular, with large animals (primates).

TOTAL: 100 Points

9. **PAST PERFORMANCE FACTOR**

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

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

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

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

When assessing performance risks, the Government, 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, 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.