1.Requisition or other Purchase Authority: 42 U.S.C. 285l		
2. Request for Proposal (RFP) Number: **75N94026R00002**	3. Issue Date: July 28, 2026	4. Set Aside: [X] No [ ] Yes See Part IV Section L
5. Title : **Chemistry Research for the Division of Translational Toxicology (DTT)**		
6. ISSUED BY: Office of Acquisitions and Logistics Management (OALM), Office of the Director (OD), Research and Development and Professional Services, Eunice Kennedy Shriver National Institute of Child Health and Human Development (on behalf of the National Institute of Environmental Health Sciences), NIAAA & NIEHS Team 6701 Rockledge Drive (RKL II) Bethesda, MD 20817		7. SUBMIT OFFERS TO: See Part IV, Section L.3
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received as specified in Part IV, Section L.1., "Packaging and Delivery of Proposals", until 4:30 PM Eastern Standard Time on **September 11, 2026**. Offers will be valid for 300 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 Part IV, Section L.1, "Packaging and Delivery of Proposals". Proposal is to be delivered electronically via the NIH electronic Contract Proposal Submission (eCPS) website, https://www.ecps.nih.gov IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED IN SECTION L.3 OF THE RFP, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Provision 52.215-1, Instructions to Offerors--Competitive Acquisition,"/HHSAR Provision 352.215-70, "Late Proposals and Revisions" LOCATED IN SECTION L OF THIS SOLICITATION.		
10. Offeror must be registered in the System for Award Management (SAM) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at https://www.sam.gov/SAM/ .		
11. FOR INFORMATION CONTACT: Sarah Bank, Contracting Officer e-MAIL: sarah.bank@nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
Questions must be submitted in writing via e-mail to sarah.bank@nih.gov and lisa.schaupp@nih.gov in accordance with Article L.2., by August 10, 2026.		Secondary Contact: Lisa Schaupp, Section Chief, OALM,OD, R&D and Professional Services, NIAAA and NIEHS Team, lisa.schaupp@nih.gov

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SECTION B - Supplies or Services/Prices

1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This acquisition is to conduct Chemistry Research for the National Institute of Environmental Health Sciences (NIEHS), Division of Translational Toxicology (DTT) and National Toxicology Program (NTP). The type and extent of chemistry research support provided will be specific to DTT and NTP research needs. Program management procedures and chemistry technical activities will be provided under eight (8) Functional Areas: Logistics and Handling, Characterization, Formulation, Biosample Analysis, Special Studies, Animal Studies, Omics and In Vitro Assays.

Specifications for the Conduct of Chemistry Activities for Toxicology Research Performed by the Division of Translational Toxicology at the National Institute of Environmental Health Sciences (DTT Chemistry Specifications)

https://ntp.niehs.nih.gov/data/research/chemistry/rfp

2. ESTIMATED COST PLUS FIXED FEE - OPTION

a. The estimated cost of the Base Period of this contract is $To Be Negotiated.

b. The fixed fee for the Base Period of this contract is $To Be Determined. The fixed fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

c. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is $To Be Negotiated.

d. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

Period of Performance	Period	Estimated Cost ($)	Fixed Fee ($)	Estimated Cost Plus Fixed Fee ($)	Level of Effort (LOE) Hours
January 18, 2027 – January 17, 2028	Base Period: Base Effort				
	Base Period: Optional Studies				
	Total Base Period (Base Plus Optional Studies)				
January 18, 2028 – January 17, 2029	Option Period 1: Base Effort				

	Option Period 1: Optional Studies				
	Total Option Period 1(Option Period 1 Plus Optional Studies)				
January 18, 2029 – January 17, 2030	Option Period 2: Base Effort				
	Option Period 2: Optional Studies				
	Total Option Period 2(Option Period 2 Plus Optional Studies)				
January 18, 2030 – January 17, 2031	Option Period 3: Base Effort				
	Option Period 3: Optional Studies				
	Total Option Period 3 (Option Period 3 Plus Optional Studies)				
January 18, 2031 – January 17, 2032	Option Period 4: Base Effort				
	Option Period 4: Optional Studies				
	Total Option Period 4(Option Period 4 Plus Optional Studies)				
January 18, 2032 – January 17, 2033	Option Period 5: Base Effort				
	Option Period 5: Optional Studies				
	Total Option Period 5(Option Period 5 Plus Optional Studies)				
January 18, 2033 – January 17, 2034	Option Period 6: Base Effort				
	Option Period 6: Optional Studies				
	Total Option Period 6 (Option Period 6 Plus Optional Studies)				
January 18, 2034 – January 17, 2035	Option Period 7: Base Effort				

	Option Period 7: Optional Studies				
	Total Option Period 7 (Option Period 7 Plus Optional Studies)				
January 18, 2035 – January 17, 2036	Option Period 8: Base Effort				
	Option Period 8: Optional Studies				
	Total Option Period 8 (Option Period 8 Plus Optional Studies)				
January 18, 2036 – January 17, 2037	Option Period 9: Base Effort				
	Option Period 9: Optional Studies				
	Total Option Period 9 (Option Period 9 Plus Optional Studies)				
January 18, 2037 – July 17, 2038 (Option to Extend Services FAR 52.217-8 – transition effort)	Option Period 10: Base Effort				
	Option Period 10: Optional Studies				
	Total Option Period 10 (Option Period 10 Plus Optional Studies)				
	Total [Base Period and Option(s)]				

Note: The period of performance of an option for increased level of effort will not exceed the term of the period in which the option is exercised.

Each item listed above may be incrementally funded (see Incremental Funding clause in Section I in full text, HHSAR 352.232-70). If incremental funding is utilized for one or more of the above items, a separate line item for each incremental funding action will be created and this Article will be modified accordingly.

3. ESTIMATED COST - INCREMENTALLY FUNDED CONTRACT, HHSAR 352.232-70 (DEC 2015)

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

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

CLIN, Task, Number, or Description	Start Date of Funding	End Date of Funding	Estimated Cost ($)	Fee ($) (as appropriate)	Estimated Cost Plus Fee ($)
Base					
Option 1					
Option 2					
Option 3					
Option 4					
Option 5					
Option 6					
Option 7					
Option 8					
Option 9					
Option 10 - Transition					
Total Base and Options			[Total]	[Total]	[Total]

*To be inserted after negotiation

c. Total funds currently obligated and available for payment under this contract are To Be Negotiated.

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

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

4. PROVISIONS APPLICABLE TO DIRECT COSTS

Items Unallowable Unless Otherwise Provided

Notwithstanding the clauses, ALLOWABLE COST AND PAYMENT, and FIXED FEE, incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

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.

5. 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.

6. Non-Personal Services and Inherently Government Functions

1. Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the Contracting Officer's Representative (COR) to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All individual employee assignments, and daily work direction, shall be given by the applicable employee supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

2. Pursuant to FAR 7.5, the Contractor shall not perform any inherently Governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change the contract and that if the other contractor believes this communication to be a direction to change their contract, they should notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

3. The Contractor shall insure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of the contract, including those related to the Government's right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

SECTION C - Description/Specifications

C.1 STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall 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 July 13, 2026, set forth in SECTION J- List of Attachments, attached hereto and made a part of this contract.

Specifications for the Conduct of Chemistry Activities for Toxicology Research Performed by the Division of Translational Toxicology at the National Institute of Environmental Health Sciences (DTT Chemistry Specifications)

https://ntp.niehs.nih.gov/data/research/chemistry/rfp

C.2. REPORTING REQUIREMENTS

All reports shall be submitted electronically. See Attachment 4- Reporting Requirements and Deliverables.

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**

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

For proposal preparation purposes, please see the Statement of Work (ATTACHMENT 3 to this RFP), Section 1.6 "Reports and Deliverables".

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. **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.)

2. Source Code and Object Code

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

3. HHS Security And Privacy Language For Information And It Procurements

Reporting requirements for HHS Security and Privacy Language for Information and Information Technology Procurements are applicable to this solicitation. Please see the Statement of Work Appendix A "HHS SECURITY AND PRIVACY LANGUAGE FOR INFORMATION AND IT PROCUREMENTS" (ATTACHMENT 2 to this RFP) for a list of applicable deliverables reporting requirements.

4. 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 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.

5. Service Contract Annual Report

The Contractor shall submit an Annual Service Contract Report to https://www.SAM.gov on or before November 15 each year (covering a reporting period of the applicable recently complete Federal Government Fiscal Year, October 1 through September 30), in accordance with FAR 52.204-14, Service Contract Reporting Requirements. The full text of this FAR clause is contained in Section I. This report is separate from the Service Contract Act, which does not apply to this requirement. The intent of this high-level reporting is for the Federal Government to assess the balance of in-house versus contracted-out work.

C.3. INVENTION REPORTING REQUIREMENT

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

The first annual utilization report shall be submitted in accordance with the DELIVERIES Article in Section F of this contract. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer's Representative (COR): _____ (to be completed upon award)

Contracting Officer (CO): _____ (to be completed upon award)

Contract Specialist (CS): _____ (to be completed upon award)

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

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

SECTION D - Packaging and 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, the Contracting Officer's Representative (TBD) is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:

National Institutes of Health (NIH)
National Institute of Environmental Health Sciences (NIEHS)
Research Triangle Park, NC 27709

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.

RFO 52.246-9 Inspection of Research and Development (Short Form). (APR 1984)

RFO 52.246-5 Inspection of Services—Cost-Reimbursement APR 1984

SECTION F - Deliveries or Performance

1. PERIOD OF PERFORMANCE

a. The period of performance of the Base Period of this contract shall be from January 18, 2027 through January 17, 2028.

b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Period
Option Period 1	January 18, 2028 – January 17, 2029
Option Period 2	January 18, 2029 – January 17, 2030
Option Period 3	January 18, 2030 – January 17, 2031
Option Period 4	January 18, 2031 – January 17, 2032
Option Period 5	January 18, 2032 – January 17, 2033
Option Period 6	January 18, 2033 – January 17, 2034
Option Period 7	January 18, 2034 – January 17, 2035
Option Period 8	January 18, 2035 – January 17, 2036
Option Period 9	January 18, 2036 – January 17, 2037
Option Period 10 – Option to Extend Services	January 18, 2037 – July 17, 2038

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 brief description of Reporting Requirements and Deliverables is in the Statement of Work (SOW) and additional details are in Chapter 7 of the specifications, https://ntp.niehs.nih.gov/data/research/chemistry/rfp.

See Section J- Attachment 4 for Reporting Requirements and Delivery Schedule.

3. LEVEL OF EFFORT

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

Labor Hours

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10
Senior Research Professional										
Research Professional										
Technical Staff										
Support Staff										
Totals										
Option Studies Labor Category	**Year 1**	**Year 2**	**Year 3**	**Year 4**	**Year 5**	**Year 6**	**Year 7**	**Year 8**	**Year 9**	**Year 10**
Senior Research Professional										
Research Professional										
Technical Staff										
Support Staff										
Totals										

NOTE: See Section L, Proposal Instructions, for further information on estimating hours. See Attachment 24, Sub-Attachment E, to be completed by the Offeror. Sub-Attachment B (Sample Research Outlines) provides examples of anticipated work; anticipated annual efforts and estimated quantities are provided in Attachment 24, Table 5.

b. The Contractor shall have satisfied the requirement herein if not less than 90% nor more than 110% of the total direct labor hours specified herein are furnished. These terms and conditions do not supersede the requirements of either the "Limitation of Cost" or "Limitation of Funds" clause.

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

4. RFO 52.252-2 Clauses Incorporated by Reference. (FEB 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es): 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/browse/index/far.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) - **Alternate I** (April 1984) is applicable to this contract.

(End of clause)

SECTION G - Contract Administration Data

1. CONTRACTING OFFICER REPRESENTATIVE (COR)

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

[To be specified at 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 following 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.

[To be specified at award]

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 and/or ACOR designation.

2. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

1. 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.

a. The Contractor must submit invoices to the Department of Treasury's Invoice Processing Platform (IPP) at https://www.ipp.gov with a copy of the invoice to the approving official, as directed below.

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

Official: Contracting Officer

Name- [To Be Specified Prior to Award] Email Address- [To Be Specified Prior to Award]

Contracting Officer's Representative

Name- [To Be Specified Prior to Award] Email Address- [To Be Specified Prior to Award]

For inquiries regarding the status of invoices, contact OFM Customer Service via email at ofm_customer_service@mail-cmp.niceincontact.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.

c. 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 OALM, OD, R&D and Professional Services- Division B.

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:

Chemistry Research for the Division of Translational Toxicology (DTT)

g. Contract Line Item Numbers (CLIN) as follows:

Line Item #	Line Item Description
CLIN 100	Base Period
CLIN 200	Option Period 1
CLIN 300	Option Period 2
CLIN 400	Option Period 3
CLIN 500	Option Period 4
CLIN 600	Option Period 5
CLIN 700	Option Period 6
CLIN 800	Option Period 7
CLIN 900	Option Period 8
CLIN 100	Option Period 9
CLIN 1100	Option Period 10

Contract Lines for optional studies will be added as funding is obligated.

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

3. 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.'

1. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the 30th working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in that part of the Instructions for Completing Form NIH 2706, entitled " **PREPARATION INSTRUCTIONS** ," all columns A through J, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full **[Calendar Month/Three Calendar Months]** following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a **[Monthly/Quarterly]** basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The following is a listing of expenditure categories to be reported:

Expenditure Category A	Percentage of Effort/Hours
(1) Direct Labor	
(a) Principal Investigator	
(b) Co-Principal Investigator	
(c) Key Personnel	
(i)	
(ii)	
(iii)	
(2) Other Professional Personnel	
(3) Personnel - Other	
(4) Fringe Benefits	
(5) Accountable Personal Property	
(6) Materials/Supplies	
(7) Patient Care Costs	
(8) Travel	
(9) Consultant Costs	
(10) Premium Pay	
(11) Computer Costs	
(12) Subcontract Costs	
(13) Other Direct Costs	
(14) Indirect Costs	
(15) G&A Expense	
(16) Total Cost	
(17) Fee	
(18) Total Cost Plus Fixed Fee	

f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

3. 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.

4. 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 on the anniversary of the award date.

Interim and Final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted sixty 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.

a. 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

5. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, 'HHS Contracting Guide for Contract of Government Property,' Appendix Q, which can be found at:

https://oamp.od.nih.gov/sites/default/files/DGS/HHS%20Contracting%20Guide%20for%20Contract%20of%20Government%20Property-Appendix%20Q.pdf

7. HHSAR 352.237-75 Key Personnel. (DEC 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 positions are considered to be essential to the work being performed hereunder:

Name	Title
	Principal Investigator (PI)
	Deputy Principal Investigator (PI)

8. RFO 52.232-40 Providing Accelerated Payments to Small Business Subcontractors. (MAR 2023)

(a)(1) In accordance with 31 U.S.C. 3903 and 10 U.S.C. 3801, within 15 days after 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.

(2) The Contractor agrees to make such payments to its small business subcontractors without any further consideration from or fees charged to the 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, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial products or commercial services.

(End of clause)

SECTION H - Special Contract Requirements

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.

2. 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 https://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research, whether preclinical or otherwise, as appropriate. More information is available at https://grants.nih.gov/policy/reproducibility/index.htm, including FAQs and a General Policy Overview.

3. 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) electronic versions of all Author Accepted Manuscripts arising from this contract in whole or in part, upon acceptance for publication. NIH defines the Author Accepted Manuscripts as the author's final version that has been accepted for journal publication and includes all revisions resulting from the peer review process, including all associated tables, graphics, and supplemental material. NIH-funded investigators shall notify their Contracting Officers and Contracting Officer Representatives upon the acceptance of an Author Accepted Manuscript resulting from the contract, even if co-authored with those not using contract funds. Through execution of this contract, contractor, and through implementation of this provision by contractor to each of contractor's investigators and subcontractor, and through implementation of this provision to each of subcontractor's investigators, conducting work under this contract or a subcontract, respectively, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this contract, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy. Upon receipt of a PMCID,

investigators should report the PMCID to their Contracting Officers and Contracting Officer Representatives to demonstrate compliance with this term of the contract. 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-25-047.html and https://grants.nih.gov/policy-and-compliance/policy-topics/public-access

4. 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.

5. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

6. 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), which is incorporated by reference.

7. INTRODUCTION OF RODENTS AND RODENT PRODUCTS - NIEHS

No rodent or rodent product shall be delivered to NIEHS directly or through collaborative research or holding facilities under contract to NIEHS except by prior approval by the Comparative Medicine Branch, NIEHS. The approval form, Application to Introduce Rodents and Rodent Products into NIEHS, is available by contacting the Comparative Medicine Branch, Quality Assurance Laboratory at 984-287-3912. Approval must be obtained by the Contractor prior to shipment to NIEHS of the rodents and/or rodent products. The Contractor must be sure that this approval exists and is current before transferring rodents or rodent products into the NIEHS. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Requests for approval should be submitted within 30 days of the shipping date to: NIEHS, Comparative

Medicine Branch, Quality Assurance Laboratory, PO Box 12233, MD C1-06, Building 101, Room C128, Research Triangle Park, NC, 27709. United States Department of Agriculture permits are required for the importation of monoclonal antibodies, hybridoma cell lines, cell cultures, and other biologic materials that have been in contact with material of animal origin. USDA permit forms and information are available online (https://www.aphis.usda.gov/aphis/resources/permits). A copy of the completed permit form should be submitted to the Comparative Medicine Branch.

8. 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.

9. GUN CONTROL

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

10. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item and FAR Clause 52.217-9, Option to Extend the Term of the Contract set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost (plus fixed fee) of the contract will be increased as set forth in the ESTIMATED COST PLUS FIXED FEE Article in SECTION B of this contract.

11. 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**

1. An offeror is to submit their respective subcontracting plan electronically using the U.S. Department of Health and Human Services (HHS) Small Business Customer

Experience (SBCX) system at https://osdbu.hhs.gov. The offeror shall follow the instructions outlined in the SBCX Industry Guide at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j to successfully submit their subcontracting plan by the proposal submission deadline.

2. The official point of receipt for determining timely submission of an offeror's subcontracting plan is the SBCX system and/or email notification. Once the subcontracting plan is successfully submitted in the SBCX system the offeror should receive an email notification and confirmation message of completion upon submission.

3. If an offeror's subcontracting plan is not confirmed as received within the SBCX system by the proposal submission date specified in the solicitation, it will be considered late in accordance with subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offeror-Competition Acquisition. Disposition of late submittals of a subcontracting plan by an offeror via the SBCX system is at the discretion of the Contracting Officer.

4. Any technical questions regarding the use of the SBCX system may be submitted via email message to the SBCX help desk at client.support@apexlogic.com. The client support hours of operation are Monday - Friday, 6:00 a.m. - 8:00 p.m. Eastern Standard Time (EST). Note: help desk tickets can be submitted 24 hours a day / 7 days a week and a representative will respond within the presented client support hours of operation for assistance.

5. Individual Subcontract Reports (ISR)

The Contractor must submit the following Subcontracting reports electronically via https://www.sam.gov.

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

6. Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report must 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 must be included as a contact for notification purposes at the following e- mail address:

Sarah.Bank@nih.gov

12. HHSAR 352.204-74 Supply Chain Risk Assessment (OCT 2024) (DEVIATION)

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

Contract means as defined in FAR 2.101.

Foreign person means as defined in 31 CFR 800.224.

Mission-critical acquisition means the acquisition of products, materials, information, or services that are identified as—

(1) Contract support or development services for HHS or OpDiv/StaffDiv research and development;

(2) Contract support or development services for HHS or OpDiv/StaffDiv financial databases and services;

(3) Contract support services that require utilization or sharing of HHS or OpDiv/StaffDiv Intellectual property;

(4) Contract services supporting HHS or OpDiv/StaffDiv continuity of operations (COOP) mission essential functions;

(5) Contract support services or development initiatives for HHS or OpDiv/StaffDiv critical infrastructure;

(6) An HHS or OpDiv/StaffDiv high-value/dollar acquisition; or

(7) Other acquisitions for critical assets or services as identified by OpDiv/StaffDiv leadership.

Office of National Security (ONS) means the HHS office responsible for the management, oversight, policy, guidance, and implementation of the HHS Enterprise Supply Chain Risk Management (E-SCRM) Program, including the conducting of supply chain risk assessments.

State-owned enterprise means a legal entity that is created by a government in order to partake in commercial activities on the government's behalf. A state-owned enterprise or government-owned enterprise is a business enterprise where the government or state has significant control through full, majority, or significant minority ownership.

Supply chain risk means the potential for harm or compromise that arises as a result of security risks from suppliers, their supply chains, and their products, materials, information, or services. Supply chain risks include exposures, threats, and vulnerabilities associated with the products and services traversing the supply chain as well as the exposures, threats, and vulnerabilities to the supply chain.

Supply chain risk assessment means a systematic examination of supply chain risks, likelihoods of their occurrence, and potential impacts.

Supply chain risk management (SCRM) means a systematic process for managing risk to the integrity, trustworthiness, and authenticity of products, materials, information, and services within the supply chain. It

addresses the activities of foreign and other adversaries aimed at compromising the supply chain, which may include the introduction of counterfeit or malicious items into the supply chain. It is conducted through identification of threats, vulnerabilities, and consequences throughout the supply chain and development of mitigation strategies to address the respective risks presented by the supplier, the supplied products, materials, information, and services, or the supply chain at any point during the life cycle.

(b) *Supply chain risk assessment*. The Office of National Security (ONS) or delegated designee may perform a supply chain risk assessment of the Offeror's proposal. In performing the supply chain risk assessment, the Government may consider public and non-public information relating to the Offeror's supply chain.

(c) *Required information submittal*. The Offeror shall provide the following information for products, materials, information, or services provided under their proposal:

(1) Description of the type of products, materials, information, or services provided.

_____

(2) Vendor and manufacturer's company, if applicable, including name and address.

_____

(3) If known, vendor's and manufacturer's web site, and the Commercial and Government Entity (CAGE) code and Unique Entity Identifier (UEI).

_____

(d) *Representations*. The Offeror represents that—

(1) It [ ] does, [ ] does not have any foreign ownership, outside of retail shareholders, who control more than 10% of the company's total shares. If yes, identify the legal name of the owning organization/individual and their country of affiliation.

_____

(2) It [ ] does, [ ] does not have any of the following business affiliations with foreign entities: technology development partnerships, strategic partnerships, joint ventures, foreign subsidiaries, grants from a foreign entity. If yes, identify the legal name of the organization, its foreign address, and the nature of the relationship.

_____

(3) It [ ] does, [ ] does not have any foreign governments, or state-owned enterprises that have investments or ownership interest in the company. If yes, identify the foreign government, the ownership stake percentage, and the nature of the relationship.

_____

(4) The company leadership (C-Suite executives, Board members, etc.) [ ] does, [ ] does not have any substantial ties to foreign countries, including being citizens of a foreign country, graduates of a foreign university, or investments in a foreign country. If yes, identify the individual, the nature of the tie, and the country they are tied to.

_____

(5) It [ ] has, [ ] has not violated export controls or the Foreign Corrupt Practices Act within 5 years. If yes, enter the event, the date, and any remediation the company committed after the event.

_____

(6) It [ ] has, [ ] has not been prohibited from doing business with the government of the US or any of its administrative subdivisions to include agencies, states, territories or municipalities. If yes, enter the event, the date, and any remediation the company committed after the event.

_____

(7) It [ ] has, [ ] has not been prohibited from doing business with any foreign governments or subdivisions thereof. If yes, enter the event, the date, and any remediation the company committed after the event.

_____

(8) It [ ] has had, [ ] has not had affiliations with any entities prohibited (e.g. Huawei, see SAM.gov "exclusions" page for additional information regarding prohibited entities) from doing business with the government of the US or any of its administrative subdivisions to include agencies, states, territories or municipalities? If yes, enter the event, the date, and any remediation the company committed after the event.

_____

(9) It [ ] has, [ ] has not been suspended or debarred at any point while doing business with the U.S. Government or any of its administrative subdivisions to include agencies, states, territories or municipalities. If yes, enter the event, the date, and details below.

_____

(10) It [ ] has previously filed for or is currently in, [ ] has not previously filed for or is not currently in bankruptcy in the last 10 years. If yes, enter the event, the date, and details below.

_____

(11) It [ ] was or is currently in, [ ] was not or is not currently in litigation in the last 10 years. If yes, enter the event, the date, and details below.

_____

(e) *Supply chain risk determination*. Findings from the supply chain risk assessment will be considered in connection with a determination of the Offeror's responsibility and eligibility for award. Failure of the Offeror to furnish the information required in this provision or provide additional information as requested by the Contracting Officer may render the Offeror non-responsible and ineligible for award. The Government reserves the right to limit the disclosure of information to the Offeror regarding the risk in accordance with all applicable laws or regulations.

(f) *Mitigation plans*. Any mitigation plans and amendments determined necessary and to be implemented and sustained during contract performance will be incorporated into the contract.

(g) *Subcontracts*. The Offeror shall include the substance of this provision, including the information and representations at paragraphs (c) and (d), and including this paragraph (g), in subcontracts with persons or entities proposed to be used involving the development or delivery of any mission-critical products, materials, information, or services. The Offeror shall submit all potential subcontractor information and representations with its proposal for any mission-critical products, materials, information, or services provided for in the proposal.

(End of provision)

13. SUPPLY CHAIN RISK ASSESSMENT DURING CONTRACT PERFORMANCE, HHSAR 352.204-75 (October 2024) (DEVIATION)

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

Contract means as defined in FAR 2.101.

Foreign person means as defined in 31 CFR 800.224.

Mission-critical acquisition means the acquisition of products, materials, information, or services that are identified as-

(1) Contract support or development services for HHS or OpDiv/StaffDiv research and development;

(2) Contract support or development services for HHS or OpDiv/StaffDiv Financial databases and services;

(3) Contract support services that require utilization or sharing of HHS or OpDiv/StaffDiv Intellectual property;

(4) Contract services supporting HHS or OpDiv/StaffDiv continuity of operations (COOP) mission essential functions;

(5) Contract support services or development initiatives for HHS or OpDiv/StaffDiv critical infrastructure;

(6) An HHS or OpDiv/StaffDiv high-value/dollar acquisition; or

(7) Other acquisitions for critical assets or services as identified by OpDiv/StaffDiv leadership.

Office of National Security (ONS) means the HHS office responsible for the management, oversight, policy, guidance, and implementation of the HHS Enterprise Supply Chain Risk Management (E-SCRM) Program, including the conducting of supply chain risk assessments.

State-owned enterprise means a legal entity that is created by a government in order to partake in commercial activities on the government's behalf. A state-owned enterprise or government-owned enterprise is a business enterprise where the government or state has significant control through full, majority, or significant minority ownership.

Supply chain risk means the potential for harm or compromise that arises as a result of security risks from suppliers, their supply chains, and their products, materials, information, or services. Supply chain risks include exposures, threats, and vulnerabilities associated with the products and services traversing the supply chain as well as the exposures, threats, and vulnerabilities to the supply chain.

Supply chain risk assessment means a systematic examination of supply chain risks, likelihoods of their occurrence, and potential impacts.

Supply chain risk management (SCRM) means a systematic process for managing risk to the integrity, trustworthiness, and authenticity of products, materials, information, and services within the supply chain. It addresses the activities of foreign and other adversaries aimed at compromising the supply chain, which may include the introduction of counterfeit or malicious items into the supply chain. It is conducted through identification of threats, vulnerabilities, and consequences throughout the supply chain and development of mitigation strategies to address the respective risks presented by the supplier, the supplied products, materials, information, and services, or the supply chain at any point during the life cycle.

(b) *Supply chain risk assessment*. The Office of National Security (ONS) or delegated designee may perform a supply chain risk assessment of the Contractor. In performing the supply chain risk assessment, the Government may consider public and non-public information relating to the Contractor's supply chain.

(c) *Updated information and representations*. If requested by the Contracting Officer, or if there are any changes to the information or representations the Contractor has submitted prior to award or during contract performance, the Contractor must submit to the Contracting Officer the information and representations in paragraphs (d) or (e).

(d) *Required information submittal.* The Contractor shall provide the following information for products, materials, information, or services provided during contract performance:

(1) Description of the type of products, materials, information, or services provided.

[_____]

(1) Vendor and manufacturer's company, if applicable, including name and address.

[_____]

(3) If known, vendor's and manufacturer's web site, and the Commercial and Government Entity (CAGE) code and Unique Entity Identifier (UEI).

[_____]

(e) Representations. The Contractor represents that –

(1) It [ ] does, [ ] does not have any foreign ownership, outside of retail shareholders, who control more than 10% of the company's total shares. If yes, identify the legal name of the owning organization/individual and their country of affiliation.

[_____]

(2) It [ ] does, [ ] does not have any of the following business affiliations with foreign entities: technology development partnerships, strategic partnerships, joint ventures, foreign subsidiaries, grants from a foreign entity. If yes, identify the legal name of the organization, its foreign address, and the nature of the relationship.

[_____]

(3) It [ ] does, [ ] does not have any foreign governments, or state-owned enterprises that have investments or ownership interest in the company. If yes, identify the foreign government, the ownership stake percentage, and the nature of the relationship.

[_____]

(4) The company leadership (C-Suite executives, Board members, etc.) [ ] does, [ ] does not have any substantial ties to foreign countries, including being citizens of a foreign country, graduates of a foreign university, or investments in a foreign country. If yes, identify the individual, the nature of the tie, and the country they are tied to.

[_____]

(5) It [ ] has, [ ] has not violated export controls or the Foreign Corrupt Practices Act within 5 years. If yes, enter the event, the date, and any remediation the company committed after the event.

[_____]

(6) It [ ] has, [ ] has not been prohibited from doing business with the government of the US or any of its administrative subdivisions to include agencies, states, territories or

municipalities. If yes, enter the event, the date, and any remediation the company committed after the event.

[_____]

(7) It [ ] has, [ ] has not been prohibited from doing business with any foreign governments or subdivisions thereof. If yes, enter the event, the date, and any remediation the company committed after the event.

[_____]

(8) It [ ] has had, [ ] has not had affiliations with any entities prohibited (e.g. Huawei, see SAM.gov "exclusions" page for additional information regarding prohibited entities) from doing business with the government of the US or any of its administrative subdivisions to include agencies, states, territories or municipalities? If yes, enter the event, the date, and any remediation the company committed after the event.

[_____]

(9) It [ ] has, [ ] has not been suspended or debarred at any point while doing business with the U.S. Government or any of its administrative subdivisions to include agencies, states, territories or municipalities. If yes, enter the event, the date, and details below.

[_____]

(10) It [ ] has previously filed for or is currently in, [ ] has not previously filed for or is not currently in bankruptcy in the last 10 years. If yes, enter the event, the date, and details below.

[_____]

(11) It [ ] was or is currently in, [ ] was not or is not currently in litigation in the last 10 years. If yes, enter the event, the date, and details below.

[_____]

(f) *Supply chain risk determination*. Findings from the supply chain risk assessment will be considered in connection with a determination of the Contractor's eligibility to continue performance on the contract. The Government reserves the right to limit the disclosure of information to the Offeror regarding the risk in accordance with all applicable laws or regulations.

(g) *Mitigation plans*. Any mitigation plans and amendments determined necessary and to be implemented and sustained during contract performance will be incorporated into the

contract.

(h) *Subcontracts*. The Contractor shall include the substance of this clause, including the information and representations in paragraphs (d) and (e), and this paragraph (h), in subcontracts with persons or entities involved the development or delivery of any mission critical products, materials, information, or services. The Contractor shall submit all subcontractor information and representations with its proposal for any additional mission-critical products, materials, information, or services during performance of the contract.

(End of clause).

See Attachment 6 - Supply Chain Risk Management Certification

14. SECURITY REQUIREMENTS FOR GOVERNMENT-OWNED CONTRACTOR-OPERATED AND CONTRACTOR-OWNED CONTRACTOR-OPERATED RESOURCES, HHSAR 352.239-76 (Feb 2024) (DEVIATION)

(a) *Federal policies*. The Contractor shall comply with applicable federal laws, regulations, and HHS policies that include, but are not limited to-

(1) HHS Policy for Information Security and Privacy Protection (IS2P);

(2) Federal Information Security Modernization Act (FISMA) of 2014, (44 U.S.C. 101);

(3) National Institute of Standards and Technology (NIST) Special Publication (SP) 800-53, latest revision, Security and Privacy Controls for Information Systems and Organizations;

(4) Office of Management and Budget (OMB) Circular A-130, Managing Information as a Strategic Resource; and

(5) Any other applicable federal laws, regulations, NIST guidance, and local HHS policies.

(b) *Assessment and Authorization (A&A)*. A valid authority to operate (ATO) certifies that the Contractor's information system meets the contract's requirements to protect the agency data. If the system under this contract does not have a valid ATO, the Contractor shall work with the agency and supply the deliverables required to complete the ATO within the specified timeline(s) of [Contracting Officer insert timeline(s)]. The Contractor must conduct the A&A requirements in accordance with *HHS IS2P/*[Contracting Officer insert other policies, if applicable], NIST SP 800-37, *Guide for Applying the Risk Management Framework to Information Systems: A Security Life Cycle Approach* (latest revision), NIST SP 800-53B, Control Baselines for Information Systems and Organizations, and the NIST SP 800-53A (latest revision).

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

(1) A&A package deliverables. The Contractor shall provide an A&A package within [Contracting Officer insert required timeline, process, and format for A&A package delivery or indicate timeline/format for each individual deliverable] to the Contracting Officer and/or the Contracting Officer's Representative (COR). The following A&A deliverables are required to complete the A&A package-

(i) [Contracting Officer insert specific deliverables, as applicable, in addition to the HHS baseline listed below]:

(ii) A System Security Plan (SSP) is due [Contracting Officer insert specific timeline, process, and format for deliverable]. The SSP shall comply with the NIST SP 800-18, *Guide for Developing Security Plans for Federal Information Systems*, the Federal Information Processing Standard (FIPS) 200, *Recommended Security Controls for Information Systems, and NIST SP 800-53, Security and Privacy Controls for Federal Information Systems and Organizations* applicable baseline requirements, and other applicable NIST guidance as well as HHS policies and other guidance. The SSP must be consistent with and detail the approach to IT security contained in the Contractor's bid or proposal that resulted in the award of this contract. The SSP must provide an overview of the system environment and security requirements to protect the information system (see HHSAR 302.101, Definitions) as well as describe all applicable security controls in place or planned for meeting those requirements. It should provide a structured process for planning adequate, cost-effective security protection for a system. The Contractor shall review and update the SSP at least annually thereafter and if requested, provide a copy of the updated SSP to the COR.

(iii) A Security Assessment Plan/Report (SAP/SAR) is due [Contracting Officer insert specific timeline, process and format for deliverable.] The security assessment must be conducted by [Contracting Officer include type of assessment (e.g., independent, etc.)] assessor and be consistent with NIST SP 800-53A, NIST SP 800-30, and HHS policies. The assessor will document the assessment results in the SAR. Thereafter, the Contractor, in coordination with the COR shall conduct, or as directed, in the assessment of the security controls [Contracting Officer insert specific timeline(s), if applicable] and update the SAR at least annually. A copy of the updated SAR shall be provided to the COR, if requested.

(iv) All systems shall have a completed privacy threshold analysis (PTA). If the PTA results determines the system contains personally identifiable information, a privacy impact assessment, approved by the HHS SAOP, is required.

(v) System Privacy Plan and Privacy Control Assessment. As required in OMB Circular A-130, a System Privacy Plan and Privacy Control Assessment shall be included in A&A. The plan and assessment may be included in the Security System Plan, or a separate report in the A&A, as determined by the COR.

(vi) An Independent Assessment is due [Contracting Officer insert specific timeline, process, and format for the deliverable]. The Contractor shall have an independent third-party validate the security and privacy controls in place for the system(s) commensurate with the risk levels per NIST SP 800-53B. The independent third party shall review and analyze the security authorization package and report on technical, operational, and management level deficiencies as outlined in NIST SP 800-53. The Contractor shall address all *"high"* deficiencies [Contracting Officer insert all other deficiencies that may require mitigation by Contractor] before submitting the package to the Government for acceptance and document all remaining deficiencies in a system Plan of Actions and Milestones (POA&M).

(vii) The POA&M is due as follows-

(A) [Contracting Officer insert specific overall timeline, process, and format for the deliverable] from the date the weaknesses are formally identified and documented;

(B) Critical-risk weaknesses must be mitigated within [Contracting Officer insert specific timeline] from the date the weaknesses are formally identified and documented;

(C) High-risk weaknesses must be mitigated within [Contracting Officer insert specific timeline] from the date the weaknesses are formally identified and documented;

(D) Medium weaknesses must be mitigated within [Contracting Officer insert specific timeline] from the date the weaknesses are formally identified and documented; and

(E) Low weaknesses must be mitigated within [Contracting Officer insert specific timeline], from the date the weaknesses are formally identified and documented.

(2) HHS will determine the risk rating of all vulnerabilities. Identified risks stemming from deficiencies related to the security control baseline implementation, assessment, continuous monitoring, vulnerability scanning, flaws and security defect in a system (that require to create a patch for remediation), and other security reviews and sources, as documented in the SAR, shall be documented and tracked by the Contractor for mitigation in the POA&M document consistent with the HHS Standard for Plan of Action

and Milestones policies. Depending on the severity of the risks, HHS may require designated POA&M weaknesses to be remediated before an ATO is issued. Thereafter, continue to remediate weaknesses throughout the contract. The POA&M document shall be updated at least quarterly [Contracting Officer insert timeline, process, and format if more frequent updates are needed].

(3) A Contingency Plan and Contingency Plan Test are due [Contracting Officer insert specific timeline, process and format for the deliverable]. The Contingency Plan shall be developed in accordance with NIST SP 800-34, *Contingency Planning Guide for Federal Information Systems*, and be consistent with HHS policies. Upon final acceptance by the System Owner, the Contractor, in coordination with the COR and System Owner, shall test the Contingency Plan and prepare a Contingency Plan Test Report that includes the test results, lessons learned, and any remaining action items to be addressed. The Contractor shall update and test the Contingency Plan at least *annually*.

(4) An E-Authentication Questionnaire is required. The Contractor shall collaborate with at the COR's direction to ensure that the E-Authentication Guidance requirements are implemented in accordance with OMB 04-04 and NIST SP 800-63 series, latest versions. Based on the level of assurance determined by the E-Authentication, the Contractor shall ensure appropriate authentication to the system, including remote authentication, is in-place in accordance with the assurance level determined by the E-Authentication (when required), in accordance with *HHS Guidance for Selection of e-Authentication Assurance Levels* and any other applicable HHS policies.

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

(6) *Annual assessment/penetration (pen) test*. The Contractor shall assess the system security and privacy controls (or ensure an assessment of the controls is conducted) at least annually to determine the implemented security and privacy controls are operating as intended and producing the desired results (this involves penetration testing conducted by the agency or independent third-party [Contracting Officer insert pen test requirement, if needed].) In addition, review all relevant A&A documentation (SSP, POA&M, Contingency Plan, etc.) and provide updates by the specified due date provided by the COR.

(7) *Asset management*. Using any available Security Content Automation Protocol (SCAP)-compliant automated tools for active/passive scans, the Contractor shall provide an inventory of all information technology (IT) assets for hardware and software (computers, servers, routers, databases, operating systems, etc.) that are processing

HHS-owned information and/or data. It is anticipated that this inventory information will be required to be produced at least [Contracting Officer insert specific timeframe]. IT asset inventory information shall include-

(i) IP address;

(ii) Machine name;

(iii) Operating system level;

(iv) Security patch level; and

(v) SCAP-compliant format information. The Contractor shall maintain a capability to provide an inventory of 100% of its IT assets using SCAP-compliant automated tools in accordance with the *HHS Policy for Information Technology Asset Management (ITAM)* and any other applicable HHS policy.

(8) *Configuration management*. The Contractor shall use available SCAP-compliant automated tools as per NIST IR 7511 and *HHS Minimum Security Configurations Standards Guidance* to scan all IT assets, including but not limited to computers, servers, routers, databases, operating systems, application, etc., that store and process government information. The Contractor shall provide scan reports to the COR upon request. The Contractor shall maintain a capability to provide security configuration compliance information for 100% of its IT assets using SCAP-compliant automated tools.

(9) *Vulnerability management*. The Contractor shall actively manage system vulnerabilities using automated tools and technologies where practicable and in accordance with *HHS Policy for Vulnerability Management*. Automated tools must be compliant with NIST-specified SCAP standards for vulnerability identification and management. The contractor shall maintain a capability to provide security vulnerability scanning information for 100% of IT assets using SCAP-compliant automated tools and report to the agency at least [Contracting Officer insert specific timeframe].

(10) *Patching and vulnerability remediation*. The Contractor shall install vendor-released security patches and remediate critical and high vulnerabilities in systems processing government information in an expedited manner, within vendor and agency specified timeframes.

(11) *Secure coding*. The Contractor shall follow the *HHS Policy for Software Development Secure Coding Practices* and secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team specified standards, the Software Engineering Institute (SEI) CERT and the Open Web Application Security Project, that will limit system software vulnerability exploits.

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

(13) *Government access for security assessment*.

(i) In addition to the Inspection Clause in the contract, the Contractor 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. This access includes, but is not limited to-

(1) 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, access to 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. For the purposes of this paragraph only, *Government* includes, but is not limited to, Contracting Officer, COR, the U.S. Department of Justice, U.S. Government Accountability Office, and the HHS Office of the Inspector General (OIG). The purpose of 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, Structured Query Language injection vulnerabilities, and any other known vulnerabilities.

(2) 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.

(ii) The Contractor shall segregate Government protected information and metadata on the handling of Government protected information from other information. Commingling of information is prohibited. Government inspectors, auditors, and investigators will not be precluded from having access to the sought information if sought information is commingled with other information.

(iii) The Contractor shall cooperate with inspections, audits, investigations, and reviews.

(c) *End of Life compliance*. The Contractor shall 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 if it impacts enterprise-wide systems and services, or by the OPDIV CISO if it impacts only the OPDIV). The contractor must retire and/or upgrade all software/systems that have reached end-of-life in accordance with *HHS End of Life Operating Systems, Software and Application Policy*.

(d) *Desktops, laptops, and other computing devices required for use by the Contractor*. The Contractor 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:

(1) Encrypt equipment and sensitive information stored and/or processed by such equipment in accordance with HHS encryption standard and current FIPS 140 validation certificate from the NIST Cryptographic Module Validation Program.

(2) Configure laptops and desktops in accordance with the latest applicable United States Government Configuration Baseline, [Contracting Officer insert specific security configuration baseline, if applicable], and HHS Minimum Security Configuration Standards;

(3) Maintain the latest operating system patch release and anti-virus software definitions at least [Contracting Officer, insert specific timeline(s)];

(4) 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

(5) Automate configuration settings and configuration management in accordance with HHS security policies, including but not limited to:

(i) Configuring its systems to allow for periodic HHS vulnerability and security configuration assessment scanning; and

(ii) Using SCAP-validated tools with capabilities to scan its systems at least on a monthly basis and report the results of these scans to the Contracting Officer and/or COR, Project Officer, and any other point of contract designated by the Contracting Officer or COR.

(e) *Rights to data*. Contractors shall specify any data rights asserted and mark such deliverables accordingly in accordance with applicable data rights clauses set forth in the contract.

(f) *Information and Communications Technology (ICT) Cybersecurity Supply Chain Risk Management (C-SCRM) requirements*. The Contractor shall secure their ICT supply chain in compliance with *HHS Policy for Cyber Supply Chain Risk Management* and Public Law 115-232, section 889. At a minimum, the Contractor shall-

(1) Develop rules for suppliers' development methods, techniques, or practices;

(2) Use secondary market components;

(3) Prohibit counterfeit products;

(4) Dispose and/or retain elements such as components, data, or intellectual property securely;

(5) Ensure adequate supply of components;

(6) 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;

(7) 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;

(8) Establish Service Level Agreements (SLAs), patching vehicles, and disclosure requirements in the case of an incident or new vulnerability being discovered; and

(9) 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

(10) Prohibit the use of covered telecommunications and video surveillance equipment or services.

(g) *Subcontract flow down*. The Contractor shall include the substance of this clause, including this paragraph (g), in subcontracts and third-party agreements, at any tier, of any amount and in which subcontractor employees and third-party servicers/employees, will perform functions or provide products under the scope of this contract, and have access to HHS information (including HHS sensitive information, *i.e*., protected health information), information systems, information technology (IT) or providing and accessing information technology-related contract services, support services, and related resources (see HHSAR 302.101, Definitions).

(End of clause).

SUPPLEMENT TO HHSAR 352.239-76 SECURITY REQUIREMENTS FOR GOVERNMENT-OWNED CONTRACTOR-OPERATED AND CONTRACTOR-OWNED CONTRACTOR-OPERATED RESOURCES (FEB 2024) (DEVIATION) .

GOVERNMENT WEBSITES
All new and existing public-facing government websites must be securely configured with Hypertext Transfer Protocol Secure (HTTPS) using the most recent version of Transport Layer Security (TLS). In addition, HTTPS must enable HTTP Strict Transport Security (HSTS) to instruct compliant browsers to assume HTTPS at all times to reduce the number of insecure redirects and protect against attacks that attempt to downgrade connections to plain HTTP. Configure internal-facing websites with HTTPS. Consult the *HHS Policy for Internet and Email Security* for additional information.

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.

VULNERABILITY MANAGEMENT
The Contractor shall employ vulnerability scanning tools and techniques that facilitate interoperability among tools and automate parts of the vulnerability management process by using standards for:

a. Enumerating platforms, software flaws, and improper configurations;

b. Formatting checklists and test procedures; and

c. Measuring vulnerability impact.

The Contractor shall report the scan results for vulnerabilities in the information system and hosted applications weekly (Low and Moderate systems), every seventy-two (72) Hours (High systems), and when new vulnerabilities potentially affecting the system/applications are identified and reported. If required monthly, this report may be included as part of the Technical Progress Report. Otherwise, this report shall be submitted under separate cover on a monthly basis.

DESKTOPS, LAPTOPS, AND OTHER COMPUTING DEVICES REQUIRED FOR USE BY THE CONTRACTOR

Maintain the latest operating system patch release and anti-virus software definitions at least within fifteen (15) days.

A. INFORMATION SECURITY AND/OR PHYSICAL ACCESS SECURITY

A. Baseline Security Requirements

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

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.

2. **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:** [X] Low [ ] Moderate [ ] High

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

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

• **Overall Risk Level:** [X] 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.

3. **Privacy Act**. Comply with the Privacy Act requirements (when applicable), and tailor FAR and HHSAR clauses as needed.

4. **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:

[X] No PII [ ] PII

3. 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.

5. **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* .

6. **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.

7. **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).

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

9. **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.

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

11. **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.

12. **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 https://csrc.nist.gov/publications/. Encryption keys must be provided to the COR upon request and at the conclusion of the contract.

13. **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

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 https://irtsectraining.nih.gov/default.aspx 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 at: 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.

3. Rules of Behavior

1. 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*.

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 ROB must be provided as a separate deliverable to the CO and/or COR per defined timelines above.

4. Incident Response

1. 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).'*

2. 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.

[X] 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

1. **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.

2. **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.

3. **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.*

4. **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.

5. **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.

6. 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

1. 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.

2. 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.

15. RECORDS MANAGEMENT, HHSAR 352.204-72 (FEB 2024) (DEVIATION)

(a) *Applicability*. This clause applies to contracts that include Federal records, as defined in paragraph (b).

(b) *Definition*. As used in this clause-

Federal record means all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them. See 44 U.S.C. 3301.

(1) The term Federal record-

(i) Includes HHS records;
(ii) Does not include personal materials;
(iii) Applies to records created, received, or maintained by Contractors pursuant to their contract; and
(iv) May include deliverables and documentation associated with deliverables.

(2) *Recorded information* means all traditional forms of records, regardless of physical form or characteristics, including information created, manipulated, communicated, or stored in digital or electronic form. (See 44 U.S.C. 3301.)

(3) *Personal materials* means documentary materials belonging to an individual that are not used to conduct agency business. Personal files are excluded from the definition of Federal records and are not owned by the Government. (See 36 CFR 1220.18.)

(c) *Requirements*.

(1) The Contractor shall comply with all applicable records management laws and regulations, as well as National Archives and Records Administration (NARA) records policies, including but not limited to the Federal Records Act (44 U.S.C. chapters 21, 29, 31, 33), NARA regulations at 36 CFR chapter XII subchapter B, and those policies associated with the safeguarding of records covered by the Privacy Act of 1974 (5 U.S.C. 552a). These policies include the preservation of all Federal records, regardless of form or characteristics, mode of transmission, or state of completion.

(2) In accordance with 36 CFR 1222.32, all data created for Government use and delivered to, or falling under the legal control of, the Government are Federal records subject to the provisions of 44 U.S.C. chapters 21, 29, 31, and 33, the Freedom of Information Act (FOIA) (5 U.S.C. 552), and the Privacy Act of 1974 (5 U.S.C. 552a), and must be managed and scheduled for disposition only as permitted by statute or regulation.

(3) In accordance with 36 CFR 1222.32, the Contractor shall maintain all Federal records created for Government use or created in the course of performing the contract and/or delivered to, or under the legal control of the Government and must be managed in accordance with Federal law. Electronic records and associated metadata must be accompanied by sufficient technical documentation to permit understanding and use of the records and data.

(4) The Contractor is responsible for preventing the alienation or unauthorized destruction of Federal records, including all forms of mutilation. Federal records may not be removed from the legal custody of HHS or destroyed except for in accordance with the provisions of the agency records schedules and with the written concurrence of the Contracting Officer. Willful and unlawful destruction, damage or alienation of Federal records is subject to the fines and penalties imposed by 18 U.S.C. 2701. The Contractor shall report to the Contracting Officer any unlawful or accidental removal, defacing, alteration, or destruction of Federal records.

(5) The Contractor shall immediately notify the Contracting Officer upon discovery of any inadvertent or unauthorized disclosures of information, data, documentary materials, records or equipment. Disclosure of non-public information is limited to authorized personnel with a need-to-know as described in the contract. The Contractor shall ensure that appropriate personnel are trained to adhere to these contract requirements, and that applicable, administrative, technical, and physical safeguards are established to ensure the security and confidentiality of information, data, documentary material, Federal records and/or equipment is properly protected. The Contractor shall not remove Federal Records from Government facilities or systems, or facilities or systems operated or maintained on the Government's behalf, without the express written permission of the Contracting Officer. When information, data, documentary material, Federal records and/or equipment are no longer required, it shall be returned to HHS control or the Contractor must hold it until otherwise directed. Items returned to the Government shall be hand carried, mailed, emailed, or securely electronically transmitted to the Contracting Officer or as otherwise directed by the Contracting Officer. Destruction of Federal records is expressly prohibited unless in accordance with paragraph (c)(4).

(6) The Contractor shall only use Government information technology equipment for purposes specifically authorized by the contract and in accordance with HHS policy.

(7) The Contractor shall not create or maintain any Federal records containing any non-public HHS information that are not specifically authorized by the contract.

(8) The Contractor shall not retain, use, sell, or disseminate copies of any deliverable that contains information covered by the Privacy Act of 1974 or that which is generally protected from public disclosure by an exemption to the Freedom of Information Act.

(9) All Contractor employees assigned to this contract handle Federal records are required to take HHS-provided records management training. The Contractor is responsible for confirming training has been completed according to agency policies, including initial training and any annual or refresher training.

(d) *Subcontract flowdown*. The Contractor shall incorporate the substance of this clause, its terms and requirements including this paragraph, in all subcontracts under this contract.

(End of clause).

16. CONFIDENTIALITY OF INFORMATION

1. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

2. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

3. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

4. Confidential information, as defined in paragraph 1. of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

5. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

6. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

7. The provisions of paragraph 4. of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

The following information is covered by this article:

17. 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 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.

1. 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;

2. 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;

3. 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.

4. 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. 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

f. 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).

g. 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.

h. 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.

i. 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).

j. Provide initial and ongoing FCOI reports to the NIH as required pursuant to § 94.5(b) .

k. 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.

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

m. 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.

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

1. Management of financial conflicts of interest.

2. 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.

o. 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.

p. 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:

1. 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;

2. (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.

q. 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.

r. 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.

s. 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:

1. The significant financial interest was disclosed and is still held by key personnel as defined in this part;

2. The Institution determines that the significant financial interest is related to the NIH-funded research; and

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

t. 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.

u. 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.

v. 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.

w. 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.

2. Reporting of financial conflicts of interest.

a. 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.

b. 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.

c. 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.

d. 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.

e. 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.

18. 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 Institutes of Health, Department of Health and Human Services, under Contract No. TBD."

19. 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

20. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

21. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD

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

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

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

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

22. HHSAR 352.239-73 Electronic Information and Technology Accessibility Notice. (DEC 2015)

(a) Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

(b) Accordingly, any offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at *http://www.hhs.gov/web/508*. The complete text of the Section 508 Final Provisions can be accessed at *http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards*.

(c) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document-in detail-whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site *http://www.hhs.gov/web/508*.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

(d) Respondents to this solicitation must identify any exception to Section 508 requirements. If a offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, *i.e*., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(End of provision)

23. HHSAR 352.270-5 b Care of Live Vertebrate Animals. (DEC 2015)

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

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

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

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

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate

APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov; Web site: (*http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare*).

(End of clause)

24. NEEDLE EXCHANGE (MAR 2026) (RFO DEVIATION)

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

(End of clause)

23. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH (MAR 2026) (RFO DEVIATION)

(a) The Contractor must not use any funds obligated under this contract for—

- (1) Any abortion,
- (2) Cloning of human beings, or
- (3) For the following:
    - o (i) The creation of a human embryo or embryos for research purposes; or
    - o (ii) Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).

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

(End of clause)

SECTION I - Contract Clauses

1. GENERAL CLAUSES

THE FOLLOWING ARTICLE I.1. 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 CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

This solicitation incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically as follows: FAR Clauses at: https://www.acquisition.gov/. HHSAR Clauses at: https://www.hhs.gov/grants-contracts/contracts/contract-policies-regulations/hhsar/part-352-solicitation-provisions-contract-clauses/index.html .

Clause Database	Clause Number	Clause Title
HHSAR	352.223-70	Safety and Health. (DEC 2015)
HHSAR	352.231-70	Salary Rate Limitation. (DEC 2015)
RFO	52.203-13	Contractor Code of Business Ethics and Conduct. (NOV 2021)
RFO	52.203-16	Preventing Personal Conflicts of Interest. (JUN 2020)
RFO	52.204-7	System for Award Management-Registration. (NOV 2024) (Deviation APR 2026)
RFO	52.209-10	Prohibition on Contracting With Inverted Domestic Corporations. (NOV 2015) (Deviation APR 2026)
RFO	52.210-1	Market Research. (NOV 2021) (Deviation JUL 2025)
RFO	52.217-5	Evaluation of Options. (JUL 1990) (Deviation NOV 2025)
RFO	52.217-7	Option for Increased Quantity - Separately Priced Line Item. (MAR 1989)
RFO	52.219-4	Notice of Price Evaluation Preference for HUBZone Small Business Concerns. (OCT 2022) (Deviation APR 2026)
RFO	52.223-3	Hazardous Material Identification and Safety Data. (FEB 2021) (Deviation APR 2026)
RFO	52.223-3	Hazardous Material Identification and Safety Data. (FEB 2021) (Deviation APR 2026) - Alternate I (JUL 1995) (Deviation APR 2026)
RFO	52.227-14	Rights in Data-General. (MAY 2014)
RFO	52.230-2	Cost Accounting Standards. (JUN 2020) (Deviation NOV 2025)
RFO	52.230-6	Administration of Cost Accounting Standards. (JUN 2010) (Deviation NOV 2025)
RFO	52.233-1	Disputes. (MAY 2014) (Deviation APR 2026) - Alternate I (DEC 1991) (Deviation APR 2026)
RFO	52.237-3	Continuity of Services. (JAN 1991)

Clause Database	Clause Number	Clause Title
RFO	52.242-3	Penalties for Unallowable Costs. (DEC 2022) (Deviation APR 2026)
RFO	52.246-23	Limitation of Liability. (FEB 1997)
RFO	52.246-25	Limitation of Liability - Services. (FEB 1997)
RFO	52.247-63	Preference for U.S.-Flag Air Carriers. (JAN 2025)

2. AUTHORIZED SUBSTITUTION 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. Authorized Substitutions ADD 52.215-2 *A2*

Alternate II (Aug 2016) of FAR Clause 52.215-2, Audit and Records--Negotiation (Jun 2020) is added.

*B. Authorized Substitutions ADD 52.215-14 *A1*

Alternate I (Oct 1997) of FAR Clause 52.215-14, Integrity of Unit Prices (Nov 2021) is added.

*C. Authorized Substitutions ADD 52.215-21 *A4*

Alternate IV (Oct 2010) of FAR Clause 52.215-21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data--Modifications (Nov 2021) is added.

D. Authorized Substitutions ADD 52.215-23

FAR Clause 52.215-23, Limitations on Pass-Through Charges (Jun 2020), is added.

*E. Authorized Substitutions ADD 52.219-9 *A2*

Alternate II (Nov 2016) of FAR Clause 52.219-9, Small Business Subcontracting Plan (Sep 2023) is added.

F. Authorized Substitutions REMOVE 52.232-20, ADD 52.232-22

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

3. ADDITIONAL CONTRACT CLAUSES 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.

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

A. ***RFO 52.204-14 Service Contract Reporting Requirements. (OCT 2016) (Deviation APR 2026)***

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

First-tier subcontract means a subcontract awarded directly by the Contractor to acquire supplies or services (including construction) for performing a prime contract. It does not include the Contractor's supplier agreements with vendors, such as long-term arrangements for materials or supplies that benefit multiple contracts and/or the costs of which are normally applied to a contractor's general and administrative expenses or indirect costs.

(b) *Requirement*. The Contractor shall report, according to paragraphs (c) and (d) of this clause, annually by October 31, for services performed under this contract during the preceding Government fiscal year (October 1-September 30).

(c) *Report elements*. The Contractor shall report the following information:

(1) Contract number and, as applicable, order number.

(2) The total dollar amount invoiced for services performed during the previous Government fiscal year under the contract.

(3) The number of Contractor direct labor hours expended on the services performed during the previous Government fiscal year.

(4) Data reported by subcontractors under paragraph (f) of this clause.

(d) *Remedies*. The Contractor shall submit the information required in paragraph (c) of this clause in the System for Award Management (SAM) at https://www.sam.gov (see SAM User Guide). If the Contractor fails to submit the report in a timely manner, the Contracting Officer will exercise appropriate contractual remedies. In addition, the Contracting Officer will make the Contractor's failure to comply with the reporting requirements a part of the Contractor's performance information under the Federal Acquisition Regulation part 42.

(e) *Review*. Agencies will review Contractor-reported information for reasonableness and consistency with available contract information. If the agency believes that revisions to the Contractor's reported information are warranted, the agency will notify the Contractor no later

than November 15. By November 30, the Contractor shall revise the report, or put its reason in writing for the agency.

(f) *First-tier subcontracts*.(1) The Contractor shall require each first-tier subcontractor providing services under this contract, with subcontract(s) each valued at or above the thresholds set forth in 4.303(b), to provide the following detailed information to the Contractor in sufficient time to submit the report:

(i) Subcontract number (including subcontractor name and unique entity identifier); and

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

(2) The Contractor shall tell the subcontractor that the information will be made available to the public as required by section 743 of Division C of the Consolidated Appropriations Act, 2010.

(End of clause)

B. RFO 52.209-9 Updates of Publicly Available Information Regarding Responsibility Matters. (OCT 2018) (Deviation APR 2026)

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

(b) 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 part 42.

(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 the Government has posted. FAPIIS will retain the comments 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) All information posted in FAPIIS on or after April 15, 2011, except past performance reviews, will be publicly available (section 3010 of Pub. L. 111-212).

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

(End of clause)

C. ***RFO 52.217-6 Option for Increased Quantity. (MAR 1989)***
The Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within [insert in the clause the period of time in which the Contracting Officer has to exercise the option]. Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.
(End of clause)

D. ***RFO 52.217-8 Option To Extend Services. (NOV 1999****)*

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6

months. The Contracting Officer may exercise the option by written notice to the Contractor within [insert the period of time within which the Contracting Officer may exercise the option].

(End of clause)

E. ***RFO 52.217-9 Option To Extend the Term of the Contract. (MAR 2000)***

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

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

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 10 years.

(End of clause)

F. ***RFO 52.219-28 Postaward Small Business Program Rerepresentation. (JAN 2025) (Deviation APR 2026)***

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

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern-

> (1) Means a concern, including its affiliates, that is independently owned and operated, not dominant in its field of operation, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause.
>
> (2) Affiliates, as used in this definition, means business concerns, one of whom directly or indirectly controls or has the power to control the others, or a third party or parties control or have the power to control the others. In determining whether affiliation exists, consideration is given to all appropriate factors including common ownership, common management, and contractual relationships. SBA determines affiliation based on the factors set forth at 13 CFR 121.103.

(b) If the Contractor represented that it was a small business concern, a small disadvantaged business concern, or a joint venture that was any of the small business concerns identified in

19.000(a)(3) prior to award of this contract, the Contractor shall rerepresent its size and socioeconomic status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts-

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code(s) assigned to this contract. The small business size standard corresponding to this NAICS code(s) can be found at https://www.sba.gov/document/support--table-size-standards.

(d) The small business size standard for a Contractor providing an end item that it does not manufacture, process, or produce itself, for a contract other than a construction or service contract, is 500 employees, or 150 employees for information technology value-added resellers under NAICS code 541519, if the acquisition-

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

(2) Used the HUBZone price evaluation preference regardless of dollar value, unless the Contractor waived the price evaluation preference; or

(3) Was 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.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the representation(s) required by paragraph (b) of this clause by validating or updating all its representations in the Representations and Certifications section of the System for Award Management (SAM) and its other data in SAM, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting officer in writing within

the timeframes specified in paragraph (b) of this clause, that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in SAM, or does not have a representation in SAM for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

(1) The Contractor represents that it [ ] is, [ ] is not a small business concern under NAICS Code [ ] assigned to contract number [ ].

(2) [*Complete only if the Contractor represented itself as a small business concern in paragraph (g)(1) of this clause*.] The Contractor represents that it [ ] is, [ ] is not, a small disadvantaged business concern as defined in 13 CFR 124.1001.

(3) Women-owned small business (WOSB) joint venture eligible under the WOSB Program. The Contractor represents that it [ ] is, [ ] is not a joint venture that complies with the requirements of 13 CFR 127.506(a) through (c). [The Contractor shall enter the name and unique entity identifier of each party to the joint venture: __.]

(4) Economically disadvantaged women-owned small business (EDWOSB) joint venture. The Contractor represents that it [ ] is,[ ] is not a joint venture that complies with the requirements of 13 CFR 127.506(a) through (c). [The Contractor shall enter the name and unique entity identifier of each party to the joint venture: __ .]

(5) *Service-disabled veteran-owned small business (SDVOSB) joint venture eligible under the SDVOSB Program*. The Contractor represents that it [ ] is, [ ] is not an SDVOSB joint venture eligible under the SDVOSB Program that complies with the requirements of 13 CFR 128.402. [The Contractor shall enter the name and unique entity identifier of each party to the joint venture: __.]

(6) *HUBZone joint venture eligible under the HUBZone Program*.[*Complete only if the offeror is a HUBZone small business concern*.] The offeror represents, as part of its offer, that It [ ] is, [ ] is not a HUBZone joint venture that complies with the requirements of 13 CFR 126.616(a) through (c). [The Contractor shall enter the name and unique entity identifier of each party to the joint venture: _____.] Each HUBZone small business concern participating in the HUBZone joint venture must be certified as a HUBZone concern. [Contractor to sign and date and insert authorized signer's name and title._____]

(End of clause)

G. 52.222-2 Payment for Overtime Premiums.

As prescribed in 22.102-2(b), insert the following clause:

Payment for Overtime Premiums (Deviation DATE)

*(a) The use of overtime is authorized under this contract if the overtime premium cost does not exceed * ___ or the overtime premium is paid for work—*

(1) Necessary to cope with emergencies such as those resulting from accidents, natural disasters, breakdowns of production equipment, or occasional production bottlenecks of a sporadic nature;

(2) By indirect-labor employees such as those performing duties in connection with administration, protection, transportation, maintenance, standby plant protection, operation of utilities, or accounting;

(3) To perform tests, industrial processes, laboratory procedures, loading or unloading of transportation conveyances, and operations in flight or afloat that are continuous in nature and cannot reasonably be interrupted or completed otherwise; or

(4) That will result in lower overall costs to the Government.

(b) Any request for estimated overtime premiums that exceeds the amount specified above must include all estimated overtime for contract completion and must-

(1) Identify the work unit; e.g., department or section in which the requested overtime will be used, together with present workload, staffing, and other data of the affected unit sufficient to permit the Contracting Officer to evaluate the necessity for the overtime;

(2) Demonstrate the effect that denial of the request will have on the contract delivery or performance schedule;

(3) Identify the extent to which approval of overtime would affect the performance or payments in connection with other Government contracts, together with identification of each affected contract; and

(4) Provide reasons why the required work cannot be performed by using multishift operations or by employing additional personnel.

** Insert either "zero" or the dollar amount agreed to during negotiations.*

(End of clause)

52.240-90 Security Prohibitions and Exclusions Representations and Certifications.

As prescribed in 40.205(a), insert the following provision:

Security Prohibitions and Exclusions Representations and Certifications (Deviation Date)

(a) Definitions. As used in this provision-—

Backhaul, covered article, covered telecommunications equipment or services, critical technology, FASCSA order, Intelligence community, interconnection arrangements, national security system, roaming, sensitive compartmented information, sensitive compartmented information system, source, and substantial or essential component have the meanings provided in the clause 52.240-91, Security Prohibitions and Exclusions.

Business operations means engaging in commerce in any form, including by acquiring, developing, maintaining, owning, selling, possessing, leasing, or operating equipment, facilities, personnel, products, services, personal property, real property, or any other apparatus of business or commerce.

Marginalized populations of Sudan means—

(1) Adversely affected groups in regions authorized to receive assistance under section 8(c) of the Darfur Peace and Accountability Act (Pub. L. 109-344) (50 U.S.C. 1701 note); and

(2) Marginalized areas in Northern Sudan described in section 4(9) of such Act.

Restricted business operations means business operations in Sudan that include power production activities, mineral extraction activities, oil-related activities, or the production of military equipment, as those terms are defined in the Sudan Accountability and Divestment Act of 2007 (Pub. L. 110-174). Restricted business operations do not include business operations that the person (as that term is defined in Section 2 of the Sudan Accountability and Divestment Act of 2007) conducting the business can demonstrate—

(1) Are conducted under contract directly and exclusively with the regional government of southern Sudan;

(2) Are conducted under specific authorization from the Office of Foreign Assets Control in the Department of the Treasury, or are expressly exempted under Federal law from the requirement to be conducted under such authorization;

(3) Consist of providing goods or services to marginalized populations of Sudan;

(4) Consist of providing goods or services to an internationally recognized peacekeeping force or humanitarian organization;

(5) Consist of providing goods or services that are used only to promote health or education; or

(6) Have been voluntarily suspended.

Sensitive technology—

(1) Means hardware, software, telecommunications equipment, or any other technology that is to be used specifically—

(i) To restrict the free flow of unbiased information in Iran; or

(ii) To disrupt, monitor, or otherwise restrict speech of the people of Iran; and

(2) Does not include information or informational materials the export of which the President does not have the authority to regulate or prohibit pursuant to section 203(b)(3) of the International Emergency Economic Powers Act (50 U.S.C. 1702(b)(3)).

(b) Procedures.

(1) Covered telecommunications and video surveillance. The Offeror shall review the list of excluded parties in the System for Award Management (SAM) at https://www.sam.gov for entities excluded from receiving federal awards for "covered telecommunications equipment or services."

(2) FASCSA Orders.

(i) The Offeror shall search in SAM for the phrase "FASCSA order" for any covered article, or any products or services produced or provided by a source, if there is an applicable FASCSA order described in paragraph (e) of FAR 52.240-91, Security Prohibitions and Exclusions.

(ii) The Offeror shall review the solicitation for any FASCSA orders that are not in SAM but are effective and apply to the solicitation and resultant contract (see FAR 40.204-1(c)(2)).

(iii) FASCSA orders issued after the date of solicitation do not apply unless added by an amendment to the solicitation.

(c) Covered telecommunications equipment or services representations. By submission of its offer, the Offeror represents that, after conducting a reasonable inquiry (that looks at any information in the Offeror's possession but does not need to include an internal or third-party audit)—

(1) It 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, except as waived by the solicitation, or as disclosed in paragraph (g); and

(2) It does not use covered telecommunications equipment or services, or use any equipment, system, or service that uses covered telecommunications equipment or services, except as waived by the solicitation, or as disclosed in paragraph (g).

(d) FASCSA Representation. By submission of this offer, the offeror represents that it has conducted a reasonable inquiry, and that the offeror does not propose to provide or use in response to this solicitation any covered article, or any products or services produced or provided by a source, if the covered article or the source is prohibited by an applicable FASCSA order in effect on the date the solicitation was issued, except as waived by the solicitation, or as disclosed in paragraph (g). A reasonable inquiry will look at any information in the offeror's possession but does not need to include an internal or third-party audit.

(e) Sudan certification. By submission of its offer, the offeror certifies, after conducting a reasonable inquiry (that looks at any information in the offeror's possession but does not need to include an internal or third-party audit), that the offeror does not conduct any restricted business operations in Sudan.

(f) Iran Representation and Certifications.

(1) Except as provided in paragraph (f)(2) of this provision or if a waiver has been granted in accordance with FAR 40.203-3, the offeror, after conducting a reasonable inquiry (that looks at any information in the offeror's possession but does not need to include an internal or third-party audit), by submission of its offer—

(i) Represents, to the best of its knowledge and belief, that the offeror does not export any sensitive technology to the government of Iran or any entities or individuals owned or controlled by, or acting on behalf or at the direction of, the government of Iran;

(ii) Certifies that the offeror, or any person (as defined at section 15 of the Iran Sanctions Act of 1996, Pub. L. 104-172, 50 U.S.C. 1701 note) owned or controlled by the offeror, does not engage in any activities for which sanctions may be imposed under section 5 of the Act. These sanctioned activities are in the areas of development of the petroleum resources of Iran, production of refined petroleum products in Iran, sale and provision of refined petroleum products to Iran, and contributing to Iran's ability to acquire or develop certain weapons or technologies; and

(iii) Certifies that the offeror, and any person owned or controlled by the offeror, does not knowingly engage in any transaction that exceeds $15,000 with Iran's Revolutionary Guard Corps or any of its officials, agents, or affiliates, the property and interests in property of which are blocked pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701 et

seq.) (see OFAC's Specially Designated Nationals and Blocked Persons List at https://www.treasury.gov/resource-center/sanctions/SDN-List/Pages/default.aspx)

(2) Exception for trade agreements. The representation and certification requirements of paragraph (f)(1) of this provision do not apply if—

(i) This solicitation includes a trade agreements notice or certification (e.g., 52.225-6, Trade Agreements Certificate); and

(ii) The offeror has certified that all the offered products to be supplied are designated country end products or designated country construction material.

(iii) The offeror shall email questions concerning sensitive technology to the Department of State at CISADA106@state.gov.

(g) Disclosure.

(1) If the Offeror is not able to represent compliance with the prohibitions in paragraphs (c) or (d), then the Offeror shall disclose within 72 hours to the contracting office identified in paragraph (g)(2) the following information for each product or service not compliant:

(i) Contract number and order number, if applicable;

(ii) Identification of whether this disclosure relates to paragraph (c) on covered telecommunication equipment or services, or to paragraph (d) on FASCSA orders;

(iii) A description of the products or services that the Contractor identifies or has reason to suspect is prohibited (include brand; model number, such as the original equipment manufacturer (OEM) number, manufacturer part number, or wholesaler number; and item description, as applicable);

(iv) The entity that produced the product or service (include entity name, unique entity identifier, Contractor and Government Entity (CAGE) code, facilities responsible for design, fabrication, assembly, packaging, and test of the product, and whether the entity was the OEM or a distributor (provide manufacturer codes and distributor codes used for the product));

(v) Description of the functionality of the product or service and how that functionality impacts the risk to the product or service;

(vi) An explanation of any factors relevant to determining if the product or service should be permitted by an applicable exception, exemption, or waiver (if the offeror would like the Government to consider a waiver);

(vii) Whether alternative products or services are available that would be compliant with the prohibition;

(viii) If the product or service is related to item maintenance, include the following information on the item being maintained:

(A) Brand;

(B) Model number, OEM number, manufacturer part number, or wholesaler number; and

(C) Item description, as applicable.

(ix) Any readily available information about mitigation actions undertaken or recommended.

(2) If a disclosure is required to be submitted to a contracting office, the offeror shall submit the disclosure as follows:

(i) If a Department of Defense contracting office, the offeror shall submit the disclosure to the website at https://dibnet.dod.mil.

(ii) For all other contracting offices, the Offeror shall submit the disclosure to the Contracting Officer.

(3) If the disclosure provided does not contain any of the information required by paragraph (1), and the Offeror later discovers new information that is required by paragraph (1), then the Offeror shall submit a subsequent disclosure within 72 hours of discovering the new information.

(h) Executive agency review of disclosures. The Contracting Officer will review disclosures provided in paragraph (g) to determine if any applicable waiver may be sought. The Contracting Officer may choose not to pursue a waiver and may instead make an award to an Offeror that does not require a waiver.

(End of provision)

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RFO 52.240-93 Basic Safeguarding of Covered Contractor Information Systems. (Deviation NOV 2025)

(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-

(1) 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

(2) Does not include information provided by the Government to the public (such as on public websites) or simple transactional information (such as information 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*.

(1) Basic requirements. The Contractor shall safeguard its covered contractor information systems by implementing, at 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 departments and agencies 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, or commercial services), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

5. SERVICE CONTRACT LABOR STANDARDS

Any contract awarded from this RFP will contain the following article:
SERVICE CONTRACT LABOR STANDARDS
This contract is subject to the Service Contract Labor Standards. The following clauses are hereby incorporated and made a part of this contract.

52.222-40 Notification of Employee Rights Under the National Labor Relations Act.
52.222-41 Service Contract Labor Standards

SECTION J - List of Documents, Exhibits and Other Attachments

Attachment Number	Title	Date	Number of Pages
1	Packaging and Delivery of Proposals - NIH electronic Contract Proposal Submission (eCPS) Website	3/12/18	2
2	Proposal Intent Response Sheet	-	1
3	Statement of Work	7/13/26	19
4	Reporting Requirements and Deliverables; Specifications (Chapter 7)	4/13/26	2
5	Section K - Representations, Certifications, and Other Statements of Offerors	5/25	10
6	Supply Chain Risk Management Certification	--	4
7	Technical Proposal Cost Summary	1/11	1
8	Summary of Related Activities	1/11	1
9	Contract Proposal Vertebrate Animal Section (VAS) Worksheet	--	
10	HHS Section 508 Product Assessment Template	--	-
11	Proposal Summary and Data Record, NIH-2043	7/8	1
12	Small Business Subcontracting Plan- Submission Guide	--	6
13	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	8/19/15	-
14	Offeror's Points of Contact	1/11	1
15	Certificate of Current Cost or Pricing Data	--	
16	Disclosure of Lobbying Activities, OMB Form SF-LLL	--	-
17	Invoice/Financing Request Instructions- CR - NIH (RC)-1	4/26	7
18	Government Property Schedule	--	-
19	Roster of Employees Requiring Suitability Investigations	--	-
20	Employee Separation Checklist	--	1
21	Contractor Non-Disclosure Agreement	--	2
22	Safety and Health, HHSAR Clause 352.223-70	12/15	2
23a	NIH FORM 2706- Instructions NIH Form 2706	--	2
23b	NIH FORM 2706- Financial Report of Individual Project/Contract	--	1
24	Additional Proposal Instructions and Evaluation Criteria	--	1
	Sub. Attachment A- Experience Form	--	2
	Sub. Attachment B- Sample Research Outlines	--	19
	Sub. Attachment C- Past Performance Questionnaire	--	4
	Sub. Attachment D- Biographical Sketch Form	--	1

Attachment Number	Title	Date	Number of Pages
	Sub. Attachment E- Level of Effort Worksheet	--	7
	Sub. Attachment F- Government Furnished Materials	--	
25	Attachments and Links	--	3

SECTION K - Representations, Certifications, and Other Statements of Bidders

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).

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST:

a. 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

b. 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 Bidders

GENERAL INFORMATION

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 TBD; 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.

1. **NAICS CODE AND SIZE STANDARD**

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

1. The North American Industry Classification System (NAICS) code for this acquisition is 541715.

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

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the

North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

3. **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 January 18, 2027.

2. It is anticipated that the award(s) from this solicitation will be a multiple-year cost reimbursement type completion contract with a base period of one (1) year plus nine (9) 12-month options. An additional option year to extend services is included for a 6-month period. The period of performance is contemplated for January 18, 2027 to January 17, 2037 with an option to extend services to July 17, 2037. Incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a Contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled "Adequate Accounting System" in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

4. **LEVEL OF EFFORT**

The Government's requirement for the work set forth in the Statement of Work of this solicitation is TBD direct labor hours for the base period, TBD direct labor hours for all option periods if all exercised and TBD direct labor hours for the six (6) month extension if exercised. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7	Year 8	Year 9	Year 10	6-month option to extend contract
Senior Research Professional											
Research Professional											
Technical Staff											
Support Staff											
Totals											

5. **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.

6. **PROMOTING EFFICIENT SPENDING**

On September 21, 2011, the Office of Management and Budget issued Memorandum M-11-35, https://obamawhitehouse.archives.gov/sites/default/files/omb/memoranda/2011/m11-35.pdf entitled, "Eliminating Conference Spending and Promoting Efficiency in Government," emphasizing the President's priority to ensure that the Government operates with the utmost efficiency and eliminates unnecessary or wasteful spending. This was followed by the Executive Order on Delivering an Efficient, Effective, and Accountable Government (EO 13576) and the Executive Order on Promoting Efficient Spending (EO 13589). On January 23, 2015, the Department of Health and Human Services (DHHS) issued the memorandum "HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings Spaces, Food, Promotional Items, and Printing, and Publications" (See http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html).

In support of these directives, the NIH issued a November 1, 2015, Memorandum, entitled, "NIH Guidance Related to the HHS Policies on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meeting Space, Food, Promotional Items, and Printing and Publications." (See https://oamp.od.nih.gov/news/NIH-efficient-spending-policy)

Any contract awarded as a result of this solicitation will:

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

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

7. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

8. **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.

9. **PREPARATION COSTS**

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

10. **SERVICE OF PROTEST** FAR 52.233-2 (Sep 2006) (Deviation NOV 2025)

(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:

Sarah Bank, Contracting Officer
NIH, OALM, OD, Research and Development and Professional Services – Division B

(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).

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

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, the Government may consider a proposal received after the date specified for receipt if it appears to offer significant cost or technical value to the Government and it was received before proposals were distributed for evaluation, or within 5 calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision).

d. **INSTRUCTIONS TO OFFERORS**

1. **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.

a. **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement level of effort type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as

required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

b. **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 electronically through the **NIH Electronic Contract Proposal System (eCPS)**, 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 and paginated 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, 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.

c. **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).

d. **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.

e. **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.

f. **Evaluation of Proposals**

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

g. **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.

h. **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.

i. **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.

j. **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 adjectival ratings 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 NIEHS's policy to conduct discussions with all offerors in the competitive range, NIEHS 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 NIEHS 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 NIEHS requirements. Synopses of awards exceeding $25,000 will be published in Contract Opportunities at: https://sam.gov.

k. **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.

l. **Past Performance Information**

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

A list of the last 3 contracts completed during the past three years that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant

acquisition. For the purposes of this solicitation, a "major subcontract" is defined as $100,000 or more.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization

2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)

3. Contract Type

4. Total Contract Value

5. Description of Requirement

6. Contracting Officer's Name and Telephone Number

7. Program Manager's Name and Telephone Number

8. North American Industry Classification System (NAICS) Code

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

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

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):

System for Award Management, FAR Provision 52.204-7 (Oct 2018).

Alternate I (Oct 2018) is NOT applicable to this solicitation.

Unique Entity Identifier, FAR Provision 52.204-6 (Oct 2016).

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

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

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

Preaward On-Site Equal Opportunity Compliance Evaluation, ($10,000,000 or Over), FAR Clause 52.222-24, (Feb 1999).

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

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. See Attachment 24- Additional Proposal Instructions and Evaluation Criteria for additional details.

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.

a. **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.

5. Resumes

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

a. **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.

b. Other factors you feel are important and support your proposed research.Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

d. **Technical Evaluation**

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

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).

d. **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.

e. **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future

avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guidelines for Recipients of NIH Research Grants and Policy," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf.

A. **Management and Sharing of Research Data**

Note: This policy applies to **all** NIH contracts, regardless of dollar value or level or type of funding, degree of funding (whole or partial), or type of NIH funding mechanism, that are expected to generate research data.

NIH encourages, to the maximum extent practicable, the sharing of final research data to expedite the translation of research results into knowledge, products, services, and/or procedures to improve the human health condition. This contract is anticipated to generate such research data. Therefore, the Offeror shall submit a plan in its technical proposal for data management and sharing or state why such data sharing is not possible. If data sharing is limited, the Offeror shall explain the rationale and nature of such limitations in its Data Management and Sharing Plan. NIH's Data Management and Sharing Policy may be found at the following Web site:

NOT-OD-21-013: Final NIH Policy for Data Management and Sharing.

NIH Sharing Policies and Related Guidance on NIH-Funded Research Resources are found at: https://grants.nih.gov/policy/sharing.htm.

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

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

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

300- Functional Performance Requirements- (Chapter 3- Always Apply - comparable 1194.31)
600- Support Services & Documentation Standards - (Chapter 6 - Always Apply - comparable 1194.41)
WCAG Level A Requirements - (Overlaps with Chapter 4 and 5)
WCAG Level AA Requirements- (Overlaps with Chapter 4 and 5)

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

a. **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.

3. **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $750,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled 'Small Business Subcontracting Plan,' FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation. **In accordance with RFO 19.109 and RFO Clause 52.219-9, the submission of a subcontracting plan by other than small business offeror(s) is a requirement as a part of the proposal submission process and is to be submitted separately from the technical and cost proposals.** An offeror's subcontracting plan must be determined to be acceptable, by the Contracting Officer, prior to the contract award. **This clause does not apply to small business concerns.**

1. An offeror is to submit their respective subcontracting plan electronically using the U.S. Department of Health and Human Services (HHS) Small Business Customer Experience (SBCX) system at https://osdbu.hhs.gov. The offeror must follow the instructions outlined in the SBCX Industry Guide instructions outlined in the SBCX Industry Guide at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j to successfully submit their subcontracting plan by the proposal submission deadline.

2. The official point of receipt for determining timely submission of an offeror's subcontracting plan is the SBCX system and/or email notification. Once the subcontracting plan is successfully submitted in the SBCX system the offeror should receive an email notification and confirmation message of completion upon submission.

3. If an offeror's subcontracting plan is not confirmed as received within the SBCX system by the proposal submission date specified in the solicitation, it will be considered late in accordance with subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offeror-Competition Acquisition. Disposition of late submittals of a subcontracting plan by an offeror via the SBCX system is at the discretion of the Contracting Officer.

4. Any technical questions regarding the use of the SBCX system may be submitted via email message to the SBCX help desk at client.support@apexlogic.com. The client support hours of operation are Monday - Friday, 6:00 a.m. - 8:00 p.m. Eastern Standard Time (EST). Note: help desk tickets can be submitted 24 hours a day / 7 days a week and a representative will respond within the presented client support hours of operation for assistance.

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:

i. 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.

ii. 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.

iii. 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.

iv. 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.

v. 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.

vi. 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.

4. Each plan must contain the following:

i. 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.

ii. 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.

iii. 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.

iv. A description of the method used to develop the subcontracting goals.

v. A description of the method used to identify potential sources for solicitation purposes.

vi. 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.

vii. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.

viii. 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.

ix. Assurances that the offeror will include in all subcontracts the contract clause 'Utilization of Small Business Concerns.' Assure that all subcontractors, other than small businesses, in excess of $750,000 adopt a plan similar to the plan agreed upon by the offeror.

x. 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 at https://www.sam.gov/.

xi. 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.

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

32% 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.

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

c. 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 https://www.sam.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).

5. **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.

6. **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.

7. **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-Furnished Property

No Government Furnished Property is offered for this acquisition.

B. **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.

C. **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.

D. **Incremental Funding**

An incrementally funded contract is a contract in which funds are obligated, as they become available, to cover specific periods of performance.

Incremental Funding, HHSAR 352.232-70 (December 2015).

The Government intends to negotiate and award a cost-reimbursement contract using incremental funding as described in the clauses at FAR 52.232-22, "Limitation of Funds." The initial obligation of funds under the contract is expected to cover TBD at award . The Government intends to obligate additional funds up to and including the full estimated cost of the contract for the remaining years of performance by unilateral contract modification. However, the Government is not required to reimburse the Contractor for costs incurred in excess of the total amount obligated, nor is the Contractor required to perform beyond the level supported by the total amount obligated.

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.

f. **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. See Attachment 24, Sub. Attachment A.

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.

g. **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.

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

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

j. **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.

1. HHSAR 352.270-5 a Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. (DEC 2015)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW),

National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (Email: *olaw@od.nih.gov*; Phone: 301-496-7163).

(End of provision)

2. RFO 52.215-22 Limitations on Pass-Through Charges-Identification of Subcontract Effort. (OCT 2009) (Deviation APR 2026)

(a) *Definitions*. Added value, excessive pass-through charge, subcontract, and subcontractor, as used in this provision, are defined in the clause of this request for proposals entitled "Limitations on Pass-Through Charges" (FAR 52.215-23).

(b) *General*. The offeror's proposal shall exclude excessive pass-through charges.

(c) Performance of work by the Contractor or a subcontractor. (1) The offeror shall identify in its proposal the total cost of the work to be performed by the offeror, and the total cost of the work to be performed by each subcontractor, under the contract, task order, or delivery order.

(2) If the offeror intends to subcontract more than 70 percent of the total cost of work to be performed under the contract, task order, or delivery order, the offeror shall identify in its proposal-

(i) The amount of the offeror's indirect costs and profit/fee applicable to the work to be performed by the subcontractor(s); and

(ii) A description of the added value provided by the offeror as related to the work to be performed by the subcontractor(s).

(3) If any subcontractor proposed under the contract, task order, or delivery order intends to subcontract to a lower-tier subcontractor more than 70 percent of the total cost of work to be performed under its subcontract, the offeror shall identify in its proposal-

(i) The amount of the subcontractor's indirect costs and profit/fee applicable to the work to be performed by the lower-tier subcontractor(s); and

(ii) A description of the added value provided by the subcontractor as related to the work to be performed by the lower-tier subcontractor(s).

(End of provision)

3. RFO 52.204-7 SYSTEM FOR AWARD MANAGEMENT-REGISTRATION. (NOV 2024) (Deviation APR 2026)

The Offeror shall have an active Federal Government contracts registration in the System for Award Management (SAM) when submitting an offer or quotation in response to this solicitation and at the time of award. As part of the SAM registration process, the Government collects information, as described in paragraphs (b) through (d) of this provision, that is necessary to identify the Offeror and for the Offeror to be awarded Federal Government contracts. To register in SAM, go to https://www.sam.gov. Allow for processing time when registering in SAM. If the Offeror is not registered in SAM, it should register immediately after receiving this solicitation.

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

Commercial and Government Entity (CAGE) code has the meaning provided in the clause at the Federal Acquisition Regulation (FAR) 52.204-13, System for Award Management-Maintenance, of this solicitation.

Electronic Funds Transfer (EFT) indicator means a bank account identifier to establish additional System for Award Management records for identifying alternative EFT accounts (see part 32) for the same entity.

Highest-level owner means the entity that owns or controls an immediate owner of the offeror, or that owns or controls one or more entities that control an immediate owner of the offeror. No entity owns or exercises control of the highest-level owner.

Immediate owner means an entity, other than the offeror, that has direct control of the offeror. Indicators of control include, but are not limited to, one or more of the following: ownership or interlocking management, identity of interests among family members, shared facilities and equipment, and the common use of employees. There may be more than one immediate owner (e.g., joint ventures).

Predecessor means an entity whose assets were acquired by the offeror or another entity (most often through merger or acquisition) and whose affairs are now carried out by the offeror or the other entity under a new name.

Taxpayer identification number means the number required by the Internal Revenue Service (IRS) to be used by the offeror to report income tax and other returns. It may be either a Social Security Number or an Employer Identification Number.

Unique entity identifier (UEI) has the meaning provided in the clause at FAR 52.204-13, System for Award Management-Maintenance, of this solicitation.

(b) *Identifiers*. The Offeror shall obtain and provide the following identifying information:

(1) Unique entity identifier (UEI).

(i) The Offeror shall obtain a UEI to register in SAM. The Government will independently validate the existence and uniqueness of the Offeror before assigning a UEI to the Offeror. Go to https://www.sam.gov for instructions on obtaining a UEI.

(ii) The Offeror shall enter, in the block with its name and address on the cover page of its offer, the annotation "Unique Entity Identifier" followed by the UEI that identifies the Offeror's name and address exactly as stated in the offer. The Offeror shall also enter its EFT indicator, if applicable.

(iii) The Contracting Officer will use the UEI to verify that the Offeror has an active Federal Government contracts registration in SAM.

(2) Taxpayer identification number (TIN).

(i) The Offeror shall provide its TIN or related information to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d); reporting

requirements of 26 U.S.C. 6041, 6041A, and 6050M; and implementing regulations issued by the IRS. The Offeror shall consent for TIN validation; and

(3) Commercial and Government Entity (CAGE) code.

(i) The Offeror shall provide a CAGE code and legal business name (Do not use a "doing business as" name) for-

(A) Itself;

(B) Its immediate owner(s), if any;

(C) Its highest-level owner, if any; and

(D) Any predecessor(s), or predecessor of an Offeror's predecessor, that held a Federal contract or grant within the last three years.

(ii) If the Offeror is in the United States or its outlying areas and does not already have a CAGE code assigned, the DLA CAGE Branch will assign a CAGE code to the Offeror as a part of the SAM registration process. For information on obtaining a CAGE code go to https://cage.dla.mil/.

(iii) The Offeror shall get from any immediate and/or highest-level owner(s) their respective CAGE code(s) to provide the code(s) as part of the registration (FAR 52.204-7(b)(3)(i)).

(iv) If the Offeror is located outside of the United States or its outlying areas, and does not already have a CAGE code assigned, the Offeror may obtain a CAGE code as indicated in the following table.

If the Offeror is...	**Then...**
Located in a country that is a member of the North Atlantic	Contact the appropriate National Codification Bureau (https://www.nato.int/structur/ac/135/about/contacts)

Treaty Organization (NATO) or a sponsored nation	
Located in a country that is not a member of NATO or a sponsored nation	Contact the NATO Support and Procurement Agency (NSPA) (https://eportal.nspa.nato.int/AC135Public/scage/CageList.aspx)

(c) *Representations and certifications*.

(1) The following FAR solicitation provisions contain entity-level representations and certifications that the Offeror shall submit as part of their Federal Government contracts registration in SAM:

Provision	**Title**	**Date**
52.204-5	Women-Owned Business (Other Than Small Business)	Oct 2014
52.209-2	Prohibition on Contracting with Inverted Domestic Corporations-Representation	Nov 2015
52.209-5	Certification Regarding Responsibility Matters	Aug 2020
52.209-11	Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law	Feb 2016
52.219-1	Small Business Program Representations	Feb 2024
52.219-1 Alt I	Small Business Program Representations, with its Alternate I	Feb 2024
52.219-1 Alt II	Small Business Program Representations, with its Alternate II	March 2023
52.226-2	Historically Black College or University and Minority Institution Representation	Oct 2014

(2) By submitting its offer, the Offeror verifies that, as of the date of its offer, its representations and certifications posted electronically in SAM for the provisions listed in paragraph (c)(1) of this provision are current, accurate, and complete. The Offeror's representations and certifications in SAM are hereby incorporated by reference into its offer.

(d) *Other information*. The Offeror shall provide more information on its business operations and type that is necessary to be considered for award of certain contracts and financial information necessary to receive payment under contracts.

(End of provision)

4. RFO 52.252-1 Solicitation Provisions Incorporated by Reference. (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 of those 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/these address(es): [Insert one or more Internet addresses]

(End of provision)

SECTION M - Evaluation Factors for Award

See Attachment 24 for Additional Evaluation Specifications and Requirements.