

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Requisition or other Purchase Authority: P.L. 99-158 as amended		
2. Request for Proposal (RFP) Number: 75N95022R00108	3. Issue Date: 11/22/2022	4. Set Aside: [X] No [] Yes See Part IV Section L
5. Title : Development and Maintenance of a Multigenotypic Aged Rat Colony		
6. ISSUED BY: NIDA/NIA Contracts Management Branch Office of Acquisition C/O NIH Mail Center NIDA 3WFN MSC 6023 16071 Industrial Drive Gaithersburg, MD 20892		7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 4:00 pm local time on January 6, 2023. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.		
9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS. IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition," LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
10. Offeror must be registered in the System for Award Management (SAM) when submitting a proposal and continue to be registered until time of award, during performance, and through final payment of any contract, basic agreement, basic ordering agreement, or blanket purchasing agreement resulting from a solicitation. Offerors who are not registered in SAM should consider applying for registration immediately upon receipt of this solicitation. See FAR 52.204-7 System for Award Management (Oct 2018) and https://www.sam.gov for information on registration.		
11. FOR INFORMATION CALL: Fred Ettehadieh PHONE: 301-443-9154 e-MAIL: Fred.Ettehadieh@nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
All questions pertaining to this solicitation must be submitted to Fred Ettehadieh by eMail (see Item 11) no later than 4:00 pm local time on December 16, 2022.		Fred Ettehadieh Contracting Officer Office of Acquisition

1. Requisition or other Purchase Authority: P.L. 99-158 as amended

NIDA/NIA

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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

Develop, maintain and distribute a standing colony of aged, genetically defined laboratory rats for use by investigators in studies of aging. This colony is to be developed and maintained within controlled and defined barrier environments where animals are monitored and characterized for disease status and markers of genetic purity.

ARTICLE B.2. PRICES/COSTS

- a. This is an Indefinite Quantity contract as contemplated by FAR 16.504. The Contractor shall be reimbursed by the Government in an amount not less than a total of \$374,599 (minimum) nor more than a total of \$31,925,107 (maximum) for successful performance of this contract.
- b. The costs set forth in this ARTICLE will cover the contract period September 30, 2023 through September 29, 2033.
- c. The Government will issue cost reimbursement Task Orders based on the work described in SECTION C of this contract.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated November 2022, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports shall be submitted electronically.

These reports 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: <https://www.hhs.gov/web/section-508/index.html> and at: <https://www.section508.gov/create/documents>, "Create Accessible Documents."

- a. **Technical Progress Reports**

Refer to Reporting Requirements and Other Deliverables document in Section J – List of Attachments.

Summary of Salient Results

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

- 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: <https://www.ecfr.gov/current/title-45/part-94>.

See Part 94.5, Responsibilities of Institutions regarding Investigator financial conflicts of interest for complete information on reporting requirements.

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

HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS

INFORMATION AND/OR PHYSICAL SECURITY

I. 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). To determine the designation, the Position Designation Tool (PDT) discussion is found at: <https://www.ors.od.nih.gov/ser/dpsac/resources/Pages/investigation-requirements-for-your-position.aspx> and the link to access the tool is found at: <https://pdt.nbis.mil/>.

The following position sensitivity designation levels apply to this solicitation/contract:

☐ Tier 5: Critical Sensitive and Special Sensitive National Security, including Top Secret, SCI, and "Q" access eligibility.
☐ Tier 5SR: Reinvestigation.

☐ Tier 4: High Risk Public Trust (HRPT).
☐ Tier 4SR: Reinvestigation.

☐ Tier 3: Non-Critical Sensitive, National Security, including Secret and "L" access eligibility.
☐ Tier 3SR: Reinvestigation.

☒ Tier 2S with Subject Interview: Moderate Risk Public Trust (MRPT).
☐ Tier 2SR: Reinvestigation.

☐ Tier 1: Low Risk, Non-Sensitive, including HSPD-12 Credentialing.

J. HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

Roster-

The Contractor (and/or any subcontractor) must 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 must 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 must 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://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j>

- a. If the Contractor is filling a new position, the Contractor must 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.
- b. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor must complete and submit the required forms within 30 days of the notification.

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

K. CONTRACT INITIATION AND EXPIRATION

- a. **General Security Requirements-** The Contractor (and/or any subcontractor) must 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 must follow the HHS EPLC framework and methodology or and in accordance with the HHS Contract Closeout Directive (2018) located at: <https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HHS-Closeout-Directive-2018.pdf>. HHS EA requirements located at: <https://www.hhs.gov/sites/default/files/eplc-policy-dec-2016.pdf> and NIH EA requirements are located at: <https://ocio.nih.gov/PM/Pages/EPLC.aspx>.
- b. **System Documentation-** Contractors (and/or any subcontractors) must follow and adhere to HHS System Development Life Cycle requirements, 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.
- c. **Sanitization of Government Files and Information-** As part of contract closeout and at expiration of the contract, the Contractor (and/ or any subcontractor) must 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.
- d. **Notification -** The Contractor (and/ or any subcontractor) must notify the CO and/ or COR and system ISSO within fifteen days before an employee stops working under this contract.

- e. **Contractor Responsibilities Upon Physical Completion of the Contract-** The Contractor (and/ or any subcontractors) must 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 must 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.
- f. The Contractor (and/or any subcontractor) must 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 must be made available to the CO and/ or COR upon request.
- g. **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 must be submitted to the Contracting Officer (CO) and/ or CO Representative (COR) prior to performing any work under this acquisition.
- h. **Government Access for Security Assessment.** In addition to the Inspection Clause in the contract, the Contractor (and/or any subcontractor) must 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:
 - i. 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.
 - ii. 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.
 - iii. 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.

- iv. Cooperate with inspections, audits, investigations, and reviews.

2. Section 508 Annual Report

The Contractor must submit an annual Section 508 report in accordance with the schedule set forth by the Contracting Officer (CO)/Contracting Officer's Representative (COR). The Section 508 Report Template and Instructions for completing the report are available at: https://www.hhs.gov/sites/default/files/web/508/contracting/technology/section_508_annual_report.doc.

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:
National Institute of Health
National Institute on Aging
Bethesda, MD

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract shall be from September 30, 2023 through September 29, 2033.

ARTICLE F.2. DELIVERIES

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

- a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING.
- b. Refer to Reporting Requirements and Other Deliverables document in Section J – List of Attachments.

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989)

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

SECTION G - CONTRACT ADMINISTRATION DATA

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

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

TO BE SPECIFIED AT TIME OF AWARD

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

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

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

The Government may unilaterally change its COR designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.237-75 (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
<i>TO BE SPECIFIED AT TIME OF AWARD</i>	

ARTICLE G.3. TASK ORDER PROCEDURE

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

a. General

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

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

b. Requesting Task Order Proposals.

The Contracting Officer or a designated individual may solicit responses to requirements from Contractors within a technical area covered by a task order requirement in writing. A Task Order Request for Proposals (TORFP) will be prepared and issued for each task order requirement.

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

1. Statement of Work;
2. Reporting Requirements and Deliverables;
3. Proposal Due Date and Location to Deliver Proposals;
4. Period of Performance of Task Order;
5. Anticipated type of Task Order;
6. Technical Proposal Instructions;
7. Business proposal Instructions
8. Evaluation Factors for Award

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

c. Evaluation and Award of Task Order Proposals

The Government will evaluate the Task Order proposals against the requirements of the TORFP. Upon completion of evaluations, the Contracting Officer will issue a task order to the Contractor.

ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

- a. Invoice Submission/Contract Financing Request, NIH(RC)-1 for NIH Cost-Reimbursement Type Contracts are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. The Contractor must submit invoices to the Department of Treasury's Invoice Processing Platform (IPP) at <https://www.ipp.gov> with a copy to the approving official, as directed below. The Contractor must follow step-by-step instructions as stated in the NIH/OFM [Electronic Invoicing Instructions for NIH Contractors/Vendors](#), which is included as an attachment in Section J of this contract. The invoice shall be transmitted as an attachment via email to the address listed above in one of the following formats: Word, or Adobe Portable Document Format (PDF). The Contractor must submit only one invoice per email. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your invoice unless specified elsewhere in the contract or requested by the Contracting Officer.

The Contractor shall submit a copy of the electronic invoice to the following Approving Official (Contracting Officer) and Contracting Officer Representative:

Approving Official: Contracting Officer

Name- TBD Email Address- TBD

Contracting Officer Representative

Name- TBD Email Address- TBD

For inquiries regarding the status of invoices, contact [OFM Customer Service](#) via email at ofm_customer_service@incontactemail.com or via phone at 301-496-6088. To send your inquiries via other available communication methods refer to the OFM Customer Service website at <https://ofm.od.nih.gov/Pages/Customer-Service.aspx>.

Note: The OFM Customer Service is open Eastern Standard Time Monday - Friday from 8:30 a.m. to 5:00 p.m. and is closed between 12:00 p.m. to 1:00 p.m.

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 Institute on Drug Abuse (NIDA) .
 - 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, Unique Entity Identifier

(UEI), or VIN, contact the Contracting Officer. Note: The Contractor shall not include TIN if it is a Social Security Number.

- c. Unique Entity Identifier (UEI). The UEI is located in the System for Award Management (SAM) and replaces the Dun & Bradstreet Data Universal Numbering System (DUNS) number. The UEI 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 UEI 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, UEI, 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:

Development and Maintenance of a Multigenotypic Aged Rat Colony

- g. Contract Line Items as follows:

Line Item #	Line Item Description
TO BE SPECIFIED AT TIME OF AWARD	

- b. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.
- c. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to HHSAR Clause 352.231-70, Salary Rate Limitation in SECTION I of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

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

ARTICLE G.5. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (Nov 2021)

- 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.6. 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. Go to the Indirect Cost Submission web page: <https://oamp.od.nih.gov/division-of-financial-advisory-services/indirect-cost-branch/indirect-cost-submission> for electronic copies of the Branch's information package documents.

ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

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

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

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

b. Electronic Access to Contractor Performance Evaluations

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

<https://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. CORONAVIRUS DISEASE 2019 (COVID - 19) - ONSITE CONTRACTORS RETURN TO PHYSICAL WORKSPACE

Coronavirus disease 2019 (COVID-19) - NIH policy may allow for voluntary or mandatory COVID-19 testing for contractor personnel. Contractor personnel who test positive for COVID-19 or who do not wish to submit to mandatory COVID-19 testing will not have access to or be permitted to work in NIH [ICs] until they have satisfied the access requirements in the NIH policy. A contractor personnel's decision to opt out of mandatory COVID-19 testing will not

automatically constitute grounds for any performance delays or establish any government liability for additional costs. The Contracting Officer may determine that an excusable delay is appropriate under applicable FAR clauses (e.g., 52.242-14 (Suspension of Work), 52.242-15 (Stop-work Order), 52.249-14 (Excusable Delays), and 52.212-4(f) (Excusable Delays)) in cases where a positive test result is recorded and contract personnel must be quarantined due to an exposure to COVID-19. However, cases where a positive test result is recorded will not establish any government liability for additional costs.

Contractors shall ensure compliance with all Federal, HHS, NIH and individual IC COVID-19 policies related to health and safety, including relevant Codes of Conduct and reporting requirements applicable to contractor personnel. The Contractor shall discuss the Code of Conduct with contractor personnel, retain signed Codes of Conduct, and confirm their signature with the Contracting Officer. Reporting requirements include: 1) Ensure open reporting of safety and health related concerns; 2) Ensure staff understand reporting of COVID-like symptoms to contract supervisors, if they have had a high-risk exposure to someone with COVID disease, or if they have tested positive for COVID-19, and that staff do not report to the workplace with symptoms or if they have tested positive for COVID-19; 3) Ensure staff are complying with the return to work plans, policies and reporting requirements and enforcing these requirements when necessary; and 4) Ensure contract supervisors inform the Contracting Officer of personnel with COVID-19 symptoms.

The Return-to-Work Guidance and Code of Conduct for On-Site Contractors (Appendix 1) are incorporated into this contract. Contractors shall ensure contract personnel are aware they are to contact their company/supervisor for guidance.

Testing conducted by the NIH Occupational Medical Service (OMS) falls within Privacy Act System of Records Notice (SORN), 09-25-0105, Administration: Health Records of Employees, Visiting Scientists and Others Who Receive Medical Care through Employees Health Unit, HHS/NIH/ORS.

Information regarding the Countermeasures Injury Compensation Program under the Health Resources and Services Administration is available at 1-855-266-2427 or

<http://www.hrsa.gov/cicp/>.

ARTICLE H.3. 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.4. 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 any NIH-funded or conducted research, supported in whole or in part with direct costs from NIH regardless of NIH funding mechanism. NIH defines the author's final manuscript as the final version accepted for journal publication, which includes all modifications that result from the publishing and peer review process, and which should be made accessible as soon as possible, and no later than the time of an associated publication or the end of the award/support period, whichever comes first. The PMC archive will permanently preserve and retain these manuscripts for use by the public, health care providers, educators, scientists, and NIH. NIH Policy directs electronic submissions to the NIH/NLM/PMC: <https://www.ncbi.nlm.nih.gov/pmc/>.

Additional information is available at: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-013.html> and <https://publicaccess.nih.gov/>.

ARTICLE H.5. ACKNOWLEDGEMENT OF FEDERAL FUNDING

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

ARTICLE H.6. 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.7. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (December 2015)

- a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United States Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.
- b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1 2.11, or from a source that is exempt from licensing under those sections.
- c. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care 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.
- d. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS/AC, 4700 River Road, Unit 84, Riverdale, Maryland 20737 (Email: animalcare@usda.gov; Web site: <https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare>.)

(End of clause)

ARTICLE H.8. 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: <https://olaw.nih.gov/policies-laws/phs-policy.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.9. INTRODUCTION OF RODENTS AND RODENT PRODUCTS

No rodent or rodent product shall be delivered into the NIH, NIA environment (NIH) directly, or through collaborative research or holding facilities under contract to TBD 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, NIA 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.10. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

ARTICLE H.11. GUN CONTROL

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

ARTICLE H.12. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

b. Subcontracting Reports

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

1. Individual Subcontract Reports (ISR)

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

April 30th

October 30th

Expiration Date of Contract

2. Summary Subcontract Report (SSR)

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

October 30th

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

TBD

Contracting Officer

ARTICLE H.13. HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS

ARTICLE H.13.1. INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

A. Baseline Security Requirements

- a. **Applicability.** The requirements herein apply whether the entire contract or order (hereafter "contract"), or portion thereof, includes either or both of the following:
 - i. **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.
 - ii. **Operate a Federal System Containing Information:** A Contractor (and/or any subcontractor) will operate a federal system and 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.
- b. **Safeguarding Information and Information Systems.** All government information and information systems must be protected in accordance with HHS/NIH policies and level of risk. At a minimum, the Contractor (and/or any subcontractor) must:
 - i. Protect the:
 - **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.
 - ii. Categorize all information owned and/or collected/managed on behalf of HHS/NIH and information systems that store, process, and/or transmit HHS information 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](#)). Based on information provided by the ISSO, CISO, OpDiv SOP, or other representative, the impact level for each Security Objective (Confidentiality, Integrity, and Availability) and the Overall Impact Level, which is the highest watermark of the three factors of the information or information system are the following:

- **Confidentiality:** ☒ Low ☐ Moderate ☐ High
- **Integrity:** ☐ Low ☒ Moderate ☐ High
- **Availability:** ☒ Low ☐ Moderate ☐ High
- **Overall Risk Level:** ☒ Low ☐ Moderate ☐ High

- iii. Based on the agreed-upon level of impact, implement the necessary safeguards to protect all information systems and information collected and/or managed on behalf of HHS/NIH regardless of location or purpose.
 - iv. Report any discovered or unanticipated threats or hazards by either the agency or contractor, or if existing safeguards have ceased to function immediately after discovery, **within one (1) hour or less**, to the government representative(s).
 - v. Adopt and implement all applicable policies, procedures, controls, and standards required by the HHS/NIH 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 all applicable security and privacy policies by contacting the CO/COR or HHS/NIH security and/or privacy officials.
- c. **Privacy Act.** Comply with the Privacy Act requirements (when applicable), and tailor FAR and HHSAR clauses as needed.
- d. **Privacy Compliance.** Comply with the E-Government Act of 2002, NIST SP 800-53, and applicable HHS/OpDiv privacy policies, and complete all the requirements below:
- i. Per the Office of Management and Budget (OMB) Circular A-130, Personally Identifiable Information (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.
 - ii. Based on information provided by the ISSO, system/ data owner, or other security or privacy representative, it has been determined that this solicitation/ contract involves:

☒ No PII ☐ PII
 - iii. The Contractor must support the agency with conducting a Privacy Threshold Analysis (PTA) for the information system and/ or information handled under this contract to determine whether or not a full Privacy Impact Assessment (PIA) needs to be completed.
 - If the results of the PTA show that a full PIA is needed, the Contractor must support the agency 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*.
 - The Contractor must support the agency 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.
- e. **Controlled Unclassified Information (CUI).** Executive Order 13556 defines CUI 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. The requirements below apply only to nonfederal systems that process, store, or transmit CUI, or that provide security protection for such components. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, must be:

- i. Marked appropriately;
 - ii. Disclosed to authorized personnel on a Need-To-Know basis;
 - iii. Protected in accordance with NIST SP 800-53, *Security and Privacy Controls for 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
 - iv. Returned to HHS control, destroyed when no longer needed, or held until otherwise directed. Information and/or data must be disposed of in accordance with NIST SP 800-88, *Guidelines for Media Sanitization*.
- f. **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) must protect all government information that is or may be sensitive by securing it with a solution that is validated with current FIPS 140 validation certificate from the NIST CMVP.
- g. **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 must be used only for the purpose of carrying out the provisions of this contract and must 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 must ensure that all work performed by its employees and subcontractors must 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 must 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 must 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:
- i. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
 - ii. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and
 - iii. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).
- h. **Information and Communications Technology (ICT).** ICT products and services from prohibited entities/sources must not be used/acquired in compliance with Public Law 115-232, Section 889 Parts A and B, FAR 4.21, FAR 52.204.23, FAR 52.204.24, and FAR 52.204.25. The contractor (and/or any subcontractor) must notify the government if they identify prohibited ICT products and/or services are used during the contract performance.
- i. **Contract Documentation.** The Contractor must use provided templates, policies, forms and other agency documents. NIH will specify which documents/forms will be provided to comply with contract deliverables as appropriate.
- j. **Standard for Encryption.** The Contractor (and/or any subcontractor) must:
- i. Comply with the *HHS Standard for Encryption of Computing Devices and Information* to prevent unauthorized access to government information.
 - ii. 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 encryption solution that is validated with current FIPS 140 validation certificate from the NIST CMVP.

- iii. 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).
- iv. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with current FIPS 140 validation certificate from the NIST CMVP. The Contractor must provide a written copy of the validation documentation to the COR within **15 days** of the validation.
- v. 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 <http://csrc.nist.gov/publications/>. Encryption keys must be provided to the COR upon request and at the conclusion of the contract.
- k. **Contractor Non-Disclosure Agreement (NDA).** Each Contractor (and/or any subcontractor) employee having access to non-public government information under this contract must complete the OpDiv non-disclosure agreement, <https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf>, as applicable. Contractors (and/or subcontractors) must submit a copy of each signed and witnessed NDA to the Contracting Officer (CO) and/or CO Representative (COR) prior to performing any work under this acquisition.

2. Training Requirements

- a. **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.
- b. **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 at: <https://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/index.html>.
- c. **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.

3. Rules of Behavior

- a. The Contractor (and/or any subcontractor) must ensure that all employees performing on the contract comply with the *HHS Information Technology General Rules of Behavior*, *HHS Rules of Behavior for Privileged Users*.
- b. 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 ROB must be provided as a separate deliverable to the CO and/or COR per defined timelines above.

4. Incident Response

- a. The Contractor (and/or any subcontractor) must 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. In accordance with OMB M-17-12, *Preparing for and Responding to a Breach of Personally Identifiable Information (PII)*, an incident is "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" and a privacy breach is "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." For additional information on the HHS breach response process, please see the *HHS Policy and Plan for Preparing for and Responding to a Breach of Personally Identifiable Information (PII)*."

- b. In the event of a suspected or confirmed incident or breach, the Contractor (and/or any subcontractor) must:
- i. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract, with encryption solution that is validated with current FIPS 140 validation certificate from the NIST CMVP.
 - ii. 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 must send NIH approved notifications to affected individuals in accordance with https://wiki.ocio.nih.gov/wiki/index.php/US-CERT_Federal_Incident_Notification_Guidelines
 - iii. Report all suspected and confirmed information security and privacy incidents and breaches to the OpDiv Incident Response Team (IRT) via email at IRT@mail.nih.gov, COR, CO, OpDiv SOP (or his or her designee), and other stakeholders, including breaches 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 OpDiv 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, contact information, impact classifications/threat vector, and the type of information compromised. In addition, the Contractor must:
 - Cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
 - Not include any sensitive information in the subject or body of any reporting e-mail; and
 - Encrypt sensitive information in attachments to email, media, etc.
 - iv. Comply with OMB M-17-12, *Preparing for and Responding to a Breach of Personally Identifiable Information*, and HHS/NIH and NIH privacy breach response policies when handling PII breaches.
 - v. 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.

5. 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:

- ☐ Tier 5: Critical Sensitive and Special Sensitive National Security, including Top Secret, SCI, and "Q" access eligibility.
- ☐ Tier 5SR: Reinvestigation.
- ☐ Tier 4: High Risk Public Trust (HRPT).
- ☐ Tier 4SR: Reinvestigation.
- ☐ Tier 3: Non-Critical Sensitive, National Security, including Secret and "L" access eligibility.
- ☐ Tier 3SR: Reinvestigation.
- ☒ Tier 2S with Subject Interview: Moderate Risk Public Trust (MRPT).
- ☐ Tier 2SR: Reinvestigation.
- ☐ Tier 1: Low Risk, Non-Sensitive, including HSPD-12 Credentialing.

6. Homeland Security Presidential Directive (HSPD)-12

The Contractor (and/or any subcontractor) and its employees must comply with Homeland Security Presidential Directive (HSPD)-12, *Policy for a Common Identification Standard for Federal Employees and Contractors*; OMB M-05-24; OMB M-19-17; 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>

7. Roster

The Contractor (and/or any subcontractor) must 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 must be submitted to the COR and/or CO within **fourteen (14) calendar days** of the effective date of this contract. Any revisions to the roster as a result of staffing changes must 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://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j>

If the employee is filling a new position, the Contractor must 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.

8. Contract Initiation and Expiration

- a. **General Security Requirements.** The Contractor (and/or any subcontractor) must 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 must follow the HHS EPLC framework and methodology and in accordance with the HHS Contract Closeout Directive (2018) located at: <https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HHS-Closeout-Directive-2018.pdf>. HHS EA requirements are located at: <https://www.hhs.gov/web/governance/digital-strategy/it-policy-archive/hhs-policy-for-enterprise-architecture.html> and NIH EA requirements are located at: <https://ocio.nih.gov/PM/Pages/EPLC.aspx>.

- b. **Sanitization of Government Files and Information.** As part of contract closeout and at expiration of the contract, the Contractor (and/or any subcontractor) must 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*.
- c. **Notification.** The Contractor (and/or any subcontractor) must notify the CO and/or COR and system ISSO within fifteen days before an employee stops working under this contract.
- d. **Contractor Responsibilities upon Physical Completion of the Contract.** The Contractor (and/or any subcontractors) must 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 must 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.
- e. The Contractor (and/or any subcontractor) must perform and document the actions identified in the NIH 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 must be available to the CO and/or COR upon request.

9. Records Management and Retention

- a. The Contractor (and/or any subcontractor) must 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 Policy for Records Management* and NIH policies and must not dispose of any records unless authorized by HHS/NIH.
- b. In the event that a contractor (and/or any subcontractor) accidentally disposes of or destroys a record without proper authorization, he/she must document and report the incident in accordance with HHS/NIH policies.

10. High Value Asset (HVA)

If a system is identified as HVA, ^[23] the Contractor must comply with the HHS Policy for the High Value Asset (HVA) Program and the DHS HVA Control Overlay ^[24] in addition to the above requirements.

ARTICLE H.13.2. GOVERNMENT INFORMATION PROCESSED ON GOCO OR COCO SYSTEMS

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

- a. **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.

- b. **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:
- i. 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.
- ii. 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.
- 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.
 - Cooperate with inspections, audits, investigations, and reviews.
- d. **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.
- e. **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:

- i. Encrypt equipment and sensitive information stored and/or processed by such equipment in accordance with HHS and FIPS 140-3 encryption standards.
- ii. Configure laptops and desktops in accordance with the latest applicable United States Government Configuration Baseline (USGCB), and HHS Minimum Security Configuration Standards;
- iii. Maintain the latest operating system patch release and anti-virus software definitions within 15 days.
- iv. 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
- v. 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.
- f. **Rights to Data.** All contracts that require data to be produced, furnished, acquired, or used in meeting contract performance requirements, must contain terms that delineate the respective rights and obligations of the Government and the contractor regarding the use, reproduction, and disclosure of that data. Data rights clauses do not specify the type, quantity or quality of data that is to be delivered, but only the respective rights of the Government and the contractor regarding the use, disclosure, or reproduction of the data. Accordingly, the contract must specify the data to be delivered.
- g. **Information and Communications Technology (ICT) Cybersecurity Supply Chain Risk Management (C-SCRM) requirements.** The Contractor (and/or any subcontractor) must secure their ICT supply chain in compliance with *HHS Policy for Cyber Supply Chain Risk Management* and Public Law 115-232 § 889. At a minimum, they must implement the following:
 - i. Develop rules for suppliers' development methods, techniques, or practices;
 - ii. Use of secondary market components;
 - iii. Prohibit counterfeit products;
 - iv. Dispose and/or retain elements such as components, data, or intellectual property securely;
 - v. Ensure adequate supply of components;
 - vi. Require external providers handling federal information or operating systems on behalf of the federal government to meet the same security and privacy requirements as federal agencies;
 - vii. Require external providers to express security and privacy requirements (including the controls for systems processing, storing, or transmitting federal information) in contracts or other formal agreements;
 - viii. Establish Service Level Agreements (SLAs), patching vehicles and disclosure requirements in the case of a security incident or new vulnerability being discovered; and
 - ix. Ensure that the supplier applies same contractual requirements to any sub-contractors/suppliers that they involve in the provision of the product or service to the customer; and
 - x. Prohibit the use of covered telecommunications and video surveillance equipment or services.

ARTICLE H.14. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY NOTICE HHSAR 352.239-73 (December 2015)

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

(End of provision)

The "HHS Section 508 Product Assessment Template (PAT)" updated to the "Voluntary Product Accessibility Template (VPAT)" is included in SECTION J - List of Attachments, of this solicitation.

ARTICLE H.15. RESPONSIBILITIES OF INSTITUTIONS 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: <https://www.ecfr.gov/current/title-45/part-94>.

As required by 45 CFR Part 94.4, **Responsibilities of Institutions regarding Investigator financial conflicts of interest**, each Institution shall:

- a. Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this part, and make such policy available via a publicly accessible Web site. If the Institution does not have any current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request. If, however, the Institution acquires a presence on a publicly accessible Web site during the time of the NIH award, the requirement to post the information on that Web site will apply within 30 calendar days. If an Institution maintains a policy on financial conflicts of interest that includes standards that are more stringent than this part (e.g., that require a more extensive disclosure of financial interests), the Institution shall adhere to its policy and shall provide FCOI reports regarding identified financial conflicts of interest to the NIH Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by this part.
- b. Inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any NIH-funded contract and at least every four years, and immediately when any of the following circumstances apply:
 1. The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
 2. An Investigator is new to an Institution; or
 3. An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.
- c. If the Institution carries out the NIH-funded research through a subrecipient (e.g., subcontractors, or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this part by
 1. Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.
 - i. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this part. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;
 - ii. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the NIH as required by this part;
 - iii. Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this part.
 2. Providing FCOI reports to the NIH Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this part, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

- d. Designate an institutional 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.
- e. (1) 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 interests (and those of the Investigator's spouse and dependent children) no later than date of submission of the Institution's proposal for NIH-funded research.
 - 2. Require 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. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to [paragraph \(e\)\(1\)](#) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a NIH-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).
 - 3. Require each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.
- f. Provide guidelines consistent with this part for the designated institutional 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, through 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. The Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the NIH-funded 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.
- g. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to [paragraph \(c\)](#) of this section. 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 [§ 94.5\(a\)](#).
- h. Provide initial and ongoing FCOI reports to the NIH as required pursuant to [§ 94.5\(b\)](#).
- i. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest), and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date of final payment or, where applicable, for the time periods specified in [48 CFR part 4, subpart 4.7](#).
- j. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- k. Certify, in each contract proposal to which this part applies, that the Institution:
 - 1. Has in effect at that Institution an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the NIH;
 - 2. Shall promote and enforce Investigator compliance with this part's requirements including those pertaining to disclosure of significant financial interests;
 - 3. Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the NIH Awarding Component consistent with this part;

4. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and
5. Shall fully comply with the requirements of this part.

As required by 45 CFR Part 94.5, Management and reporting of financial conflicts of interest:

a. Management of financial conflicts of interest.

1. Prior to the Institution's expenditure of any funds under a NIH-funded research project, the designated official(s) of an Institution shall, consistent with [§ 94.4\(f\)](#) : review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to NIH-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
 - i. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
 - ii. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
 - iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, resulting from the financial conflict of interest;
 - iv. Modification of the research plan;
 - v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
 - vi. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
 - vii. Severance of relationships that create financial conflicts.
2. Whenever, in the course of an ongoing NIH-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the designated official(s) of the Institution shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to NIH-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-funded research project between the date of disclosure and the completion of the Institution's review.
3. Whenever an Institution identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to NIH-funded research; determine whether a financial conflict of interest exists; and, if so:
 - i. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
 - ii. (A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution's determination of

noncompliance, complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

B. The Institution is required to document the retrospective review; such documentation shall include, but not necessarily be limited to, all of the following key elements:

1. Project number;
2. Project title;
3. PD/PI or contact PD/PI if a multiple PD/PI model is used;
4. Name of the Investigator with the FCOI;
5. Name of the entity with which the Investigator has a financial conflict of interest;
6. Reason(s) for the retrospective review;
7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);
8. Findings of the review; and
9. Conclusions of the review.

iii. Based on the results of the retrospective review, if appropriate, the Institution shall update the previously submitted FCOI report, specifying the actions that will be taken to manage the financial conflict of interest going forward. If bias is found, the Institution is required to notify the NIH Awarding Component promptly and submit a mitigation report to the NIH Awarding Component. The mitigation report must include, at a minimum, the key elements documented in the retrospective review above and a description of the impact of the bias on the research project and the Institution's plan of action or actions taken to eliminate or mitigate the effect of the bias (e.g., impact on the research project; extent of harm done, including any qualitative and quantitative data to support any actual or future harm; analysis of whether the research project is salvageable). Thereafter, the Institution will submit FCOI reports annually, as specified elsewhere in this part. Depending on the nature of the financial conflict of interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

4. Whenever an Institution implements a management plan pursuant to this part, the Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the NIH-funded research project.
5. (i) Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:
 - A. The significant financial interest was disclosed and is still held by key personnel as defined in this part;
 - B. The Institution determines that the significant financial interest is related to the NIH-funded research; and

C. The Institution determines that the significant financial interest is a financial conflict of interest.

- ii. The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: The Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.
 - iii. If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the NIH-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the NIH-funded research project, if the Institution determines that the significant financial interest is related to the NIH-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.
 - iv. Information concerning the significant financial interests of an individual subject to [paragraph \(a\)\(5\)](#) of this section shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.
6. In addition to the types of financial conflicts of interest as defined in this part that must be managed pursuant to this section, an Institution may require the management of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

b. Reporting of financial conflicts of interest.

- 1. Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution shall provide to the NIH Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this part. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of NIH-awarded funds, the Institution shall not submit an FCOI report to the NIH Awarding Component.
- 2. For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing NIH-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the NIH Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this part.

Pursuant to [paragraph \(a\)\(3\)\(ii\)](#) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also is required to complete a retrospective review to determine whether any NIH-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to [paragraph \(a\)\(3\)\(iii\)](#) of this section, if bias is found, the Institution is required to notify the NIH Awarding Component promptly and submit a mitigation report to the NIH Awarding Component.

3. Any FCOI report required under [paragraphs \(b\)\(1\)](#) or [\(b\)\(2\)](#) of this section shall include sufficient information to enable the NIH Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:
 - i. Project/Contract number;
 - ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
 - iii. Name of the Investigator with the financial conflict of interest;
 - iv. Name of the entity with which the Investigator has a financial conflict of interest;
 - v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
 - vi. Value of the financial interest (dollar ranges are permissible: \$0-\$4,999; \$5,000-\$9,999; \$10,000-\$19,999; amounts between \$20,000-\$100,000 by increments of \$20,000; amounts above \$100,000 by increments of \$50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
 - vii. A description of how the financial interest relates to the NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
 - viii. A description of the key elements of the Institution's management plan, including:
 - A. Role and principal duties of the conflicted Investigator in the research project;
 - B. Conditions of the management plan;
 - C. How the management plan is designed to safeguard objectivity in the research project;
 - D. Confirmation of the Investigator's agreement to the management plan;
 - E. How the management plan will be monitored to ensure Investigator compliance; and
 - F. Other information as needed.
4. For any financial conflict of interest previously reported by the Institution with regard to an ongoing NIH-funded research project, the Institution shall provide to the NIH Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the NIH-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Institution shall provide annual FCOI reports to the NIH Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the NIH Awarding Component.
5. In addition to the types of financial conflicts of interest as defined in this part that must be reported pursuant to this section, an Institution may require the reporting of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

ARTICLE H.16. 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 Institute on Aging, National Institutes of Health, Department of Health and Human Services, under Contract No. TBD"

ARTICLE H.17. 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: <https://oig.hhs.gov/fraud/report-fraud/> 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.18. 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.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** (Aug 2016) of FAR Clause **52.215-2, Audit and Records--Negotiation** (Jun 2020) is added.
- b. FAR Clause **52.215-23, Limitations on Pass-Through Charges** (Jun 2020), is added.
- c. **Alternate II** (Nov 2016) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (Oct 2022) is added.
- d. FAR Clauses **52.249-6, Termination (Cost-Reimbursement)** (May 2004) and **52.249-14, Excusable Delays** (Apr 1984), are deleted in their entirety and FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)** (Aug 2016), is substituted therefore.

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** (Nov 2021).
2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (Nov 2021).

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

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	https://core-docs.s3.amazonaws.com/documents/asset/uploaded_file/576385/OIG_Hotline_Poster_1_.pdf

3. FAR Clause **52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts** (Oct 2016).
4. FAR Clause **52.209-10, Prohibition on Contracting with Inverted Domestic Corporations** (Nov 2015).
5. FAR Clause **52.210-1, Market Research** (Nov 2021).
6. FAR Clause **52.216-15, Predetermined Indirect Cost Rates** (Apr 1998).
7. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (Oct 2022).

"(c) Waiver of evaluation preference.....
☐ Offeror elects to waive the evaluation preference."
8. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (Oct 2022).
9. FAR Clause **52.222-26, Equal Opportunity** (Sep 2016).
10. FAR Clause **52.222-53, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Requirements** (May 2014).
11. **Alternate IV** (Dec 2007), FAR Clause **52.227-14, Rights in Data - General** (May 2014).
12. FAR Clause **52.230-2, Cost Accounting Standards** (Jun 2020).

13. FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (Jun 2020).
 14. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (Jun 2020).
 15. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (Jun 2010).
 16. FAR Clause **52.237-3, Continuity of Services** (Jan 1991).
 17. FAR Clause **52.239-1, Privacy or Security Safeguards** (Aug 1996).
 18. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2014).
 19. FAR Clause **52.243-2, Changes--Cost Reimbursement** (Aug 1987), **Alternate V** (Apr 1984).
 20. FAR Clause **52.246-23, Limitation of Liability** (Feb 1997).
- 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 **352.231-70, 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.)

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** (Nov 2021)

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 products, 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 **52.204-24, Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment** (Nov 2021)

The Offeror shall not complete the representation at paragraph (d)(1) of this provision if the Offeror has represented that it "does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument" in paragraph (c)(1) in the provision at [52.204-26](#), Covered Telecommunications Equipment or Services-Representation, or in paragraph (v)(2)(i) of the provision at [52.212-3](#), Offeror Representations and Certifications-Commercial Items. The

Offeror shall not complete the representation in paragraph (d)(2) of this provision if the Offeror has represented that it "does not use covered telecommunications equipment or services, or any equipment, system, or service that uses covered telecommunications equipment or services" in paragraph (c)(2) of the provision at [52.204-26](#), or in paragraph (v)(2)(ii) of the provision at [52.212-3](#).

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

Backhaul, covered telecommunications equipment or services, critical technology, interconnection arrangements, reasonable inquiry, roaming, and substantial or essential component have the meanings provided in the clause [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.

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. Nothing in the prohibition shall be construed to-

- i. Prohibit the head of an executive agency from procuring with an entity to provide a service that connects to the facilities of a third- party, such as backhaul, roaming, or interconnection arrangements; or
- ii. Cover telecommunications equipment that cannot route or redirect user data traffic or cannot permit visibility into any user data or packets that such equipment transmits or otherwise handles.

(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. 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. Nothing in the prohibition shall be construed to-

- i. Prohibit the head of an executive agency from procuring with an entity to provide a service that connects to the facilities of a third- party, such as backhaul, roaming, or interconnection arrangements; or
- ii. Cover telecommunications equipment that cannot route or redirect user data traffic or cannot permit visibility into any user data or packets that such equipment transmits or otherwise handles.

c. *Procedures.* The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (<https://www.sam.gov>) for entities excluded from receiving federal awards for" covered telecommunications equipment or services".

d. *Representation.* The Offeror represents that-

(1) It [] will, [] will not provide covered telecommunications equipment or services to the Government in the performance of any contract, subcontract or other contractual instrument resulting from this solicitation. The Offeror shall provide the additional disclosure information required at paragraph (e)(1) of this section if the Offeror responds "will" in paragraph (d)(1) of this section; and

(2) After conducting a reasonable inquiry, for purposes of this representation, the Offeror represents that-

It [] does, [] does not use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services. The Offeror shall provide the additional disclosure information required at paragraph (e)(2) of this section if the Offeror responds " does" in paragraph (d)(2) of this section.

- e. *Disclosures.* (1) Disclosure for the representation in paragraph (d)(1) of this provision. If the Offeror has responded "will" in the representation in paragraph (d)(1) of this provision, the Offeror shall provide the following information as part of the offer:

i. For covered equipment-

- (A) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the original equipment manufacturer (OEM) or a distributor, if known).
- (B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and
- (C) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

ii. For covered services-

- (A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or
- (B) If not associated with maintenance, the Product Service Code (PSC) of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(1) of this provision.

- (2) Disclosure for the representation in paragraph (d)(2) of this provision. If the Offeror has responded " does" in the representation in paragraph (d)(2) of this provision, the Offeror shall provide the following information as part of the offer:

iii. For covered equipment-

- (A) The entity that produced the covered telecommunications equipment (include entity name, unique entity identifier, CAGE code, and whether the entity was the OEM or a distributor, if known).
- (B) A description of all covered telecommunications equipment offered (include brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); and
- (C) Explanation of the proposed use of covered telecommunications equipment and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of this provision.

iv. For covered services-

- (A) If the service is related to item maintenance: A description of all covered telecommunications services offered (include on the item being maintained: Brand; model number, such as OEM number, manufacturer part number, or wholesaler number; and item description, as applicable); or
- (B) If not associated with maintenance, the PSC of the service being provided; and explanation of the proposed use of covered telecommunications services and any factors relevant to determining if such use would be permissible under the prohibition in paragraph (b)(2) of this provision.

(End of provision)

3. FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (Oct 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 (SAM) database at <https://sam.gov/content/home>.
- 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).

4. FAR Clause **FAR 52.204-26, Covered Telecommunications Equipment or Services-Representation** (Oct 2020)

- a. *Definitions.* As used in this provision, "covered telecommunications equipment or services" and "reasonable inquiry" have the meaning provided in the clause [52.204-25](#), Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment.
- b. *Procedures.* The Offeror shall review the list of excluded parties in the System for Award Management (SAM) (<https://www.sam.gov>) for entities excluded from receiving federal awards for "covered telecommunications equipment or services".
- c. (1) *Representation.* The Offeror represents that it [] does, [] does not provide covered telecommunications equipment or services as a part of its offered products or services to the Government in the performance of any contract, subcontract, or other contractual instrument.

(2) After conducting a reasonable inquiry for purposes of this representation, the offeror represents that it [] does, [] does not use covered telecommunications equipment or services, or any equipment, system, or service that uses covered telecommunications equipment or services.

(End of provision)

5. FAR Clause **52.216-18, Ordering** (Aug 2020).

- a. Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from 09/30/2023 through 09/29/2033 .
- b. All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.
- c. If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of clause).

6. FAR Clause **52.216-19, Order Limitations** (Oct 1995).

- a. **Minimum Order.** When the Government requires supplies or services covered by this contract in an amount of less than \$374,599, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.
- b. **Maximum Order.** The Contractor is not obligated to honor--
 - 1. Any order for a single item in excess of \$31,925,107.
 - 2. Any order for a combination of items in excess of \$31,925,107; or
 - 3. A series of orders from the same ordering office within 30 days that together call for quantities exceeding the limitation in subparagraph (1) or (2) above.
- c. If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) above.
- d. Notwithstanding paragraphs (b) and (c) above, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to

the ordering office within 7 days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

(End of clause).

7. FAR Clause **52.216-22, Indefinite Quantity** (Oct 1995)

- a. This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.
- b. Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."
- c. Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.
- d. Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after 09/29/2034 .

(End of clause).

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

HH\$AR 352.232-71 Electronic Submission of Payment Requests (February 2, 2022).

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

Payment request means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at <https://www.ipp.gov> or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(End of clause).

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposals for Use with the NIH electronic Contract Proposal Submission (eCPS) Website	See Attached
Attachment 2:	Proposal Intent Response Sheet	See Attached
Attachment 3:	Statement of Work	See Attached
Attachment 4:	Reporting Requirements and Other Deliverables	See Attached
Attachment 5:	Section K - Representations, Certifications, and Other Statements of Offerors	See Attached

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 6:	Technical Proposal Cost Summary	https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf
Attachment 7:	Summary of Related Activities	https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf
Attachment 8:	Contract Proposal Vertebrate Animal Section (VAS) Worksheet	https://grants.nih.gov/grants/olaw/vascontracts.pdf
Attachment 9:	Voluntary Product Accessibility Template (VPAT)	https://www.section508.gov/sell/vpat/

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 10:	Proposal Summary and Data Record, NIH-2043	https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf
Attachment 11:	Small Business Subcontracting Plan	https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j
Attachment 12:	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 and https://oamp.od.nih.gov/sites/default/files/DFASDocs/buscntrectprpslsprdsht08-2014_508.xlsx
Attachment 13:	Offeror's Points of Contact	https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf

Attachment No.	Title	Location
Attachment 14:	Certificate of Current Cost or Pricing Data	https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/cert-current-cost.pdf
Attachment 15:	Disclosure of Lobbying Activities, OMB Form SF-LLL	https://www.gsa.gov/forms-library/disclosure-lobbying-activities
Attachment 16:	Additional Business Proposal Instructions	See Attached
Attachment 17:	Proposed Task Order 1	See Attached

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 18:	Invoice/Financing Request Instructions-CR-NIH(RC)-1	https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j
Attachment 19:	NIDA Supplemental Billing Instructions, Exhibit A to NIH(RC)-1	https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j
Attachment 20:	Commitment to Protect Non-Public Information Contractor Agreement	https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf
Attachment 21:	Roster of Employees Requiring Suitability Investigations	https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j
Attachment 22:	Employee Separation Checklist	https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf
Attachment 23:	Electronic Invoicing Instructions for NIH Contractors/Vendors	<ol style="list-style-type: none"> 1. Electronic Invoicing Instructions Notification to NIH Contractors/Vendors, located at: https://oamp.od.nih.gov/sites/default/files/dgs/Communication%20to%20Vendors%20on%20Deadline%20to%20Stop%20Accepting%20Mailed%20Invoice%20Final%2011-4-20-508.pdf 2. Electronic Invoicing Step-by-Step Instructions for NIH Contractors/Vendors, located at: https://oamp.od.nih.gov/sites/default/files/DGS/Electronic Invoicing Step-by-Step Instructions 7-22.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the **System for Award Management (SAM)** and complete the Representations and Certifications. The SAM website may be accessed at: <https://www.sam.gov/content/home>; 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 52.215-1 (Nov 2021)**

(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. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall-

(1) Mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed-in whole or in part-for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of-or in connection with-the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]; and

(2) Mark each sheet of data it wishes to restrict with the following legend:

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

(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 the 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 products, the make and model of the product 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 (Oct 1997). As prescribed in FAR 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

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

b. NAICS CODE AND SIZE STANDARD

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

1. The North American Industry Classification System (NAICS) code for this acquisition is 112990.
2. The small business size standard is \$1,000,000.

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(s) will be made on/about September 30, 2023.
2. It is anticipated that the award(s) from this solicitation will be an IDIQ type contract with ten (10) year ordering period. (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 116 FTEs. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

Labor Hours

Year 1- Task Order 1	Year 2- Task Order 2	Year 3- Task Order 3	Year 4- Task Order 4	Year 5- Task Order 5	Year 6- Task Order 6	Year 7- Task Order 7	Year 8- Task Order 8	Year 9- Task Order 9	Year 10- Task Order 10
1 FTE	3 FTEs	10 FTEs	15 FTEs	19 FTEs	19 FTEs	19 FTEs	14 FTEs	10 FTEs	6 FTEs

e. COMMITMENT OF PUBLIC FUNDS

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

f. COMMUNICATIONS PRIOR TO CONTRACT AWARD

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

g. RELEASE OF INFORMATION

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

h. PREPARATION COSTS

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

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

(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
C/O NIH Mail Center
NIDA 3WFN MSC 6023
16071 INDUSTRIAL DRIVE

GAITHERSBURG, MD 20892- ____

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

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

1. Contract Type and General Clauses

It is contemplated that an Indefinite-Delivery Indefinite-Quantity (IDIQ) 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, Unique Entity Identifier (UEI) No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

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

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

5. **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and 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.

6. **Evaluation of Proposals**

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

7. **Potential Award Without Discussions**

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

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

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

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

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

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

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

9. Privacy Act - Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

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

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

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

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

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

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

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

10. Selection of Offerors

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

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

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

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

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

While it is NIA's policy to conduct discussions with all offerors in the competitive range, NIA reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR Part 315.

- e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.
- f. The NIA 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 NIA requirements. Synopses of awards exceeding \$25,000 will be published in Contract Opportunities at: <https://sam.gov/content/home>

11. 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: <https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94>

12. 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.

13. Certification Regarding Tax Matters, FAR 52.209-12 (Oct 2020)

(a) This implements section 523 of Division B of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113- 235), and similar provisions, if contained in subsequent appropriations acts.

(b) If the Offeror is proposing a total contract price that will exceed \$5.5 million (including options), the Offeror shall certify that, to the best of its knowledge and belief, it

(1) Has ☐ filed all Federal tax returns required during the three years preceding the certification;

(2) Has ☐ been convicted of a criminal offense under the Internal Revenue Code of 1986; and

(3) 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.

(End of provision)

14. Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation, FAR 52.203-18 (Jan 2017)

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

Internal confidentiality agreement or statement, subcontract, and subcontractor, are defined in the clause at [52.203-19](#), Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements.

b. In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use funds appropriated (or otherwise made available) for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, 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.

c. The prohibition in paragraph (b) of this provision does not contravene requirements applicable to Standard Form 312, (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

d. *Representation.* By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or

statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(End of provision)

15. Past Performance Information

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

A list of the last 3 contracts completed during the past Three years and THE LAST 5 CONTRACTS AWARDED 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. Include the following information for each contract or subcontract listed:

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

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

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

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

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 and 732 of Title 5, Code of Federal Regulations (CFR). To determine the designation, the Position Designation Tool (PDT) discussion is found at: <https://www.ors.od.nih.gov/ser/dpsac/resources/Pages/investigation-requirements-for-your-position.aspx> and the link to access the tool is found at: <https://pdt.nbis.mil/>

The following position sensitivity designation levels apply to this solicitation/contract:

☐ Tier 5: Critical Sensitive and Special Sensitive National Security, including Top Secret, SCI, and "Q" access eligibility.

☐ Tier 5SR: Reinvestigation.

☐ Tier 4: High Risk Public Trust (HRPT).

☐ Tier 4SR: Reinvestigation.

☐ Tier 3: Non-Critical Sensitive, National Security, including Secret and "L" access eligibility.

☐ Tier 3SR: Reinvestigation.

☒ Tier 2S with Subject Interview: Moderate Risk Public Trust (MRPT).

☐ Tier 2SR: Reinvestigation.

☐ Tier 1: Low Risk, Non-Sensitive, including HSPD-12 Credentialing.

HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

The Contractor (and/or any subcontractor) and its employees must 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-

1. 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 C use at: <https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j>.
2. 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.

3. 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.
4. 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.
5. 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.
6. 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.
7. Typically, the Government investigates personnel at no cost to the Contractor. However, multiple investigations for the same position may, at the Contracting Officer's discretion, justify reduction(s) in the contract price of no more than the cost of the additional investigation(s).
8. 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).
9. The Contractor shall direct inquiries, including requests for forms and assistance, to the Contracting Officer or designee.
10. 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. Standard for Encryption

The Contractor (and/or any subcontractor) shall:

1. Comply with the HHS Standard for Encryption of Computing Devices and Information to prevent unauthorized access to government information.
2. 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 140-3 validated encryption solution.
3. 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).
4. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with FIPS 140-3. The Contractor shall provide a written copy of the validation documentation to the Contracting Officer and the Contracting Officer Technical Representative within 15 days of the validation.
5. 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:

1. A (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.
2. 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 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.
 - 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.
 - 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
 - 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 ☐ Moderate ☐ High

Integrity: ☐ Low ☒ Moderate ☐ High

Availability: ☒ Low ☐ Moderate ☐ High

Overall Risk Level: ☒ Low ☐ Moderate ☐ High

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

☒ No PII ☐ Yes

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 Directive (2018) located at: <https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HHS-Closeout-Directive-2018.pdf>. HHS Enterprise Architecture (EA) requirements are located at: <https://www.hhs.gov/sites/default/files/eplc-policy-dec-2016.pdf>
2. **System Documentation-** Contractors (and/or any subcontractors) must follow and adhere to NIST SP 800-160, Systems Security Engineering: Considerations for a Multidisciplinary Approach in the Engineering of Trustworthy Secure Systems, 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 Employee Separation
7. 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.

L. 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://www.hhs.gov/about/agencies/asa/ocio/cybersecurity/security-awareness-training/index.html>
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.

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/aboutus/publicinfosecurity/securitytraining/Pages/NIH_IT_GeneralRulesofBehavior.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 one(1) hour of discovery, 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 140-3 validated encryption.
2. DO 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 in accordance with https://wiki.ocio.nih.gov/wiki/index.php/US-CERT_Federal_Incident_Notification_Guidelines.
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:

- cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
 - not include any sensitive information in the subject or body of any reporting e- mail; and
 - 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.

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 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:

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.

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

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

(End of provision)

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

18. Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (Feb 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 (Oct 2018)
Alternate I (Oct 2018) 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, (Oct 1997).
- d. Limitations on Pass-Through Charges--Identification of Subcontract Effort, FAR Provision 52.215-22, (Oct 2009).
- e. Preaward On-Site Equal Opportunity Compliance Evaluation, (\$10,000,000 or Over), FAR Clause 52.222-24, (Feb 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

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

1. Technical Discussions

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

a. Statement of Work

1. Objectives

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

2. Approach

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

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

3. Methods

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

4. Schedule

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

b. Personnel

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

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

1. Single Principal Investigator/Project Director

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

2. Other Investigators

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

3. Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis.

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

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

4. Resumes

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

2. Other Considerations

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

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

3. Technical Evaluation

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

4. 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, 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, MD 20892-6910 (Email: olaw@od.nih.gov; Phone: 301-496-7163).

The PHS Policy is available on the internet at: <https://olaw.nih.gov/>.

(End of provision)

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: <https://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](#).

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. Certified Cost or Pricing Data

a. General Instructions

A. You must provide the following information 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 of contract administration office (if available);
5. Type of contract action (that is, new contract, change order, price revision/ redetermination, letter contract, unpriced order, or other);
6. Proposed cost; profit or fee; and total;
7. Whether you will require the use of Government property in the performance of the contract, and, if so, what property. See Item 16. Other Administrative Data, subparagraph a.2. Government Property of this Section L.2.c of this solicitation;
8. Whether your organization is subject to cost accounting standards; whether your organization has submitted a CASB Disclosure Statement, and if it has been determined adequate; whether you have been notified that you are or may be in noncompliance with your Disclosure Statement or CAS, and, if yes, an explanation; whether any aspect of this proposal is inconsistent with your disclosed practices or applicable CAS, and, if so, an explanation; and whether the proposal is consistent with your established estimating and accounting principles and procedures and FAR Part 31, Cost Principles, and, if not, an explanation;
9. The following statement: This proposal reflects our estimates and/or actual costs as of this date and conforms with the instructions in FAR 15.403 5(b)(1) and Table 15 2. By submitting this proposal, we grant the Contracting Officer and authorized representative(s) the right to examine, at any time before award, those records, which include books, documents, accounting procedures and practices, and other data, regardless of type and form or whether such supporting information is specifically referenced or included in the proposal as the basis for pricing, that will permit an adequate evaluation of the proposed price;
10. Date of submission; and
11. Name, title and signature of authorized representative.

B. In submitting your proposal, you must include an index, appropriately referenced, of all the certified cost or pricing data and information accompanying or identified in the proposal. In addition, you must annotate any future additions and/or revisions, up to the date of agreement on price, or an earlier date agreed upon by the parties, on a supplemental index.

C. As part of the specific information required, you must submit, with your proposal, certified cost or pricing data (as defined at FAR 2.101). You must clearly identify on your cover

sheet that certified cost or pricing data are included as part of the proposal. In addition, you must submit with your proposal any information reasonably required to explain your estimating process, including

1. The judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data; and
 2. The nature and amount of any contingencies included in the proposed price.
- D. You must show the relationship between contract line item prices and the total contract price. You must attach cost element breakdowns for each proposed line item, using the appropriate format prescribed in the "Formats for Submission of Line Item Summaries" section of this table. You must furnish supporting breakdowns for each cost element, consistent with your cost accounting system.
- E. When more than one contract line item is proposed, you must also provide summary total amounts covering all line items for each element of cost.
- F. Whenever you have incurred costs for work performed before submission of a proposal, you must identify those costs in your cost/price proposal.
- G. If you have reached an agreement with Government representatives on use of forward pricing rates/factors, identify the agreement, include a copy, and describe its nature.
- H. As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406 2, submit a Certificate of Current Cost or Pricing Data.

b. **Cost Elements**

Depending on your system, you must provide breakdowns for the following basic cost elements, as applicable:

- A. **Materials and services.** Provide a consolidated priced 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.). Include raw materials, parts, components, assemblies, and services to be produced or performed by others. For all items proposed, identify the item and show the source, quantity, and price. Conduct price analyses of all subcontractor proposals. Conduct cost analyses for all subcontracts when certified cost or pricing data are submitted by the subcontractor. Include these analyses as part of your own certified cost or pricing data submissions for subcontracts expected to exceed the appropriate threshold in FAR 15.403-4. Submit the subcontractor certified cost or pricing data as part of your own certified cost or pricing data as required in paragraph A.2. below. These requirements also apply to all subcontractors if required to submit certified cost or pricing data.
1. *Adequate Price Competition.* Provide data showing the degree of competition and the basis for establishing the source and reasonableness of price for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding, or expected to exceed, the appropriate threshold set forth at FAR 15.403-4 priced on the basis of adequate price competition. For interorganizational transfers priced at other than the cost of comparable competitive commercial work of the division, subsidiary, or affiliate of the contractor, explain the pricing method (see FAR 31.205 26(e)).
 2. *All Other.* Obtain certified cost or pricing data from prospective sources for those acquisitions (such as subcontracts, purchase orders, material order, etc.) exceeding the threshold set forth in FAR 15.403-4 and not otherwise exempt, in accordance with FAR 15.403-1(b) (i.e., adequate price competition, commercial items, prices set by

law or regulation or waiver). Also provide data showing the basis for establishing source and reasonableness of price. In addition, provide a summary of your cost analysis and a copy of certified cost or pricing data submitted by the prospective source in support of each subcontract, or purchase order that is the lower of either \$12.5 million or more, or both more than the pertinent cost or pricing data threshold and more than 10 percent of the prime contractor's proposed price. Also submit any information reasonably required to explain your estimating process (including the judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data, and the nature and amount of any contingencies included in the price). The Contracting Officer may require you to submit certified cost or pricing data in support of proposals in lower amounts. Subcontractor certified cost or pricing data must be accurate, complete and current as of the date of final price agreement, or an earlier date agreed upon by the parties, given on the prime contractor's Certificate of Current Cost or Pricing Data. The prime Contractor is responsible for updating a prospective subcontractor's data. For standard commercial items fabricated by the offeror that are generally stocked in inventory, provide a separate cost breakdown, if priced based on cost. For interorganizational transfers priced at cost, provide a separate breakdown of cost elements. Analyze the certified cost or pricing data and submit the results of your analysis of the prospective source's proposal. When submission of a prospective source's certified cost or pricing data is required as described in this paragraph, it must be included, along with your own certified cost or pricing data submission, as part of your own certified cost or pricing data. You must also submit any other certified cost or pricing data obtained from a subcontractor, either actually or by specific identification, along with the results of any analysis performed on that data.

- B. **Direct Labor.** Provide a time phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category, and furnish bases for estimates.
- C. **Indirect Costs.** Indicate how you have computed and applied your indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation.
- D. **Other Costs.** List all other costs not otherwise included in the categories described above (e.g., special tooling, travel, computer and consultant services, preservation, packaging and packing, spoilage and rework, and Federal excise tax on finished articles) and provide bases for pricing.
- E. **Royalties.** If royalties exceed \$1,500, you must provide the following information on a separate page for each separate royalty or license fee:
 - 1. Name and address of licensor.
 - 2. Date of license agreement.
 - 3. Patent numbers.
 - 4. Patent application serial numbers, or other basis on which the royalty is payable.
 - 5. Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
 - 6. Percentage or dollar rate of royalty per unit.
 - 7. Unit price of contract item.
 - 8. Number of units.
 - 9. Total dollar amount of royalties.

10. If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.202 and 31.205-37).

F. **Facilities Capital Cost of Money.** When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB CMF and show the calculation of the proposed amount (see FAR 31.205 10).

c. **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (Section J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

d. **General Information**

- A. There is a clear distinction between submitting certified cost or pricing data and merely making available books, records, and other documents without identification. The requirement for submission of certified cost or pricing data is met when all accurate cost or pricing data reasonably available to the offeror have been submitted, either actually or by specific identification, to the Contracting Officer or an authorized representative. As later information comes into your possession, it should be submitted promptly to the Contracting Officer in a manner that clearly shows how the information relates to the offeror's price proposal. The requirement for submission of certified cost or pricing data continues up to the time of agreement on price, or an earlier date agreed upon between the parties if applicable.
- B. By submitting your proposal, you grant the Contracting Officer or an authorized representative the right to examine records that formed the basis for the pricing proposal. That examination can take place at any time before award. It may include those books, records, documents, and other types of factual information (regardless of form or whether the information is specifically referenced or included in the proposal as the basis for pricing) that will permit an adequate evaluation of the proposed price.

3. **Requirements for Certified Cost or Pricing Data and Data Other than Certified Cost or Pricing Data, FAR Clause 52.215-20 (Nov 2021)**

(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 paragraphs. 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 product and commercial service exception.* For a commercial product and commercial service exception, the offeror shall submit, at a minimum, information on prices at

which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include:

- (A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
- (B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
- (C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

(b) *Requirements for certified cost or pricing data.* If the offeror is not granted an exception from the requirement to submit certified cost or pricing data, the following applies:

- (1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.
- (2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

Alternate I (October 2010) of FAR Clause **52.215-20, Requirements for Certified Cost or Pricing Data and Data Other than Cost or Pricing Data** (Nov 2021). As prescribed in 15.408(l)(and see 15.403-5(b)(1)), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

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

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

4. 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.

5. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$700,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

- a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
- b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c. The offeror understands that:
 1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
 2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
 3. If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

4. Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
 5. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
 6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d. Each plan must contain the following:
1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
 2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
 4. A description of the method used to develop the subcontracting goals.
 5. A description of the method used to identify potential sources for solicitation purposes.
 6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
 7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
 8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
 9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$700,000 adopt a plan similar to the plan agreed upon by the offeror.
 10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government.
 11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small

Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

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

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

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

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

- a. Large business prime Contractors serving as mentors in the HHS Mentor-Protege Program are eligible for HHS subcontracting plan credit, and shall submit a copy of their HHS Office of Small and Disadvantaged Business Utilization (OSDBU) approved mentor-protege agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protege firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at <https://www.esrs.gov/>. The mentor firm and protege firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a \$10,000 subcontract awarded to a protege firm and provision of \$5,000 of developmental assistance as \$15,000 of subcontracting plan credit.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.
- b. The program consists of--
 1. Mentor firms--large businesses that:
 - (i) Demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and
 - (ii) Have a Mentor-Protege agreement approved by HHS' OSDBU;
 2. Protege firms--firms that:
 - (i) Seek developmental assistance;
 - (ii) Qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned small businesses; and
 - (iii) Have a Mentor-Protege agreement approved by HHS' OSDBU; and
 3. Mentor-Protege agreements--joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

7. 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>.

8. 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.

9. 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 (Jul 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:

1. Complies with Generally Accepted Accounting Principles (GAAP).
2. Provides for:
 - a. Proper segregation of direct costs from indirect costs.

- b. Identification and accumulation of direct costs by contract.
 - c. A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
 - d. Accumulation of costs under general ledger control.
 - e. A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
 - f. A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
 - g. Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
 - h. 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.
 - i. 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.
 - j. Segregation of preproduction costs from production costs, if applicable.
3. Accounting system provides financial information:
- a. Required by contract clause concerning limitation of cost (FAR 52.232-20) or limitation on payments (FAR 52.216-16).
 - b. Required to support requests for progress payments.
4. 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.
5. 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. Facilities Capital Cost of Money, FAR 52.215-16, (Jun 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.

10. **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.

11. **Subcontractors**

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

- a. Willingness to perform as a subcontractor for specific duties (list duties).
- b. What priority the work will be given and how it will relate to other work.
- c. The amount of time and facilities available to this project.

- d. Information on their cognizant field audit offices.
- e. How rights to publications and patents are to be handled.
- f. A complete cost proposal in the same format as the offeror's cost proposal.

12. Proposer's Annual Financial Report

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

13. Travel Costs/Travel Policy

a. Travel Costs - Commercial

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

b. Travel Policy

One copy of the offeror's (and any proposed subcontractor's) written travel policy shall be included in the business proposal (original only). If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

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. TECHNICAL EVALUATION FACTORS

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

A. Facilities (40 Points)

- Suitability of facilities for re-derivation, breeding and maintenance of the rat strains required in this project, including but not limited to a minimum of two helicobacter-free barrier facilities.
- Demonstrated effectiveness of environment controls.
- Demonstrated effectiveness of back-up support system for barrier facility.
- Demonstrated systems of effective customer service and animal distribution.

B. Experience (40 Points)

- Documented evidence of key personnel having experience in breeding, rearing and maintaining animal colonies of similar magnitude and having similar health and environmental requirements as those listed in the Statement of Work.
- Documented capability to re-derive the breeding rats by embryo transfer.
- Demonstrated ability to maintain an effective barrier for an extended period (10 years).
- Evidence of a corps of personnel trained in breeding, rearing, and maintaining animal colonies having similar health and environmental requirements.
- Evidence of effective on-the-job training for new employees through proven training programs and experienced instructors.
- Demonstrated capability of providing excellent customer service and ability to distribute animals to investigators in a safe and timely manner.

C. Awareness (20 Points)

- Demonstrated awareness of problems and complications likely to be observed in the conduct of this project and methods to address them.

- Demonstrated awareness and knowledge of the importance of maintenance of the high standard of health and genetic purity.
- Suitability of a plan to deal with accidental contamination or environmental emergencies.

TOTAL POSSIBLE POINTS: 100

5. EVALUATION OF ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY - SECTION 508

The offeror's proposal must demonstrate compliance with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194 for all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order, including EIT deliverables such as electronic documents and reports.

If your proposal does not include a completed HHS "Section 508 Product Assessment Template" (hereafter referred to as the "Template") which demonstrates that EIT products and services proposed support applicable Section 508 accessibility standards, or, if the completed "Template" included in your proposal is considered "noncompliant," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify the "Template" during discussions and in your Final Proposal Revision (FPR). If your "Template" is still considered "noncompliant" by the Government after discussions, your proposal may not be considered further for award.

6. PAST PERFORMANCE FACTOR

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

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

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

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 will focus on the past performance of the offeror as it relates to all acquisition requirements, such as the offeror's record of performing according to specifications, including standards of good workmanship; the offeror's record of controlling and forecasting costs; the offeror's adherence to contract schedules, including the administrative aspects of performance; the offeror's reputation for reasonable and cooperative behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

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.

Attachment 1 - Packaging and Delivery of Proposals for Use with the NIH electronic Contract Proposal Submission (eCPS) Website

I. PROPOSAL SUBMISSION

A. eCPS

1. Proposals must be submitted via the electronic Contract Proposal Submission (eCPS) website at <https://ecps.nih.gov>.
2. Proposals submitted by facsimile or e-mail will not be accepted.
3. Follow the “How to Submit an Electronic Proposal” instructions provided on the eCPS website at: <https://ecps.nih.gov/home/howto>. Please note that creating an account to submit may take up to three (3) business days. Please apply for a new account early to allow enough time for the registration process.
4. Offerors are solely responsible for submitting proposals and any modifications or revisions so as to reach the Government office designated above by the date and time specified in the solicitation. If your proposal is not received by the date and time specified in the solicitation, it will be considered a “late proposal,” in accordance with **FAR Clause 52.215-1 Instructions to Offerors – Competitive Acquisition**.

B. Creating and Naming Files:

1. **Create one PDF file of your Technical Proposal, including all attachments.** The Technical Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned, but must be merged into the Technical Proposal PDF file.

2. **Create one PDF file of your Business Proposal, including all attachments:**

The Business Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned, but must be merged into the Business Proposal PDF file.

Additionally, the “Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet” (http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx) must be included in the Business Proposal.

3. **Create your Business Document Excel.** The Excel file should be the “Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet” (http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx) included in the Business Proposal in its original Excel format, not PDF. Multiple Excel files may be included, as necessary.
4. Each of the proposals, Technical and Business, must be separate and complete in itself. Do not reference one proposal in another.

5. File naming convention: It is requested that the filenames for your Technical Proposal, Business Proposal, and Excel Workbook include the name of the offeror, the solicitation number and the type of proposal (i.e., Technical, Business, or Excel Workbook).

Examples:

Technical Proposal: *XYZ Company_NIHAI2012001_Technical.pdf*

Business Proposal: *XYZ Company_NIHAI2012001_Business.pdf*

Excel Workbook: *XYZ Company_NIHAI2012001_Business.xlsx*

PROPOSAL INTENT RESPONSE FORM

RFP No:

RFP Title:

Please review the Request for Proposal (RFP). Furnish the information requested below and return this page to the Contracting Officer/Contract Specialist identified on **Section A-Solicitation/Contract Form** by

Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Choose one of the following Options:

Do intend to submit a proposal

Do Not intend to submit a proposal

If you are not responding to this RFP, please provide your reason(s):

Please provide the following contact information:

Name (First, Middle Initial, Last):

Title:

Organization:

E-mail:

STATEMENT OF WORK

“Development and Maintenance of a Multigenotypic Aged Rat Colony”

1. BACKGROUND

Current and projected experiments using rodents to model the aging processes and age-related diseases in humans require animals of defined genotype and controlled environmental and health status. Only with the meticulous, long-term control of genetic and environmental variables is it possible to maintain relevant animal models that may be used to study many of the biological and behavioral processes in aging. Therefore, a continuous supply of genetically defined, well characterized inbred and hybrid laboratory animals is essential for a program of research on aging.

2. OBJECTIVE(S)

The objective is to develop, maintain and distribute a standing colony of aged, genetically defined laboratory rats for use by investigators in studies of aging. This colony is to be developed and maintained within controlled and defined barrier environments where animals are monitored and characterized for disease status and markers of genetic purity.

3. WORK TO BE PERFORMED

Independently, and not as an agent of the government, the Contractor shall furnish all necessary services, qualified personnel, materials, facilities, and equipment not otherwise provided by the Government as needed to perform the work described below.

The Contractor shall develop, maintain, and distribute a standing colony of aged rats of the National Institute on Aging (NIA)-specified genotypes for use by investigators in studies of aging. The expected duration of this colony, and therefore of this contract, is ten (10) years. During years 1 through 3, animals shall be entered into the colony, but few animals shall be removed from the colony except for the purposes of monitoring health and genetic purity. However, if the need should arise, animals may be distributed from the colony at any time at the direction of the Contracting Officer's Representative (COR). During years 4 through 7, animals shall continue to be entered into the colony and animals shall be distributed to investigators. This should be a period of stable operation with young animals entering the colony at approximately the same rate as older animals leave the colony due to distribution and normal attrition. The final three-year period, years 8 through 10, will serve as the colony close-out period. Animals shall be maintained and distributed, but entry of animals shall cease at the beginning of year 8 or when entries begin in a renewal contract colony. Thus, the population in this contract colony will decline over the last three-year period to a point of near zero or very few animals at the end of year 10.

The colony population at the end of each year of the ten-year period should be approximately as

presented in Table 1:

Table 1. Approximate colony population at year end.

Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
4,000	21,000	32,000	38,000	38,000	38,000	38,000	22,000	6,000	Near 0

Task Area 1. Provision of Barrier Environment

- a) This animal colony shall be divided into at least two, approximately equal, separate segments. Each segment shall be maintained behind a totally independent barrier, specific pathogen- and parasite free, for the entire contract period. All segments shall specifically be helicobacter negative. The purpose of colony division is to ensure the survival of at least one half of the colony in the event of pathologic breach of a barrier, mechanical failure of environmental maintenance systems, or accidental disaster such as fire or flood. Total independence of colony segments, therefore, means separation of buildings, power systems and back-up systems, environmental controls (heat, air conditioning, and air filtration), and breeding stock. Each barrier shall have an independent back-up generator and alarm system in case of loss of power.
- b) The total monthly entry level for each strain shall be divided approximately equally amongst the barriers. Exceptions might be made for strains with very low entry levels, but such exceptions shall require written approval from the COR.
- c) Each colony segment shall be maintained solely within its barrier facility without intermingling. Entries are to be divided approximately equally between the two colony segments. Exceptions may be granted but, each exception shall require the prior written approval of the COR.

Task Area 2. Supply of the Rat Genotype

- a) Within sixty (60) calendar days of the start date of the associated task order, the Contractor shall acquire, from the Government, cryopreserved embryos of the genotypes (foundation stock) described herein and as directed by the COR. The inbred strains designated to start this colony are F344-CDF (Charles River Derived Fisher 344) and BN/Crl (Brown Norway/Crl). The Government may alter the number of entries of specific genotypes and change genotypes as research demands change during the performance period. Alterations in the number or genotype of rats entered require the specific written approval of the Contracting Officer (CO). Alterations in genotypes might require the Contractor to acquire new foundation stock during the contract period of performance.
- b) The foundation stock shall be re-derived by embryo transfer prior to development of the breeding colony. Discrete space within the re-derivation area shall be provided for re-derivation of the rats. No other animals shall be housed within an isolator housing the rats from this contract, other than this contract's animals and foster mothers. Foster

mothers shall be of a strain that is easily distinguished from the subject genotype by color and/or genetic markers. Use of foster mothers with different coat color is preferred when possible. The choice of strain of foster mothers shall require prior approval by the COR.

- c) The Contractor shall provide the COR with documentation of the health status and genetic purity of the re-derived stock within one hundred and twenty (120) calendar days after the birth of the re-derived litters (Task 7.a.).

Task Area 3. Development of Breeding Colonies Entries for Each Colony Segment

- a. The Contractor shall develop breeding colonies consisting of two or three tiers: foundation colony, and expansion and/or production colonies, dependent on the entry levels required for the aging colonies. Monthly reports shall be provided during the development of the breeding colony (Task 7.b.). The numbers of breeding rats to be maintained shall be at a level that permits the addition of male and female weanling rats at the rate listed below.

Table 2. Initial Monthly Entry Levels into the Aging Colony for Each Strain

STRAIN	SEX	TOTAL ENTERED
F344	Male	650
F344	Female	450
BN	Male	60
BN	Female	20
F344BN F1	Male	365
F344BN F1	Female	250

- b. After the foundation stock animals for each colony segment have been re-derived, they shall be entered from isolators into the barrier system without contamination by pathogens or parasites and shall be maintained as such. All offspring, whether part of the breeding colony or the aging colony, shall be considered Government owned property. Animals shall be removed from the barrier only for shipment to investigators, for monitoring of genetic purity or colony health or for other purposes as directed by the COR. In both colony segments no other types of animals and no other types of activity other than that defined in the work-scope shall be permitted in the barrier rooms used to rear and maintain the rat genotypes specified.
- c. Breeding and recording of pedigrees of animals shall conform to the standards established for laboratory rat strains by the Institute for Laboratory Animal Resources (ILAR) "Guide for the Care and Use of Laboratory Animals"
<https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf>.

- d. Litters larger than 8 animals shall have the smallest pups culled within five (5) calendar days of birth to bring the litter size down to 8; animals from litters smaller than 3 shall be excluded from introduction into the aging colony.
- e. Rats shall be weaned at three to four (3-4) weeks of age and entered into the aging colony at the levels described in Table 2 above.
- f. Mating, isolation, and primary enclosures shall meet or exceed minimum floor space requirements per rat, and population size per cage as stated in the ILAR "Guide for the Care and Use of Laboratory Animals". All primary enclosures shall require the prior approval of the COR. Mating cages shall be numbered consecutively. The type of cage bedding is subject to review and approval by the COR within sixty (60) calendar days of award of contract.
- g. Records of date of birth, health, breeding, environment, and colony monitoring shall be maintained by the Contractor. These records shall be supplied to the investigators upon request by the COR.
- h. The Contractor shall provide discrete production space for each breeding colony segment within the barrier or isolation area for that segment. This space shall be defined within each unit, and the animals held therein until the scheduled removal or expiration of the animals. Facilities set aside for these colonies shall be provided with all equipment, materials, and supplies necessary to maintain these animals effectively within the barrier enclosure in a stable condition and environment.
- i. No animal shall be medicated during any part of the breeding, rearing, or maintenance period except on specific instruction of the COR.
- j. The Contractor shall provide for quarterly positive assurance of genetic quality control, including histocompatibility antigen and/or micro-satellite testing, sampling 35% of the breed cages in the nucleus breeding colonies of the inbred strains and 50% of the cages in the production breeding colony of the hybrid strain. Genetic monitoring reports shall be due no more than sixty (60) calendar days after the animals were submitted for testing, and the report shall also be included in the semi-annual progress report. Procedures for genetic quality control are subject to the prior written approval of the COR.
- k. Upon obtaining pathologic or other evidence that a barrier has been breached, the Contractor shall notify the COR and the CO by telephone and/or email within four (4) hours of discovery of the breach. A written *Report of Unexpected Event* shall be provided via email to the CO and the COR within three (3) calendar days of the event. The CO shall arrange a teleconference or meeting of the Contractor's representative, the COR, and the CO as soon as practicable, but in all cases within seven (7) calendar days, to determine an appropriate course of action. Such action may range from medication to reestablishment

of the colony in newly constituted barrier facilities. Final determination of the appropriate course of action will be made by the COR, and all associated costs shall be borne by the Contractor. Potentially affected investigators shall be notified by written notice approved by the COR.

Task Area 4. Aging Colony Development

- a) The Contractor shall provide discrete production space for each colony segment within the barrier or isolation area for that segment. This space shall be defined within each unit, and the animals held therein until the scheduled removal or expiration of the animals. Facilities set aside for these colonies shall be provided with all equipment, materials, and supplies necessary to maintain these animals effectively within the barrier enclosure in a stable condition and environment. The weanling rats shall be from barrier-maintained parents and shall be maintained within the barrier until scheduled for removal (shipment or sacrifice) or natural expiration of the animal. The numbers of rats of each strain that shall be entered into the aging colony during the contract base period are provided in Table 2 under Task 3.a. No change in the entry level shall be made without written authorization from the CO.
- b) All cages of rats shall be permanently identified by their genotypes, sex, and age. Age shall be denoted as month/year of birth with the additional notation on the cage card of the week of the month when born, such as week 1, week 2, and so on. Recombination or consolidation of cages is prohibited.
- c) Each rat shall be permanently marked by tail tattoo to identify month (2 digits) and year (2 digits) of birth (a rat born in August of 2022 would receive the tattoo '0822').
- d) No animal shall be medicated during any part of the breeding, rearing, or maintenance period except on specific instruction of the COR.
- e) Routine monitoring for disease and postmortem examinations shall be performed by either an independent laboratory approved by the COR or the Contractor if Contractor plans, personnel, and facilities are approved by the COR. Selection of animals for monitoring shall be evenly divided between colony segments and represent all genotypes and sexes which are maintained in each segment. Numbers of each genotype and sex submitted for monitoring shall reflect the proportion of that genotype/sex in the colony. Sixty (60) rats per quarter or twenty (20) rats per month shall be submitted for routine health monitoring, unless otherwise specified by the COR. Rats to be submitted for routine monitoring shall be a minimum of four (4) months old. Approximately half of the rats tested each quarter shall be 4-12 months old and the other half 12-20 months old. The schedule for removal shall be developed by the Contractor and shall require the approval of the COR.
- f) In addition to conducting routine in-house health monitoring, the Contractor shall

periodically submit up to sixty (60) rats per quarter for independent health evaluation by a qualified animal diagnostic laboratory designated by the COR. Shipping costs shall be charged to the contract.

g) Routine clinical and postmortem evaluation shall include:

1. Descriptive clinical condition of the animals including general condition, weight, and visible lesions and symptoms;
2. Gross pathologic observations of body tissues and organs;
3. Microbial, parasitological, and serological evaluation necessary and approved by the COR to monitor effectiveness of the barrier system and animal health;
4. Histopathology of major organs and systems.

h) In addition, serology on pooled samples from up to eight (8) breeders being retired from the breeding colony shall be performed monthly using a prevalent agents panel, and environmental swabs from each barrier shall be tested by PCR monthly using a prevalent agents panel.

i) Rats shall be monitored for wounds and open lesions caused by fighting or excessive scratching and for visible tumors. Rats shall be euthanized when wounds, age-related decline or tumors are extreme enough to cause pain, wasting or decreased mobility in the animal. Rats shall be euthanized when a tumor reaches 1 cm in diameter regardless of its impact on mobility or behavior. Unless the COR instructs the Contractor to perform necropsies on animals that are euthanized, the Contractor is free to dispose of the carcasses in any manner they deem appropriate, including donation to raptor rescue groups or zoos and contribution of the carcasses to academic researchers for research purposes.

j) All spontaneous deaths in the aging colony shall be reported in table form by strain, sex, and age in the semiannual progress reports (Task 7.c.) and on the weekly inventory report (Task 7.d.). Necropsies shall not be performed on rats unless there is an unusual pattern of animal deaths or upon the direction of the COR. Postmortem findings in such cases shall be tabulated, summarized, and provided to the COR within sixty (60) calendar days of the death. Primary and secondary lesions possibly attributable to cause of death are to be described. Differences in strain specific or colony wide findings between colony segments shall be identified and reported in the semiannual progress report. Unless the COR instructs the Contractor to perform necropsies on animals that are found dead in the cages, the Contractor is free to dispose of the carcasses in any manner they deem appropriate, including donation to raptor rescue groups or zoos and contribution of the carcasses to academic researchers for research purposes.

k) Upon obtaining pathologic or other evidence that a barrier has been breached, the Contractor shall notify the COR and the CO by telephone and/or email within four (4) hours of discovery of the breach. The CO shall arrange a teleconference or meeting of the Contractor's representative, the COR, and the CO as soon as practicable, but in all cases

within two (2) business days, to determine an appropriate course of action. Such action may range from medication to reestablishment of the colony in newly constituted barrier facilities. Final determination of the appropriate course of action will be made by the COR. Potentially affected investigators shall be notified by written notice approved by the COR.

Task Area 5. Environmental and Husbandry Requirements

- a) Weaned rats assigned to the aging colony shall receive a laboratory animal feed, the formulation of which is consistent with NIH31 (Rader et al., 1986, J. Nutrition 116:1777-88) diet with regard to ingredients, both in kind and amount. The kind of ingredients shall be absolute; the percentage of the kinds of ingredients may vary dependent on nutrient content provided the final formulation remains consistent with NIH31 diet. The laboratory animal feed formulation shall be reviewed and approved by the COR.
- b) The barrier system or isolation room shall be operated and constructed to effectively exclude pathogens, ecto-, endo-parasites as well as vermin. Personnel shall follow the sanitary and/or sterile practices and techniques that have been established for the maintenance of barrier-sustained animals as described in the ILAR "Guide for the Care and Use of Laboratory Animals" <https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf>.
- c) The following items shall be controlled within the ranges specified: temperature (68-74°F), humidity (40-70%), light cycles (12/12 hours), air circulation (0.25m/hr/animal) and filtration (HEPA), and water chlorination and acidification (water shall be chlorinated and the pH controlled so as to not exceed pH 7.3 and 7-8 PPM chlorination at discharge end). A maximum of 25% re-circulated air within the barrier is allowed. The COR shall be notified immediately if the ambient temperature remains outside the above noted temperature range for a period in excess of four (4) hours or if there is a loss of animals due to a breakdown of environmental controls.
- d) Current ILAR <https://grants.nih.gov/grants/olaw/guide-for-the-care-and-use-of-laboratory-animals.pdf> and Department of Health and Human Services (DHHS) guidelines <http://grants.nih.gov/grants/olaw/references/phspol.htm> for breeding, care and maintenance of laboratory rats shall apply where specifications have not been detailed.

Task Area 6. Shipment of Animals to Investigators

- a) Animals from the aging rat colony shall be distributed to investigators or laboratories only as specified by the COR or the designated representative of the COR. A copy of the most recent Health Evaluation Summary for the animals prepared under Task 4.g. shall be sent with each order.
- b) The aged rats shall be shipped in containers:
 - 1. Made of new materials that are non-reusable and non-returnable;
 - 2. The design and fabrication of which are approved by the COR;
 - 3. With filters for ventilation openings of a type approved by the COR; and
 - 4. Designed so that stacking will not interfere with normal circulation of air through the

- container; and
5. Containing food and a water source in each compartment; aged rats should be shipped with excess food.
- c) The number of rats per container shall not exceed six (6) animals. If animals from different cages are shipped in the same container, the container shall be sub-divided into compartments, each of which contains only cage-mates, and all compartments in the crates shall be of the same age and sex. Special provisions may be specified by the COR as needed, such as shipping singly in individual compartments.
- d) The Contractor shall report to the COR or the designated representative of the COR within twelve (12) hours of expected delivery time if there are delays in the shipment of animals.
- e) Shipment via dedicated, climate-controlled truck is the preferred method. The Contractor shall be responsible for the cost of replacing orders not filled correctly according to the instructions provided by the COR or the representative designated by the COR.
- f) When shipment by dedicated, climate-controlled truck is not possible, air freight shall be used. The Contractor shall take all necessary precautions to assure expedient delivery of animals shipped by air freight, by advising the recipient of expected arrival time, mode of transport and carrier number, and any responsibility the consignee has for pick-up at the point of arrival. When the consignee is notified that they are required to meet animals at point of arrival, late or delayed pick up of animals shall constitute neglect by recipient and Contractor is relieved of all replacement or reimbursement obligations.
- g) Rats produced under this contract shall be made available to investigators under conditions as stated herein or as otherwise specified by the COR. The contract shall bear all costs associated with delivery of the rats to the investigators, including crates, enclosures, and freight charges.

Task Area 7. Reporting Requirements and Other Deliverables

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) Post-re-derivation Health and Genetic Monitoring Report. The Contractor shall provide to the COR a report documenting the health status and genetic purity of the re-derived foundation stock within one hundred and twenty (120) calendar days after the birth of the re-derived litters.
- b) Breeding Colony Development Report. Monthly reports shall be provided during the development of the breeding colony, providing the date the foundation stock was received, updates on the re-derivation progress, the numbers of rats produced each

month for the breeding colony for each strain and the target number of breeder rats for each strain, any problems encountered with breeding the rats or litter size/survival, and the anticipated date for entries into the aging colony to begin and how that estimate has changed since the previous month's report. Any change in the trajectory for the breeding colony development that has cost implications for the contract shall be noted in the report. The breeding colony development report shall be provided to the COR by email within seven (7) calendar days from the end of the reporting period. The first reporting period for the breeding colony development report shall be the first full month after the associated task order award and the reports shall continue until all strains have begun entries into the aging colony.

- c) Semi-Annual Progress Reports. Semi-annual progress reports shall include the number of rats shipped from each barrier during the reporting period, the number of mortalities in each barrier, and any problems involving the colony, colony health, genetic monitoring, environment, or environmental control. The report shall include the results of routine genetic monitoring and all laboratory tests executed either by Contractor as a routine part of the protocol or results from tests that have direct implication for colony health or development. All deaths or sacrifices from the colony shall be accounted for by strain, gender and age of the animal sacrificed or expired. Unusual problems with the potential to impact colony health or genetic purity shall be reported to the COR immediately. Semi-annual progress reports shall be submitted to the CO and COR within thirty (30) calendar days of the end of each reporting period of the associated task order. The initial report shall be submitted for the first full six (6) months of the contract performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of six (6) full calendar months. A semi-annual progress report will not be required for the period when the final report is due. Electronic transmission of progress reports is acceptable as long as they contain the Principal Investigator's signature (ex. .PDF format).
- d) Weekly Inventory Report. A weekly inventory report shall be submitted to the COR in accordance with a format approved by the COR. Electronic transfer of the inventory in Excel spreadsheet format is the preferred means. The weekly inventory report is due to the COR no later than one (1) week (seven (7) calendar days) from date of inventory. Access to a "real-time" electronic inventory would take the place of the weekly census report subject to approval by the COR.
- e) Quarterly Health Monitoring Reports. Quarterly health monitoring reports shall be submitted to the COR no later than three (3) months from the date the animals were submitted for evaluation. Semiannual summaries of these reports shall be furnished as a part of 7.c above. Real time access to the health monitoring reports as the results come in is an acceptable alternative for these reports.
- f) Quarterly Genetic Monitoring Reports. Results of the quarterly genetic monitoring of the breeding colonies shall be reported to the COR no later than sixty (60) calendar days from the date the animals were submitted for evaluation. Semiannual summaries of these

reports shall be furnished as a part of 7.c above. Real time access to the genetic monitoring reports as the results come in is an acceptable alternative for these reports.

- g) Monthly Environmental Reports. Results of the monthly environmental monitoring shall be submitted to the COR no later than three (3) months from the date of sampling. Semiannual summaries of these reports shall be furnished as a part of 7.c above.
- h) Individual Postmortem Reports. Complete postmortem reports on individual animals chosen for additional health monitoring independent of the quarterly health monitoring shall be submitted to the COR no later than sixty (60) calendar days from the date of death.
- i) Final Report. A final report shall be submitted to the CO and COR on or before the completion date of the associated task order. The final report shall include a summation of the work performed and results obtained for the entire associated task order period of performance. This report shall be submitted on or before the associated task order completion/expiration date.
- j) Summary of Salient Results. The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the associated task order.
- k) Contract Closeout. In accordance with FAR 4.804, within sixty (60) calendar days of the contract task order expiration/completion, the Contractor shall be responsible for and provide the following items:
 - 1. Indirect cost rate proposals for all years (in which a proposal was not previously submitted);
 - 2. Final property inventory (excluding intellectual property) and Standard Forms 1428 and 1429 (if applicable);
 - 3. Settling all subcontract costs and any issues thereunder;
 - 4. Subcontracting compliance reports for all years to the electronic subcontract reporting system at <http://www.esrs.gov> (if applicable);
 - 5. Final patent and royalty reports;
 - 6. A contractor's release of claims, i.e., contractor's closing statement; Contractor's Assignment of Refunds, Rebates, and Credits; and
 - 7. A final invoice or completion voucher.
- l) Section 508 Annual Report. The Contractor must submit an annual Section 508 report in accordance with the schedule set forth by the Contracting Officer (CO)/Contracting Officer's Representative (COR). The Section 508 Report Template and Instructions for completing the report are available at:
https://www.hhs.gov/sites/default/files/web/508/contracting/technology/section_508_annual_report.doc.

REPORTING REQUIREMENTS AND OTHER DELIVERABLES

“Development and Maintenance of a Multigenotypic Aged Rat Colony”

REPORTING REQUIREMENTS

All reports shall be submitted in an electronic format approved by the Contracting Officer's Representative (COR) and electronic files shall be sent by email to the COR and the Contracting Officer (CO). All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under “Making Files Accessible.”

All reports shall include a cover page containing:

- Title of Report;
 - Period of Performance being reported;
 - Date of submission.
- a) Post-re-derivation Health and Genetic Monitoring Report. The Contractor shall provide to the COR a report documenting the health status and genetic purity of the re-derived foundation stock within one hundred and twenty (120) calendar days after the birth of the re-derived litters.
- b) Breeding Colony Development Report. Monthly reports shall be provided during the development of the breeding colony, providing the date the foundation stock was received, updates on the re-derivation progress, the numbers of rats produced each month for the breeding colony for each strain and the target number of breeder rats for each strain, any problems encountered with breeding the rats or litter size/survival, and the anticipated date for entries into the aging colony to begin and how that estimate has changed since the previous month's report. Any change in the trajectory for the breeding colony development that has cost implications for the contract shall be noted in the report. The breeding colony development report shall be provided to the COR by email within seven (7) calendar days from the end of the reporting period. The first reporting period for the breeding colony development report shall be the first full month after the associated task order award and the reports shall continue until all strains have begun entries into the aging colony.
- c) Semi-Annual Progress Reports. Semi-annual progress reports shall include the number of rats shipped from each barrier during the reporting period, the number of mortalities in each barrier, and any problems involving the colony, colony health, genetic monitoring, environment, or environmental control. The report shall include the results of routine genetic monitoring and all laboratory tests executed either by Contractor as a routine part of the protocol or results from tests that have direct implication for colony health or development. All deaths or sacrifices from the colony shall be

accounted for by strain, gender and age of the animal sacrificed or expired. Unusual problems with the potential to impact colony health or genetic purity shall be reported to the COR immediately. Semi-annual progress reports shall be submitted to the CO and COR within thirty (30) calendar days of the end of each reporting period of the associated task order. The initial report shall be submitted for the first full six (6) months of the contract performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of six (6) full calendar months. A semi-annual progress report will not be required for the period when the final report is due. Electronic transmission of progress reports is acceptable as long as they contain the Principal Investigator's signature (ex. .PDF format).

- d) Weekly Inventory Report. A weekly inventory report shall be submitted to the COR in accordance with a format approved by the COR. Electronic transfer of the inventory in Excel spreadsheet format is the preferred means. The weekly inventory report is due to the COR no later than one (1) week (seven (7) calendar days) from date of inventory. Access to a "real-time" electronic inventory would take the place of the weekly census report subject to approval by the COR.
- e) Quarterly Health Monitoring Reports. Quarterly health monitoring reports shall be submitted to the COR no later than three (3) months from the date the animals were submitted for evaluation. Semiannual summaries of these reports shall be furnished as a part of c above. Real time access to the health monitoring reports as the results come in is an acceptable alternative for these reports.
- f) Quarterly Genetic Monitoring Reports. Results of the quarterly genetic monitoring of the breeding colonies shall be reported to the COR no later than sixty (60) calendar days from the date the animals were submitted for evaluation. Semiannual summaries of these reports shall be furnished as a part of 7.c above. These reports shall be furnished as a part of the semi-annual progress report. Real time access to the genetic monitoring reports as the results come in is an acceptable alternative for these reports.
- g) Monthly Environmental Reports. Results of the monthly environmental monitoring shall be submitted to the COR no later than three (3) months from the date of sampling. Semiannual summaries of these reports shall be furnished as a part of c above.
- h) Individual Postmortem Reports. Complete postmortem reports on individual animals chosen for additional health monitoring independent of the quarterly health monitoring shall be submitted to the COR no later than sixty (60) calendar days from the date of death.
- i) Final Report. A final report shall be submitted to the CO and COR on or before the completion date of the associated task order. The final report shall include a summation of the work performed and results obtained for the entire associated task order period of performance. This report shall be submitted on or before the associated task order

completion/expiration date.

- j) Summary of Salient Results. The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the associated task order.
- k) Contract Closeout. In accordance with FAR 4.804, within sixty (60) calendar days of the contract task order expiration/completion, the Contractor shall be responsible for and provide the following items:
1. Indirect cost rate proposals for all years (in which a proposal was not previously submitted);
 2. Final property inventory (excluding intellectual property) and Standard Forms 1428 and 1429 (if applicable);
 3. Settling all subcontract costs and any issues thereunder;
 4. Subcontracting compliance reports for all years to the electronic subcontract reporting system at <http://www.esrs.gov> (if applicable);
 5. Final patent and royalty reports;
 6. A contractor's release of claims, i.e., contractor's closing statement; Contractor's Assignment of Refunds, Rebates, and Credits; and
 7. A final invoice or completion voucher.
- l) Section 508 Annual Report. The Contractor must submit an annual Section 508 report in accordance with the schedule set forth by the Contracting Officer (CO)/Contracting Officer's Representative (COR). The Section 508 Report Template and Instructions for completing the report are available at:
https://www.hhs.gov/sites/default/files/web/508/contracting/technology/section_508_annual_report.doc.

DELIVERABLE REQUIREMENTS

Deliverable	Quantity	Date
Post-Re-Derivation Health and Genetic Monitoring Report	1 to COR	120 calendar days after the birth of the re-derived litters
Breeding Colony Development Report	1 to COR	Seven (7) calendar days from the end of the reporting period
Semi-annual progress Report	1 to COR 1 to CO	30 calendar days of the end of each reporting period
Weekly Inventory Report	1 to COR	No later than one (1) week (7 calendar days) from date of inventory
Quarterly Health Monitoring Reports	1 to COR	Three (3) months from the date the animals were submitted for

Deliverable	Quantity	Date
		evaluation
Quarterly Genetic Monitoring Reports	1 to COR	60 calendar days from the date the animals were submitted for evaluation
Monthly Environmental Monitoring Report	1 to COR	No later than three (3) months from the date of sampling
Individual Postmortem Reports	1 to COR	60 calendar days from the date of death
Final Report	1 to COR 1 to CO	On or before the completion date of the associated task order
Summary of Salient Results	1 to COR 1 to CO	With Final Report
All reports and documentation including, the confirmatory license, and the government support certification	Division of Extramural Inventions and Technology Resources, OPERA, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980	On or before the completion date of the contract
Contract Closeout	To CO	As described under paragraph (k) above
Section 508 Annual Report	1 to CO 1 to COR	30 calendar days after the anniversary date of the contract each year. See paragraph (l) above
Financial Conflict of Interest (FCOI)	To CO	Annually. See Article H
INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY		
Deliverable	Quantity	Date
Roster of Employees Requiring Sustainability Investigations	1 to COR 1 to CO	Fourteen (14) calendar days after the effective date of the contract
NIH Contractor Employee Separation Checklist	1 to COR 1 to CO	Within two (2) days of the employee's exit from the contract

Deliverable	Quantity	Date
Contractor Non-Disclosure Agreements (NDA)	1 to COR 1 to CO	Prior to Performing Work Under this acquisition

**SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF
OFFERORS**

Update per FAC 2022-06

Last updated: 05/2022

To Be Completed by the Offeror: This document must be completed and included as part of your Business Proposal. By submission of its signed offer, the offeror makes the following Representations and Certifications:

52.204-8 Annual Representations and Certifications.

As prescribed in [4.1202](#)(a), insert the following provision:

ANNUAL REPRESENTATIONS AND CERTIFICATIONS (JAN 2022)

(a) (1) The North American Industry Classification System (NAICS) code for this acquisition is _____ *[insert NAICS code]*.

(2) The small business size standard is _____ *[insert size standard]*.

(3) The small business size standard for a concern that submits an offer, other than on a construction or service acquisition, but proposes to furnish an end item that it did not itself manufacture, process, or produce is 500 employees if the acquisition—

(i) Is set aside for small business and has a value above the simplified acquisition threshold;

(ii) Uses the HUBZone price evaluation preference regardless of dollar value, unless the offeror waives the price evaluation preference; or

(iii) Is an 8(a), HUBZone, service-disabled veteran-owned, economically disadvantaged women-owned, or women-owned small business set-aside or sole-source award regardless of dollar value.

(b) (1) If the provision at [52.204-7](#), System for Award Management, is included in this solicitation, paragraph (d) of this provision applies.

(2) If the provision at [52.204-7](#), System for Award Management, is not included in this solicitation, and the Offeror has an active registration in the System for Award Management (SAM), the Offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The Offeror shall indicate which option applies by checking one of the following boxes:

(i) ☐ Paragraph (d) applies.

(ii) ☐ Paragraph (d) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c) (1) The following representations or certifications in SAM are applicable to this solicitation as indicated:

(i) [52.203-2](#), Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless—

(A) The acquisition is to be made under the simplified acquisition procedures in [part 13](#);

(B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or

(C) The solicitation is for utility services for which rates are set by law or regulation.

(ii) [52.203-11](#), Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed \$150,000.

(iii) [52.203-18](#), Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation. This provision applies to all solicitations.

(iv) [52.204-3](#), Taxpayer Identification. This provision applies to solicitations that do not include the provision at [52.204-7](#), System for Award Management.

(v) [52.204-5](#), Women-Owned Business (Other Than Small Business). This provision applies to solicitations that—

(A) Are not set aside for small business concerns;

(B) Exceed the simplified acquisition threshold; and

(C) Are for contracts that will be performed in the United States or its outlying areas.

(vi) [52.204-26](#), Covered Telecommunications Equipment or Services-Representation. This provision applies to all solicitations.

(vii) [52.209-2](#), Prohibition on Contracting with Inverted Domestic Corporations-Representation.

(viii) [52.209-5](#), Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.

(ix) [52.209-11](#), Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law. This provision applies to all solicitations.

(x) [52.214-14](#), Place of Performance-Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.

(xi) [52.215-6](#), Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.

(xii) [52.219-1](#), Small Business Program Representations (Basic, Alternates I, and II). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.

(A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.

(B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.

(C) The provision with its Alternate II applies to solicitations that will result in a multiple-award contract with more than one NAICS code assigned.

(xiii) [52.219-2](#), Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.

(xiv) [52.222-22](#), Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at [52.222-26](#), Equal Opportunity.

(xv) [52.222-25](#), Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at [52.222-26](#), Equal Opportunity.

(xvi) [52.222-38](#), Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed

the simplified acquisition threshold and the contract is not for acquisition of commercial products or commercial services.

(xvii) [52.223-1](#), Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA–designated items; or include the clause at [52.223-2](#), Affirmative Procurement of Biobased Products Under Service and Construction Contracts.

(xviii) [52.223-4](#), Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA–designated items.

(xix) [52.223-22](#), Public Disclosure of Greenhouse Gas Emissions and Reduction Goals-Representation. This provision applies to solicitations that include the clause at [52.204-7](#).)

(xx) [52.225-2](#), Buy American Certificate. This provision applies to solicitations containing the clause at [52.225-1](#).

(xxi) [52.225-4](#), Buy American-Free Trade Agreements-Israeli Trade Act Certificate. (Basic, Alternates I, II, and III.) This provision applies to solicitations containing the clause at [52.225-3](#).

(A) If the acquisition value is less than \$25,000, the basic provision applies.

(B) If the acquisition value is \$25,000 or more but is less than \$50,000, the provision with its Alternate I applies.

(C) If the acquisition value is \$50,000 or more but is less than \$92,319, the provision with its Alternate II applies.

(D) If the acquisition value is \$92,319 or more but is less than \$100,000, the provision with its Alternate III applies.

(xxii) [52.225-6](#), Trade Agreements Certificate. This provision applies to solicitations containing the clause at [52.225-5](#).

(xxiii) [52.225-20](#), Prohibition on Conducting Restricted Business Operations in Sudan-Certification. This provision applies to all solicitations.

(xxiv) [52.225-25](#), Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran-Representation and Certifications. This provision applies to all solicitations.

(xxv) [52.226-2](#), Historically Black College or University and Minority Institution Representation. This provision applies to solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions.

(2) The following representations or certifications are applicable as indicated by the Contracting Officer:

[Contracting Officer check as appropriate.]

___ (i) [52.204-17](#), Ownership or Control of Offeror.

___ (ii) [52.204-20](#), Predecessor of Offeror.

___ (iii) [52.222-18](#), Certification Regarding Knowledge of Child Labor for Listed End Products.

___ (iv) [52.222-48](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment-Certification.

___ (v) [52.222-52](#), Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Certification.

___ (vi) [52.223-9](#), with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA–Designated Products (Alternate I only).

___ (vii) [52.227-6](#), Royalty Information.

___ (A) Basic.

___ (B) Alternate I.

___ (viii) [52.227-15](#), Representation of Limited Rights Data and Restricted Computer Software.

(d) The offeror has completed the annual representations and certifications electronically in SAM website accessed through <https://www.sam.gov>. After reviewing the SAM information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR [4.1201](#)); except for the changes identified below [*offeror to insert changes, identifying change by clause number, title, date*]. These amended

representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause # Title Date Change

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on SAM.

(End of provision)

Alternate I (SEP 2021). As prescribed in [4.1202](#)(a), substitute the following paragraph (a) for paragraph (a) of the basic provision:

(a)(1) The North American Industry Classification System (NAICS) codes and corresponding size standards for this acquisition are as follows; the categories or portions these NAICS codes are assigned to are specified elsewhere in the solicitation:

NAICS Code	Size standard

[Contracting Officer to insert NAICS codes and size standards].

(2) The small business size standard for a concern that submits an offer, other than on a construction or service acquisition, but proposes to furnish an end item that it did not itself manufacture, process, or produce, (i.e., nonmanufacturer), is 500 employees if the acquisition—

(i) Is set aside for small business and has a value above the simplified acquisition threshold;

(ii) Uses the HUBZone price evaluation preference regardless of dollar value, unless the offeror waives the price evaluation preference; or

(iii) Is an 8(a), HUBZone, service-disabled veteran-owned, economically disadvantaged women-owned, or women-owned small business set-aside or sole-source award regardless of dollar value.

ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS and UNIFORM BUDGET ASSUMPTIONS

Development and Maintenance of a Multigenotypic Aged Rat Colony

In addition to the instructions and format requirements for the Business Proposal that are contained in Section L of the solicitation, the information presented in this attachment is intended to provide uniform cost assumptions that apply to the solicitation.

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as attachments, the technical evaluation factors, and the RFP as a whole, in the development of their proposal. The information requested here should be used as further guidance for the development of the Business Proposal.

COST OR PRICE SUPPORT

Section L of the solicitation specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the business proposal in a clearly marked section. Cost and Pricing support should be provided for all proposed subcontractors.

The following uniform instructions shall be used by all offerors in preparation of their cost proposal.

It is anticipated that ten consecutive, severable (term/level of effort) task orders, having a performance period of 12-months each, will be issued over the course of the 10-year ordering period. It is not anticipated that other (ad-hoc) task orders will be issued; however, NIA reserves the right to issue additional (ad-hoc) task orders, based upon scientific need and availability of funds. For the purposes of proposal preparation, please consider that each of the ten anticipated consecutive task orders will correspond to each year of the 10-year ordering period, as follows:

<i>Year 1</i>	<i>Year 2</i>	<i>Year 3</i>	<i>Year 4</i>	<i>Year 5</i>	<i>Year 6</i>	<i>Year 7</i>	<i>Year 8</i>	<i>Year 9</i>	<i>Year 10</i>
<i>Task Order 1</i>	<i>Task Order 2</i>	<i>Task Order 3</i>	<i>Task Order 4</i>	<i>Task Order 5</i>	<i>Task Order 6</i>	<i>Task Order 7</i>	<i>Task Order 8</i>	<i>Task Order 9</i>	<i>Task Order 10</i>

At this time, upon award of the Base contract for this single award IDIQ, the Government anticipates awarding one Task Order as follows:

Task Order 1 will be awarded simultaneously with the Base Award. Task Order 1 will be cost-reimbursement (term/level of effort) and the period of performance will be for 12-months, beginning on or about September 30, 2023.

1. Provide a detailed budget for costs related to Task Order 1 (Year 1). In addition, also include a detailed composite budget, by task order/contract year, of all costs for the entire ten-year

ordering period. To assist offerors in preparation of their proposal for the entire ten-year ordering period, the Government considers the estimated effort to be approximately 116 full time employees (FTEs) when all anticipated task orders are combined (i.e., grand total for all ten consecutive task orders), which are constituted as follows: 1 FTE for Task Order 1 (Year 1), 3 FTEs for Task Order 2 (Year 2), 10 FTEs for Task Order 3 (Year 3), 15 FTEs for Task Order 4 (Year 4), 19 FTEs in each for Task Order 5-7 (Years 5-7), 14 FTEs for Task Order 8 (Year 8), 10 FTEs for Task Order 9 (Year 9), and 6 FTEs for Task Order 10 (Year 10). The estimated effort is inclusive of effort proposed by any subcontractors or consultants.

2. For development of the budget, please estimate shipment of 1,000 rats for Task Order 2 (Year 2), 3,000 rats for Task Order 3 (Year 3), 6,000 rats for Task Order 4 (Year 4), 6,000 rats for Task Order 5 (Year 5), 6,000 rats for Task Order 6 (Year 6), 6,000 rats for Task Order 7 (Year 7), 4,000 rats mice for Task Order 8 (Year 8), 3,000 rats for Task Order 9 (Year 9), and 1,000 rats for Task Order 10 (Year 10). Assume that 97% of rats shall be shipped to universities throughout the United States and the remaining 3% to foreign institutions.

PROPOSED TASK ORDER NUMBER 1

STATEMENT OF WORK

“Development and Maintenance of a Multigenotypic Aged Rat Colony”

Task Order Number: 1

INITIATOR'S REQUEST

I. Period of Performance:

The period of performance of this task order is twelve (12) months. The Government intends to award this task order at the time of award of the Indefinite Delivery Indefinite Quantity (IDIQ) contract.

II. Task Order 1 Description:

The purpose of this task order is for the re-derivation of foundation stocks for two (2) inbred strains of laboratory rats and the development and maintenance of the breeding and aging colonies for the two inbred strains and one hybrid strain. Where not specified below, all requirements of the contract Statement of Work shall be followed. [References in parentheses at the end of each paragraph refer to the section of the Contract Statement of Work (SOW) addressing the work specified in the Task].

III. Task Order Scope:

The Contractor shall:

- A. Within sixty (60) calendar days of the start date of the contract, the Contractor shall acquire cryopreserved embryos of the genotypes (foundation stock) described herein from the Government. Alterations in the genotypes entered require the specific written approval of the Contracting Officer. The two genotypes are F344-CDF (F344) and BN/Crl (BN). The foundation stock shall be re-derived, and the Contractor shall provide the COR with documentation of the health status and genetic purity of the re-derived stock within one hundred and twenty (120) calendar days after the birth of re-derived litters. (Contract SOW Task Areas 1 and 2)
- B. The Contractor shall develop breeding colonies consisting of two or three tiers: foundation colony, and expansion and/or production colonies, dependent on the entry levels required for the aging colonies. The numbers of breeding rats to be maintained shall be at a level that permits the addition of male and female weanling rats to the aging colony at the rate required for each colony segment as described herein (Contract SOW

Task Area 3):

STRAIN	SEX	TOTAL ENTERED
F344	Male	650
F344	Female	450
BN	Male	60
BN	Female	20
F344BN F1	Male	365
F344BN F1	Female	250

The Contractor shall provide discrete production space for each aging colony segment and rats shall be maintained within each aging colony barrier until scheduled for removal (shipment or sacrifice) or natural expiration of the animal. The Contractor shall provide animals for both in-house and independent health monitoring. (Contract SOW Task Area 4)

- C. The rats shall be raised under conditions conforming to all requirements specified in the contract SOW. (Contract SOW Task Area 5)
- D. Rats from the aging rat colony shall be distributed to investigators or laboratories only as specified by the COR or the designated representative of the COR. (Contract SOW Task Area 6)
- E. The following reports shall be provided to the COR and Contracting Officer:
 - 1. Post re-derivation Health and Genetic Monitoring Report
 - 2. Breeding Colony Development Report
 - 3. Semi-Annual Progress Report
 - 4. Weekly Inventory Report
 - 5. Quarterly Health Monitoring Reports (for animals from the aging colony)
 - 6. Quarterly Genetic Monitoring Reports (for animals from the breeding colony)
 - 7. Environmental Reports
 - 8. Individual Postmortem Reports
 - 9. Final Report
 - 10. Summary of Salient Results
 - 11. Contract Closeout

(Contract SOW Task Area 7)