

# REQUEST FOR PROPOSALS (RFP) 75N96025R00004

## SECTION A - SOLICITATION/CONTRACT FORM

1. Requisition or other Purchase Authority: 42 U.S.C. 2851		
2. Request for Proposal (RFP) Number: <b>75N96025R00004</b>	3. Issue Date: September 17, 2025	4. Set Aside: <b>100% Small Business Set Aside</b> [ ] No [X] Yes See Part IV Section L
5. Title : <b>Support for Evaluating and Conducting Computational and Alternative Toxicological Methods for the National Institute of Environmental Health Sciences</b>		
6. ISSUED BY: Office of Acquisitions, ARB, Eunice Kennedy Shriver National Institute of Child Health and Human Development (on behalf of the National Institute of Environmental Health Sciences), NIAAA & NIEHS Team 6700B Rockledge Drive, MSC 6902 Bethesda, MD 20892-6902		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.3, "Packaging and Delivery of Proposals", until <u>4:30 PM Eastern Standard Time on <b>November 3, 2025</b></u> . 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.3, "Packaging and Delivery of Proposals". Proposal is to be delivered electronically via the NIH electronic Contract Proposal Submission (eCPS) website, <a href="https://www.ecps.nih.gov">https://www.ecps.nih.gov</a>  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 <u>subparagraph (c)(3) of FAR Provision 52.215-1, Instructions to Offerors-- Competitive Acquisition,"/HHSAR Provision 352.215-70, "Late Proposals and Revisions"</u> 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 <a href="https://www.sam.gov/SAM/">https://www.sam.gov/SAM/</a> .		
11. FOR INFORMATION CONTACT: Jason Williams, Contracting Officer e-MAIL: <a href="mailto:jason.williams2@nih.gov">jason.williams2@nih.gov</a> Phone: 301-443-3877 COLLECT CALLS WILL NOT BE ACCEPTED.		
Questions must be submitted in writing via e-mail to <a href="mailto:jason.williams2@nih.gov">jason.williams2@nih.gov</a> and <a href="mailto:lisa.schaupp@nih.gov">lisa.schaupp@nih.gov</a> in accordance with Article L.2., by October 20, 2025.		Secondary Contact: Lisa Schaupp, Section Chief, NICHD ARB, NIAAA and NIEHS Team, <a href="mailto:lisa.schaupp@nih.gov">lisa.schaupp@nih.gov</a>

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## **PART I - THE SCHEDULE**

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

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

NOTE: If any LINK in this solicitation is not clickable, manually copy and paste the URL into your web browser.

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### SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

#### ***ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES***

The acquisition will support and assist the National Institute of Environmental Health Sciences (NIEHS) by conducting and evaluating toxicological testing using computational and/or alternative approaches, also referred to as New Approach Methodologies (NAMs). NAMs broadly refers to any technology, methodology, approach, and/or combination of the three that can provide information on chemical hazard and risk assessment without the use of animals, such as in silico, in chemico, in vitro, and ex vivo approaches. The areas of focus for the research include but are not limited to population variability, susceptibility, developmental neurotoxicity, carcinogenicity, ecotoxicity, acute toxicity, etc.

The outputs from this requirement will directly feed into the mission of the Department of Health & Human Services (HHS). This requirement would produce information to predict adverse human health effects from chemical exposures while also replacing, reducing, or refining the use of animals in toxicity testing. These services are necessary to support state of the art alternative toxicity testing at NIEHS. This acquisition is for continuing support services for alternative toxicological testing approaches that extend beyond the scope or capability of in-house staff.

#### ***ARTICLE B.2. ESTIMATED COST PLUS FIXED FEE – OPTION***

***Note: To be completed upon award. See Section L, Proposal Instructions, for further information on estimating hours. Article L.1.d. provides the Government's estimated effort; Article L.4.A.2. and ATTACHMENT 6 – Sample Research Outlines provide further detailed information as to anticipated types/quantities of work.***

- a. The estimated cost of the Base Period of this contract is \$ TBD.
- b. The fixed fee for the Base Period of this contract is \$ TBD. The fixed fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the 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 \$ TBD.
- 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	Period of Performance	Estimated Cost (\$)	Fixed Fee (\$)	Estimated Cost Plus Fixed Fee (\$)	Level of Effort (LOE) Hours
Base Period	6/1/2026 – 5/31/2027				
Option Period 1	6/1/2027 – 5/31/2028				
Option Period 2	6/1/2028 – 5/31/2029				

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Option Period 3	6/1/2029 – 5/31/2030				
Option Period 4	6/1/2030 – 5/31/2031				
Option Period 5	6/1/2031 – 5/31/2032				
Option Period 6	6/1/2032 – 5/31/2033				
Option Period 7	6/1/2033 – 5/31/2034				
Option Period 8	6/1/2034 – 5/31/2035				
Option Period 9	6/1/2035 – 5/31/2036				
Option to Extend Services up to 6 months IAW FAR 52.217-8	6/1/2036 – 11/30/2036				
Additional Level of Effort (LOE) Options, by performance period	Period of Performance	Estimated Cost (\$)	Fixed Fee (\$)	Estimated Cost Plus Fixed Fee (\$)	Level of Effort (LOE) Hours
ADDITIONAL LOE OPTION -- Base Period	6/1/2026 – 5/31/2027				
ADDITIONAL LOE OPTION -- Option Period 1	6/1/2027 – 5/31/2028				
ADDITIONAL LOE OPTION -- Option Period 2	6/1/2028 – 5/31/2029				
ADDITIONAL LOE OPTION -- Option Period 3	6/1/2029 – 5/31/2030				
ADDITIONAL LOE OPTION -- Option Period 4	6/1/2030 – 5/31/2031				
ADDITIONAL LOE OPTION -- Option Period 5	6/1/2031 – 5/31/2032				
ADDITIONAL LOE OPTION -- Option Period 6	6/1/2032 – 5/31/2033				
ADDITIONAL LOE OPTION -- Option Period 7	6/1/2033 – 5/31/2034				
ADDITIONAL LOE OPTION -- Option Period 8	6/1/2034 – 5/31/2035				
ADDITIONAL LOE OPTION -- Option Period 9	6/1/2035 – 5/31/2036				

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Total Base Period and All Possible Options					
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*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.

### ***ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS***

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable.

- 1) Conferences & Meetings
- 2) Food for Meals, Light Refreshments & Beverages
- 3) Promotional Items
- 4) Acquisition, by purchase or lease, of any interest in real property
- 5) Special rearrangement or alteration of facilities
- 6) Purchase or lease of any item of general-purpose office furniture or office equipment regardless of dollar value.
- 7) Travel Costs including Foreign Travel
- 8) Consultant Costs
- 9) Subcontract Costs
- 10) Patient Care Costs
- 11) Accountable Government Property
- 12) Printing costs
- 13) Research Funding

### ***ARTICLE B.4. ADVANCE UNDERSTANDINGS***

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



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### SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

#### ***ARTICLE C.1. STATEMENT OF WORK***

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

#### ***ARTICLE C.2. REPORTING REQUIREMENTS***

All reports shall be submitted electronically.

These reports shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: <https://www.hhs.gov/web/section-508/index.html> and at: <https://www.section508.gov/create/documents> , "Create Accessible Documents."

##### **a. Technical Progress Reports**

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 2 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. 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>.

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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](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 completed 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.

## ***ARTICLE C.3. INVENTION REPORTING REQUIREMENT***

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

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Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The first annual utilization report shall be due on or before the 30<sup>th</sup> day after the end of the fiscal year. Thereafter, reports shall be due on or before the working day following the reporting period. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of 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.

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### **SECTION D - PACKAGING, MARKING AND SHIPPING**

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

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### 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 COR is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:  
  
National Institute of Health  
National Institute of Environmental Health Sciences  
111 T.W. Alexander Drive  
Research Triangle Park, NC 27709
- d. INSPECT BY RECEIVING REPORT: 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.

#### CLAUSES INCORPORATED BY REFERENCE:

Database	Number	Title	Date
FAR	52.246-5	Inspection of Services—Cost-Reimbursement	APR 1984
FAR	52.246-9	Inspection of Research and Development (Short Form)	APR 1984

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### SECTION F - DELIVERIES OR PERFORMANCE

#### ***ARTICLE F.1. PERIOD OF PERFORMANCE***

- a. The period of performance of this contract shall be from 6/1/2026 through 05/31/2027.
- 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	6/1/2027 - 5/31/2028
Option Period 2	6/1/2028 - 5/31/2029
Option Period 3	6/1/2029 - 5/31/2030
Option Period 4	6/1/2030 - 5/31/2031
Option Period 5	6/1/2031 - 5/31/2032
Option Period 6	6/1/2032 - 5/31/2033
Option Period 7	6/1/2033 - 5/31/2034
Option Period 8	6/1/2034 - 5/31/2035
Option Period 9	6/1/2035 - 5/31/2036
Option to Extend Services up to 6 months IAW FAR 52.217-8	6/1/2036 - 11/30/2036

#### ***ARTICLE F.2. DELIVERIES***

- a. Satisfactory performance of this contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the Services specified in the Delivery Schedule which are described in SECTION C of this contract.
- b. Deliveries required by the Contractor shall be made F.o.b. destination as set forth in FAR Clause 52.247-35, F.o.b. Destination, Within consignees Premises (April 1984) to the address/addressee listed below:

Delivery Address
<b>Contracting Officer's Representative, NIH/NIEHS</b>
<b>NIEHS</b>
<b>Research Triangle Park, NC 27709</b>

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

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## ARTICLE F.3. LEVEL OF EFFORT

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

Period	Period of Performance	Level of Effort (LOE) Hours
Base Period	6/1/2026 – 5/31/2027	
Option Period 1	6/1/2027 – 5/31/2028	
Option Period 2	6/1/2028 – 5/31/2029	
Option Period 3	6/1/2029 – 5/31/2030	
Option Period 4	6/1/2030 – 5/31/2031	
Option Period 5	6/1/2031 – 5/31/2032	
Option Period 6	6/1/2032 – 5/31/2033	
Option Period 7	6/1/2033 – 5/31/2034	
Option Period 8	6/1/2034 – 5/31/2035	
Option Period 9	6/1/2035 – 5/31/2036	
Option to Extend Services up to 6-months IAW FAR 52.217-8	6/1/2036 – 11/30/2036	
ADDITIONAL LEVEL OF EFFORT (LOE) OPTIONS, by Period	Period of Performance	Level of Effort (LOE) Hours
ADDITIONAL LOE OPTION -- Base Period	6/1/2026 – 5/31/2027	
ADDITIONAL LOE OPTION -- Option Period 1	6/1/2027 – 5/31/2028	
ADDITIONAL LOE OPTION -- Option Period 2	6/1/2028 – 5/31/2029	
ADDITIONAL LOE OPTION -- Option Period 3	6/1/2029 – 5/31/2030	

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<b>Period</b>	<b>Period of Performance</b>	<b>Level of Effort (LOE) Hours</b>
ADDITIONAL LOE OPTION -- Option Period 4	6/1/2030 – 5/31/2031	
ADDITION LOE OPTION -- Option Period 5	6/1/2031 – 5/31/2032	
ADDITIONAL LOE OPTION -- Option Period 6	6/1/2032 – 5/31/2033	
ADDITIONAL LOE OPTION -- Option Period 7	6/1/2033 – 5/31/2034	
ADDITIONAL LOE OPTION -- Option Period 8	6/1/2034 – 5/31/2035	
ADDITIONAL LOE OPTION -- Option Period 9	6/1/2035 – 5/31/2036	
Total Base Period and All Possible Options		

***NOTE: To be completed upon award. See Section L, Proposal Instructions, for further information on estimating hours. Article L.1.d. provides the Government's estimated effort; Article I.4.A.2. and ATTACHMENT 6 – Sample Research Outlines provide further detailed information as to anticipated types/quantities of work.***

- 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.

CLAUSES INCORPORATED BY REFERENCE:



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Database	Number	Title	Date
FAR	52.242-15	Stop-Work Order--Alternate I	APR 1984
FAR	52.247-35	F.o.b. Destination, within Consignee's Premises	APR 1984

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### SECTION G - CONTRACT ADMINISTRATION DATA

#### ***ARTICLE G.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 time of award.*

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

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

*To be specified at time of award.*

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

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

The Government may unilaterally change its COR and/or ACOR designation.

#### ***ARTICLE G.2. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT***

- a. Invoice Submission/Contract Financing Request, NIH(RC)-1 for NIH Cost-Reimbursement Type Contracts are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.
  1. The Contractor must submit invoices to the Department of Treasury's Invoice Processing Platform (IPP) at <https://www.ipp.gov> with a copy of the invoice to the approving official, as directed below.

Additionally, the Contractor must submit a copy of the electronic invoice to the following Approving Official (Contracting Officer) and Contracting Officer Representative:

Official: Contracting Officer - TBD  
Contracting Officer Representative - TBD

Email Address \_\_\_\_\_  
Email Address \_\_\_\_\_

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For inquiries regarding the status of invoices, contact OFM Customer Service via email at [ofm\\_customer\\_service@mail-cmp.niceincontact.com](mailto: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.

2. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:
  - A. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is \_\_\_\_\_. (To be identified at time of award)
  - 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:

*“Support for Evaluating and Conducting Computational and Alternative Toxicological Methods for the National Institute of Environmental Health Sciences”*
  - G. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) 496-6452.

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

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

### ***ARTICLE G.3. 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 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 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	

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Expenditure Category A	Percentage of Effort/Hours
(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.

### ***ARTICLE G.4. INDIRECT COST RATES***

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

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

These rates are hereby incorporated without further action of the Contracting Officer. Go to the Indirect Cost Submission web page: <https://oamp.od.nih.gov/division-of-financial-advisory-services/indirect-cost-branch/indirect-cost-submission> for electronic copies of the Branch's information package documents.

### ***ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE***

#### ***a. Contractor Performance Evaluations***

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

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

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

b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address: <https://www.cpars.gov>.

### **ARTICLE G.6. GOVERNMENT PROPERTY**

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "HHS Contracting Guide for Contract of Government Property," 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>

### **ARTICLE G.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 calendar 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 calendar 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 individuals are considered to be essential to the work being performed hereunder:

Name	Title
To Be Named at Award	PRINCIPAL INVESTIGATOR
To Be Named at Award	PROGRAM MANAGER

## SECTION H - SPECIAL CONTRACT REQUIREMENTS

### ***ARTICLE H.1. HUMAN SUBJECTS***

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

### ***ARTICLE H.2. 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.

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

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

### ***ARTICLE H.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.

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

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

### ***ARTICLE H.6. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS***

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

### ***ARTICLE H.7. GUN CONTROL***

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

### ***ARTICLE H.8. OPTION PROVISION***

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-9, Option to Extend Services, Contract Clause 1, Option for Additional Level of Effort, and FAR Clause 52.217-8, Option to Extend Services 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 15 calendar days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST PLUS FIXED FEE Article in SECTION B of this contract.

### ***ARTICLE H.9 OTHER IT PROCUREMENTS***

#### **ARTICLE H.9.1.1. HARDWARE PROCUREMENTS**

1. **Card Readers-** The Contractor (and/or any subcontractor) must include [Federal Information Processing Standard \(FIPS\) 201-compliant](#) smart card readers (referred to as LACS Transparent Readers) with the purchase of servers, printers, desktops, and laptops.
2. **Mobile Devices-** The Contractor must follow NIST 800-124, Rev. 1, Guidelines for Managing the Security of Mobile Devices in the Enterprise and comply with Public Law 115-232 § 889, when purchasing mobile devices that process or store HHS data.

#### **ARTICLE H.9.1.2. NON-COMMERCIAL AND OPEN SOURCE COMPUTER SOFTWARE PROCUREMENTS**

The Contractor (and/or any subcontractor) must follow secure coding best practice requirements, as directed by the United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP) that will limit system software vulnerability exploits. The Contractor will be liable for malicious or defective code or failure to reduce risk.

#### **ARTICLE H.9.1.3. INFORMATION TECHNOLOGY APPLICATION DESIGN, DEVELOPMENT, OR SUPPORT**

- a. The Contractor (and/or any subcontractor) must ensure IT applications designed and developed for end users (including mobile applications and software licenses) run in the standard user context without requiring elevated administrative privileges.



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- b. The Contractor (and/or any subcontractor) must follow secure coding best practice requirements, as directed by United States Computer Emergency Readiness Team (US-CERT) specified standards and the Open Web Application Security Project (OWASP), that will limit system software vulnerability exploits.
- c. The Contractor (and/or any subcontractor) must ensure that computer software developed on behalf of HHS or tailored from an open-source product, is fully functional and operates correctly on systems configured in accordance with government policy and federal configuration standards. The contractor shall test applicable products and versions with all relevant and current updates and patches updated prior to installing in the HHS environment. No sensitive data must be used during software testing.
- d. The Contractor (and/or any subcontractor) must protect information that is deemed sensitive from unauthorized disclosure to persons, organizations or subcontractors who do not have a need to know the information. Information which, either alone or when compared with other reasonably-available information, is deemed sensitive or proprietary by HHS shall be protected as instructed in accordance with the magnitude of the loss or harm that could result from inadvertent or deliberate disclosure, alteration, or destruction of the data. This language also applies to all subcontractors that are performing under this contract.

### ***ARTICLE H.10. COMMUNICATIONS MATERIALS AND SERVICES***

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

This acquisition requires the Contractor to:

☒ Prepare, review, and/or distribute NIH Publications and Audiovisuals.  
NIH Policy Manual Chapter 1184, "Preparation and Clearance of Scientific, Technical, and Public Information Presented by NIH Employees or Produced for Distribution by NIH," is applicable to this contract. <https://policymanual.nih.gov/1184>

☒ Use the NIH name and logo.  
NIH Policy Manual Chapter 1186, "Use of NIH Names and Logos," is applicable to this contract. <https://policymanual.nih.gov/1186>

☒ Create and/or Manage a Public Website which includes NIH hosted social media site(s), Web application(s) and mobile Web Site ( s ).  
NIH Policy Manual Chapter 2804\*, "Websites and Digital Services - Management Policy," is applicable to this contract. <https://policymanual.nih.gov/2804>

☐ Create and/or Manage an NIH Website that maintains and disseminates personal information.  
NIH Policy Manual Chapter 2805\*, "NIH Web Privacy Policy," is applicable to this contract. <https://policymanual.nih.gov/2805>

☐ Create and/or Manage an NIH hosted and/or funded social media site(s), Web application(s) and mobile Web site(s). "NIH Social Media Guidelines," is applicable to this contract.

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<https://employees.nih.gov/pages/social-media/>

\* NOTE: NIH Policy Manual Chapters found in the 2800 series are currently only available to NIH personnel. If unavailable, contact the Contracting Officer for a copy.

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

### ***ARTICLE H.11. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL***

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as Contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best comply with this requirement, the Contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each Contractor employee's computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

### ***ARTICLE H.12. CONTRACTOR'S USE OF LIBRARY RESOURCES AT NIH***

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

### ***ARTICLE H.13. 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.

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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:

All Information as identified by the COR.

### **ARTICLE H.14. 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

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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 nonpublic 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,

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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).

### **ARTICLE H.15. 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

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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.

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

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

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(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.

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(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.

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(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.

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(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.

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(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.

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(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.

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(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.

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(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.

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(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.

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(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.

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(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.

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(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)

### **ARTICLE H.16. 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



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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.

[\_\_\_\_\_]

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

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[ ]

(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

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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).

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### ***ARTICLE H.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>.

1. 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

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- 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

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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:
  - a. Management of financial conflicts of interest.
  - b. 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

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- 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

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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



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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:

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- 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.

### ***ARTICLE H.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 Institute of Environmental Health Sciences, National Institutes of Health, Department of Health and Human Services, under Contract No. TO BE PROVIDED AT AWARD "

### ***ARTICLE H.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

### ***ARTICLE H.20. SHARING RESEARCH DATA***

\* Note: This section to be filled out upon award

[The Data Management and Sharing Plan submitted by the Contractor is acceptable/The Contractor's Data Management and Sharing Plan, dated TBD, is hereby incorporated by reference herein.] The

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Contractor agrees to adhere to its Data Management and Sharing Plan and shall request the prior written approval of the Contracting Officer for any changes in its Data Management and Sharing Plan.

NIH encourages, to the maximum extent practicable, the sharing of final research data to serve public health for the common good and this contract is expected to generate research data that must be shared with the public and other researchers. NIH's Data Management and Sharing policies may be found at the following websites:

- [NOT-OD-14-124 - NIH Genomic Data Sharing Policy;](#)
- [NOT-OD-21-013 - Final NIH Policy for Data Management and Sharing;](#)
- NOT-OD-21-014 - Supplemental Information to the NIH Policy for Data Management and Sharing: Elements of an NIH Data Management and Sharing Plan;
- NOT-OD-21-015 - Supplemental Information to the NIH Policy for Data Management and Sharing: Allowable Costs for Data Management and Sharing; and
- NOT-OD-21-016 - Supplemental Information to the NIH Policy for Data Management and Sharing: Selecting a Repository for Data Resulting from NIH-Supported Research.

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including but not limited to the Privacy Act of 1974 (2020 Edition), the Privacy Rule (see HHS-published documentation on the Privacy Rule at <https://www.hhs.gov/ocr/index.html>), the Health Insurance Portability & Accountability Act of 1996 (HIPAA), and the Health IT for Economic & Clinical Health (HITECH) Act, which was enacted as part of the American Recovery & Reinvestment Act of 2009 (ARRA).

As per NIH Notice NOD-OD-21-013, "Final NIH Policy for Data Management and Sharing," respect for participant autonomy and maintenance of participant privacy and confidentiality can be consistent with data sharing. The rights and privacy of people who participate in NIH-funded research shall be protected at all times and Contractors shall anonymize and aggregate (or otherwise fully protect from release) any personally identifiable information (PII), HIPAA-protected personal health information (PHI), and/or HITECH-protected electronic health information which they receive, use, and/or reference; thus, data intended for broader use should be free of any and all personal identifiers that would permit linkages to individual research participants and/or variables that could lead to any disclosure of the identity of individual subjects, direct or deductive, for which the Government shall have no liability whatsoever.

### ***ARTICLE H.21. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)***

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

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

### ***ARTICLE H.22. GOVERNMENT CONTROL OVER UNDELIVERED AND/OR UNPUBLISHED RECORDS AND DATA***

1. As used in this clause, "records and data" means: (1) any handwritten, typed, or printed documents (including, but not limited to, memoranda, letters, writings, books, brochures, transcripts, minutes, electronic transmissions, study findings, laboratory note books, chromatograms, spectra, and maps); (2) documentary material in other forms (such as punch cards, magnetic or paper tapes, instrumentation cards, computer discs, electronically stored information, audio or video recordings,

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motion pictures, photographs, slides, microfilm, and microfiche); and, (3) biological samples and pathology materials (pathology slides, paraffin blocks, and wet tissues). Records and data may or may not constitute a specific deliverable defined under the terms of the contract.

2. The purpose of this clause is to define the Government's control over records and data that are produced by the Contractor under this contract, but are not defined as a deliverable under the terms of the contract, or are not yet in the Government's physical possession if a deliverable under the terms of the contract. This clause is designed to serve public policy by limiting the disclosure of certain records and data if disclosure is made at a time when such records and data remain unvalidated and unreliable (i.e. may not have undergone a quality control nor subsequent audit and inspection as part of a quality assurance process) and could thereby lead to erroneous conclusions which might threaten public health or safety.
3. The Government shall be deemed as having no control over, or direct ownership of records and data created or produced by the Contractor in the performance of this contract until such time as the records and data have been: (1) subjected to an acceptable method of quality control and quality assurance; (2) delivered to the Government or obtained by the Government under the terms of this contract; (3) published in accordance with the terms of this contract; or (4) used by the Federal Government in developing an agency action that has the force and effect of law.
4. In the event of a contract termination, this clause does not relieve the Contractor of its obligations set forth elsewhere in this contract to transfer title and deliver to the Government work in process, completed work, supplies, and other material produced or acquired for the work terminated, or, the completed or partially completed plans, drawings, information, and other property that, if the contract had been completed, would be required to be furnished to the Government.
5. This clause shall have no effect on the Government's rights during the performance of the contract as specified elsewhere herein, including the Governments rights and abilities to request access to or be provided with such records and data for the purpose of conducting any inspections, examinations or audits as set forth in the contract.

### ***ARTICLE H.23. 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
		<input type="checkbox"/> Federal <input type="checkbox"/> NonFederal		
		<input type="checkbox"/> Federal <input type="checkbox"/> NonFederal		

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		<input type="checkbox"/> Federal <input type="checkbox"/> NonFederal		
		<input type="checkbox"/> Federal <input type="checkbox"/> NonFederal		

### ***ARTICLE H.24. GUIDELINES FOR INCLUSION OF WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES IN NIH-SUPPORTED CONFERENCES***

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

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

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

See the policy announcement for additional details and definitions at:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-21-053.html>

### ***ARTICLE H.25. USE OF FUNDS FOR PROMOTIONAL ITEMS***

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

### ***ARTICLE H.26 HHSAR 352.239-78 Information and Communication Technology Accessibility Notice. (Deviation)***

***NOTE: The following Section 508 accessibility technical standards apply to this contract: E205.1 General Electronic content shall comply with E205***

#### **INFORMATION AND COMMUNICATION TECHNOLOGY ACCESSIBILITY NOTICE (FEB 2024) (DEVIATION)**

(a) Any offeror responding to this solicitation must comply with established HHS Information and Communication Technology (ICT) accessibility standards. Information about Section 508 is available at <https://www.hhs.gov/web/section-508/index.html>.

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(b) The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-79 Information and Communication Technology Accessibility. In order to facilitate the Government's determination whether proposed ICT supplies, products, platforms, information, and documentation meet applicable Section 508 accessibility standards, offerors must submit an appropriate HHS Section 508 Accessibility Conformance Checklist (see <https://www.hhs.gov/web/section-508/accessibility-checklists/index.html>) or an Accessibility Conformance Report (ACR) (based on the Voluntary Product Accessibility Template (VPAT) see <https://www.itic.org/policy/accessibility/vpat>), in accordance with the completion instructions. The purpose of the checklists and conformance reports are to assist HHS acquisition and program officials in determining whether proposed ICT supplies, products, platforms, information, and documentation conform to applicable Section 508 accessibility standards. Checklists and ACRs evaluate—in detail—whether the ICT conforms to specific Section 508 accessibility standards and identifies remediation efforts needed to address conformance issues.

(c) If an offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies, products, platforms, information, documentation, or services support delivered do not conform to the described accessibility standards, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.

(d) In order to facilitate the Government's determination whether proposed ICT supplies meet applicable Section 508 accessibility standards, offerors must submit an Accessibility Conformance Report, in accordance with its completion instructions and tailored to the requirements in the solicitation. The purpose of the Report is to assist HHS acquisition and program officials in determining whether proposed ICT 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 at <https://Section508.gov/>.

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

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

(g) Items delivered as electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at <http://508.hhs.gov/>. Materials, other than items incidental to contract management, that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Contracting Officer's Representative.

(End of provision)



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The "Voluntary Product Accessibility Template (VPAT)" is included in SECTION J - List of Attachments, of this solicitation.

### **ARTICLE H.27. HHSAR 352.239-79 Information and Communication Technology Accessibility. (Deviation)**

#### **INFORMATION AND COMMUNICATION TECHNOLOGY ACCESSIBILITY (FEB 2024) (DEVIATION)**

**The following Section 508 accessibility technical standards apply to this contract:**

#### **E205.1 General Electronic content shall comply with E205.**

(a) Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all information and communication technology (ICT) supplies, products, platforms, information, documentation, and services support developed, acquired, maintained or delivered under this contract or order must comply with the Revised 508 Standards, which are located at 36 C.F.R. 1194.1 and Appendices A, B, and C, and are available at <https://www.access-board.gov/ict/>. Information about Section 508 is available at <https://www.hhs.gov/web/section-508/index.html>.

(b) Additional Section 508 accessibility standards applicable to this contract or order may be identified in the specification, statement of work, or performance work statement. If it is determined by the Government that ICT supplies, products, platforms, information, documentation, and services support provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(c) In the event of a modification(s) to this contract or order, which adds new ICT supplies or services or revises the type of, or specifications for, supplies, products, platforms, information, documentation, or services support, the Contracting Officer shall require that the Contractor submit a completed HHS Section 508 Accessibility Conformance Checklist (see <https://www.hhs.gov/web/section-508/accessibility-checklists/index.html>) or an Accessibility Conformance Report (ACR) (based on the Voluntary Product Accessibility Template (VPAT) see <https://www.itic.org/policy/accessibility/vpat>), and any other additional information necessary to assist the Government in determining that the ICT supplies or services conform to Section 508 accessibility standards. If it is determined by the Government that ICT supplies, products, platforms, information, documentation, and services support provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(d) If this is an Indefinite-Delivery type contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include ICT supplies, products, platforms, information, documentation, or services support will define the specifications and accessibility standards for the order. In those cases, the Contractor shall be required to provide a completed HHS Section 508 Accessibility Conformance Checklist (see <https://www.hhs.gov/web/section-508/accessibility-checklists/index.html>) or

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an ACR (based on the VPAT see <https://www.itic.org/policy/accessibility/vpat>), and any other additional information necessary to assist the Government in determining that the ICT supplies, products, platforms, information, documentation, or services support conform to Section 508 accessibility standards. If it is determined by the Government that ICT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

(e) The contractor shall identify to the Contracting Officer any perceived exception or exemption to Section 508 requirements.

(End of clause)



## PART II - CONTRACT CLAUSES

### SECTION I - CONTRACT CLAUSES

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

The complete listing of these clauses may be accessed at:

<https://www.acquisition.gov/>

<https://www.hhs.gov/grants-contracts/contracts/contract-policies-regulations/hhsar/part-352-solicitation-provisions-contract-clauses/index.html>

#### **ARTICLE I.1. GENERAL 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.

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

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

#### PROVISIONS INCORPORATED BY REFERENCE:

Database	Number	Title	Date
FAR	52.229-11	Tax on Certain Foreign Procurements—Notice and Representation	JUN 2020

#### CLAUSES INCORPORATED BY REFERENCE:

Database	Number	Title	Date
FAR	52.202-1	Definitions	JUN 2020
FAR	52.203-3	Gratuities	APR 1984
FAR	52.203-5	Covenant Against Contingent Fees	MAY 2014
FAR	52.203-6	Restrictions on Subcontractor Sales to the Government	JUN 2020
FAR	52.203-7	Anti-Kickback Procedures	JUN 2020
FAR	52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	MAY 2014
FAR	52.203-10	Price or Fee Adjustment for Illegal or Improper Activity	MAY 2014
FAR	52.203-12	Limitation on Payments to Influence Certain Federal Transactions	JUN 2020
FAR	52.203-13	Contractor Code of Business Ethics and Conduct	NOV 2021

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FAR	52.203-17	Contractor Employee Whistleblower Rights	NOV 2023
FAR	52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements	JAN 2017
FAR	52.204-9	Personal Identity Verification of Contractor Personnel	JAN 2011
FAR	52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	JUN 2020
FAR	52.204-13	System for Award Management Maintenance	OCT 2018
FAR	52.204-23	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities	DEC 2023
FAR	52.204-25	Prohibition of Contracting for Certain Telecommunications and Video Surveillance Services or Equipment	NOV 2021
FAR	52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment	NOV 2021
FAR	52.209-10	Prohibition on Contracting with Inverted Domestic Corporations	NOV 2015
FAR	52.210-1	Market Research	NOV 2021
FAR	52.215-2	Audit and Records—Negotiation	JUN 2020
FAR	52.215-8	Order of Precedence—Uniform Contract Format	OCT 1997
FAR	52.215-15	Pension Adjustments and Asset Reversions	OCT 2010
FAR	52.215-17	Waiver of Facilities Capital Cost of Money	OCT 1997
FAR	52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other Than Pensions	JUL 2005
FAR	52.215-19	Notification of Ownership Changes	OCT 1997
FAR	52.215-21	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications	NOV 2021
FAR	52.215-21	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data—Modifications--Alternate IV	OCT 2010
FAR	52.215-23	Limitations on Pass-Through Charges	JUN 2020
FAR	52.216-7	Allowable Cost and Payment	AUG 2018
FAR	52.216-8	Fixed Fee	JUN 2011
FAR	52.216-6	Notice of Total Small Business Set-Aside	NOV 2020
FAR	52.219-8	Utilization of Small Business Concerns	FEB 2024
FAR	52.219-14	Limitations on Subcontracting	OCT 2022
FAR	52.219-28	Post-Award Small Business Program Representation	FEB 2024
FAR	52.222-2	Payment for Overtime Premiums	JUL 1990
FAR	52.222-3	Convict Labor	JUN 2003
FAR	52.222-21	Prohibition of Segregated Facilities	APR 2015
FAR	52.222-26	Equal Opportunity	SEP 2016

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FAR	52.222-37	Employment Reports on Veterans	JUN 2020
FAR	52.222-40	Notification of Employee Rights Under the National Labor Relations Act	DEC 2010
FAR	52.222-50	Combating Trafficking in Persons	NOV 2021
FAR	52.222-54	Employment Eligibility Verification	MAY 2022
FAR	52.224-3	Privacy Training--Alternate I	JAN 2017
FAR	52.225-1	Buy American Act--Supplies	OCT 2022
FAR	52.225-13	Restrictions on Certain Foreign Purchases	FEB 2021
FAR	52.226-7	Drug-Free Workplace	MAY 2024
FAR	52.226-8	Encouraging Contractor Policies to Ban Text Messaging While Driving	MAY 2024
FAR	52.227-1	Authorization and Consent--Alternate I	APR 1984
FAR	52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	JUN 2020
FAR	52.227-11	Patent Rights—Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.)	MAY 2014
FAR	52.227-14	Rights in Data—General	MAY 2014
FAR	52.228-7	Insurance—Liability to Third Persons	MAR 1996
FAR	52.230-2	Cost Accounting Standards	JUN 2020
FAR	52.230-6	Administration of Cost Accounting Standards	JUN 2010
FAR	52.232-17	Interest	MAY 2014
FAR	52.232-18	Availability of Funds	APR 1984
FAR	52.232-20	Limitation of Cost	APR 1984
FAR	52.232-22	Limitation of Funds	APR 1984
FAR	52.232-23	Assignment of Claims	MAY 2014
FAR	52.232-25	Prompt Payment--Alternate I	FEB 2002
FAR	52.232-33	Payment by Electronic Funds Transfer—System for Award Management	OCT 2018
FAR	52.232-39	Unenforceability of Unauthorized Obligations	JUN 2013
FAR	52.232-40	Providing Accelerated Payments to Small Business Subcontractors	MAR 2023
FAR	52.233-1	Disputes	MAY 2014
FAR	52.233-3	Protest after Award	AUG 1996
FAR	52.233-3	Protest after Award--Alternate I	JUN 1985
FAR	52.233-4	Applicable Law for Breach of Contract Claim	OCT 2004
FAR	52.237-2	Protection of Government Buildings, Equipment, and Vegetation	APR 1984
FAR	52.237-3	Continuity of Services	JAN 1991
FAR	52.242-1	Notice of Intent to Disallow Costs	APR 1984

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FAR	52.242-3	Penalties for Unallowable Costs	DEC 2022
FAR	52.242-4	Certification of Final Indirect Costs	JAN 1997
FAR	52.242-13	Bankruptcy	JUL 1995
FAR	52.243-2	Changes—Cost Reimbursement--Alternate V	APR 1984
FAR	52.244-2	Subcontracts--Alternate I	JUN 2020
FAR	52.244-5	Competition in Subcontracting	DEC 1996
FAR	52.244-6	Subcontracts for Commercial Products and Commercial Services	AUG 2024
FAR	52.245-1	Government Property	SEP 2021
FAR	52.245-9	Use and Charges	APR 2012
FAR	52.246-23	Limitation of Liability	FEB 1997
FAR	52.247-1	Commercial Bill of Lading Notations	FEB 2006
FAR	52.249-6	Termination (Cost-Reimbursement)	MAY 2004
FAR	52.249-14	Excusable Delays	APR 1984
FAR	52.251-1	Government Supply Sources	APR 2012
HHSAR	352.203-70	Anti-Lobbying.	DEC 2015
HHSAR	352.208-70	Printing and Duplication	DEC 2015
HHSAR	352.211-2	Conference Sponsorship Requests and Conference Materials Disclaimer	DEC 2015
HHSAR	352.211-3	Paperwork Reduction Act	DEC 2015
HHSAR	352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations.	DEC 2015
HHSAR	352.223-70	Safety and Health	DEC 2015
HHSAR	352.227-70	Publications and Publicity	DEC 2015
HHSAR	352.233-71	Litigation and Claims.	DEC 2015

### ***ARTICLE I.2. ADDITIONAL CONTRACT CLAUSES INCLUDED IN FULL TEXT***

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

#### **A. FAR 52.203-14 DISPLAY OF HOTLINE POSTER(S) (NOV 2021)**

##### **(a) Definition.**

United States, as used in this clause, means the 50 States, the District of Columbia, and outlying areas.

##### **(b) Display of fraud hotline poster(s). Except as provided in paragraph (c)—**

- (1) During contract performance in the United States, the Contractor shall prominently display in common work areas within business segments performing work under this contract and at contract work sites-

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- (i) Any agency fraud hotline poster or Department of Homeland Security (DHS) fraud hotline poster identified in paragraph (b)(3) of this clause; and
  - (ii) Any DHS fraud hotline poster subsequently identified by the Contracting Officer.
- (2) Additionally, if the Contractor maintains a company website as a method of providing information to employees, the Contractor shall display an electronic version of the poster(s) at the website.
- (3) Any required posters may be obtained as follows:

### **HHS Contractor Code of Ethics and Business Conduct Poster:**

[https://core-docs.s3.amazonaws.com/documents/asset/uploaded\\_file/576385/OIG\\_Hotline\\_Poster\\_1\\_.pdf](https://core-docs.s3.amazonaws.com/documents/asset/uploaded_file/576385/OIG_Hotline_Poster_1_.pdf)

- (c) If the Contractor has implemented a business ethics and conduct awareness program, including a reporting mechanism, such as a hotline poster, then the Contractor need not display any agency fraud hotline posters as required in paragraph (b) of this clause, other than any required DHS posters.
- (d) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (d), in all subcontracts that exceed the threshold specified in Federal Acquisition Regulation 3.1004(b)(1) on the date of subcontract award, except when the subcontract—
  - (1) Is for the acquisition of a commercial product or commercial service; or
  - (2) Is performed entirely outside the United States.

(End of clause)

## **B. FAR 52.204-14 SERVICE CONTRACT REPORTING REQUIREMENTS (OCT 2016)**

### **(a) Definition.**

*First-tier subcontract* means a subcontract awarded directly by the Contractor for the purpose of acquiring supplies or services (including construction) for performance of 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) The Contractor shall report, in accordance with 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) The Contractor shall report the following information:

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- (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) The information required in paragraph (c) of this clause shall be submitted via the internet at *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 FAR subpart 42.15.

(e) Agencies will review Contractor reported information for reasonableness and consistency with available contract information. In the event the agency believes that revisions to the Contractor 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 document its rationale for the agency.

(f)(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 4.1703(a)(2), 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 advise 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)

### **C. FAR 52.204-21 BASIC SAFEGUARDING OF COVERED CONTRACTOR INFORMATION SYSTEMS (NOV 2021)**

(a) Definitions. As used in this clause—

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

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

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

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

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

(b) Safeguarding requirements and procedures.

- (1) The Contractor shall apply the following basic safeguarding requirements and procedures to protect covered contractor information systems. Requirements and procedures for basic safeguarding of covered contractor information systems shall include, at a minimum, the following security controls:
  - (i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).
  - (ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.
  - (iii) Verify and control/limit connections to and use of external information systems.
  - (iv) Control information posted or processed on publicly accessible information systems.
  - (v) Identify information system users, processes acting on behalf of users, or devices.
  - (vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.
  - (vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.
  - (viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.
  - (ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.
  - (x) Monitor, control, and protect organizational communications (*i.e.*, information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

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- (xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.
  - (xii) Identify, report, and correct information and information system flaws in a timely manner.
  - (xiii) Provide protection from malicious code at appropriate locations within organizational information systems.
  - (xiv) Update malicious code protection mechanisms when new releases are available.
  - (xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.
- (2) Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal agencies and departments relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.
- (c) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial products or commercial services, other than commercially available off-the-shelf items), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

### **D. FAR 52.204-27 PROHIBITION ON A BYTEDANCE COVERED APPLICATION (JUN 2023)**

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

Covered application means the social networking service TikTok or any successor application or service developed or provided by ByteDance Limited or an entity owned by ByteDance Limited.

Information technology, as defined in 40 U.S.C. 11101(6)—

- (1) Means any equipment or interconnected system or subsystem of equipment, used in the automatic acquisition, storage, analysis, evaluation, manipulation, management, movement, control, display, switching, interchange, transmission, or reception of data or information by the executive agency, if the equipment is used by the executive agency directly or is used by a contractor under a contract with the executive agency that requires the use—
- (i) Of that equipment; or
  - (ii) Of that equipment to a significant extent in the performance of a service or the furnishing of a product;



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(2) 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; but

(3) Does not include any equipment acquired by a Federal contractor incidental to a Federal contract.

(b) Prohibition. Section 102 of Division R of the Consolidated Appropriations Act, 2023 (Pub. L. 117-328), the No TikTok on Government Devices Act, and its implementing guidance under Office of Management and Budget (OMB) Memorandum M-23-13, dated February 27, 2023, “No TikTok on Government Devices” Implementation Guidance, collectively prohibit the presence or use of a covered application on executive agency information technology, including certain equipment used by Federal contractors. The Contractor is prohibited from having or using a covered application on any information technology owned or managed by the Government, or on any information technology used or provided by the Contractor under this contract, including equipment provided by the Contractor’s employees; however, this prohibition does not apply if the Contracting Officer provides written notification to the Contractor that an exception has been granted in accordance with OMB Memorandum M-23-13.

(c) Subcontracts. The Contractor shall insert the substance of this clause, including this paragraph (c), in all subcontracts, including subcontracts for the acquisition of commercial products or commercial services.

(End of clause)

### **E. FAR 52.204-30 FEDERAL ACQUISITION SUPPLY CHAIN SECURITY ACT ORDERS – PROHIBITION (DEC 2023)**

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

*Covered article*, as defined in 41 U.S.C. 4713(k), means-

(1) Information technology, as defined in 40 U.S.C. 11101, including cloud computing services of all types;

(2) Telecommunications equipment or telecommunications service, as those terms are defined in section 3 of the Communications Act of 1934 (47 U.S.C. 153);

(3) The processing of information on a Federal or non-Federal information system, subject to the requirements of the Controlled Unclassified Information program (see 32 CFR part 2002); or

(4) Hardware, systems, devices, software, or services that include embedded or incidental information technology.

*FASCSA order* means any of the following orders issued under the Federal Acquisition Supply Chain Security Act (FASCSA) requiring the removal of covered articles from executive agency information systems or the exclusion of one or more named sources or named covered articles from executive agency procurement actions, as described in 41 CFR 201-1.303(d) and (e):

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(1) The Secretary of Homeland Security may issue FASCSA orders applicable to civilian agencies, to the extent not covered by paragraph (2) or (3) of this definition. This type of FASCSA order may be referred to as a Department of Homeland Security (DHS) FASCSA order.

(2) The Secretary of Defense may issue FASCSA orders applicable to the Department of Defense (DoD) and national security systems other than sensitive compartmented information systems. This type of FASCSA order may be referred to as a DoD FASCSA order.

(3) The Director of National Intelligence (DNI) may issue FASCSA orders applicable to the intelligence community and sensitive compartmented information systems, to the extent not covered by paragraph (2) of this definition. This type of FASCSA order may be referred to as a DNI FASCSA order.

*Intelligence community*, as defined by 50 U.S.C. 3003(4), means the following-

- (1) The Office of the Director of National Intelligence;
- (2) The Central Intelligence Agency;
- (3) The National Security Agency;
- (4) The Defense Intelligence Agency;
- (5) The National Geospatial-Intelligence Agency;
- (6) The National Reconnaissance Office;
- (7) Other offices within the Department of Defense for the collection of specialized national intelligence through reconnaissance programs;
- (8) The intelligence elements of the Army, the Navy, the Air Force, the Marine Corps, the Coast Guard, the Federal Bureau of Investigation, the Drug Enforcement Administration, and the Department of Energy;
- (9) The Bureau of Intelligence and Research of the Department of State;
- (10) The Office of Intelligence and Analysis of the Department of the Treasury;
- (11) The Office of Intelligence and Analysis of the Department of Homeland Security; or
- (12) Such other elements of any department or agency as may be designated by the President, or designated jointly by the Director of National Intelligence and the head of the department or agency concerned, as an element of the intelligence community.

*National security system*, as defined in 44 U.S.C. 3552, means any information system (including any telecommunications system) used or operated by an agency or by a contractor of an agency, or other organization on behalf of an agency-

- (1) The function, operation, or use of which involves intelligence activities; involves cryptologic activities related to national security; involves command and control of military forces; involves equipment that is an integral part of a weapon or weapons system; or is critical to the direct fulfillment of military or intelligence missions, but does not include a system that is to be used for routine administrative and business applications (including payroll, finance, logistics, and personnel management applications); or

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(2) Is protected at all times by procedures established for information that have been specifically authorized under criteria established by an Executive order or an Act of Congress to be kept classified in the interest of national defense or foreign policy.

*Reasonable inquiry* means an inquiry designed to uncover any information in the entity's possession about the identity of any covered articles, or any products or services produced or provided by a source. This applies when the covered article or the source is subject to an applicable FASCSA order. A reasonable inquiry excludes the need to include an internal or third party audit.

*Sensitive compartmented information* means classified information concerning or derived from intelligence sources, methods, or analytical processes, which is required to be handled within formal access control systems established by the Director of National Intelligence.

*Sensitive compartmented information system* means a national security system authorized to process or store sensitive compartmented information.

*Source* means a non-Federal supplier, or potential supplier, of products or services, at any tier.

(b) *Prohibition.* (1) Unless an applicable waiver has been issued by the issuing official, Contractors shall not provide or use as part of the performance of the contract 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 orders as follows:

(i) For solicitations and contracts awarded by a Department of Defense contracting office, DoD FASCSA orders apply.

(iii) For all other solicitations and contracts DHS FASCSA orders apply.

(2) The Contractor shall search for the phrase "FASCSA order" in the System for Award Management (SAM) at <https://www.sam.gov> to locate applicable FASCSA orders identified in paragraph (b)(1).

(3) The Government may identify in the solicitation additional FASCSA orders that are not in SAM, which are effective and apply to the solicitation and resultant contract.

(4) A FASCSA order issued after the date of solicitation applies to this contract only if added by an amendment to the solicitation or modification to the contract (see FAR 4.2304(c)). However, see paragraph (c) of this clause.

(5)(i) If the contractor wishes to ask for a waiver of the requirements of a new FASCSA order being applied through modification, then the Contractor shall disclose the following:

- (A) Name of the product or service provided to the Government;
- (B) Name of the covered article or source subject to a FASCSA order;
- (C) If applicable, name of the vendor, including the Commercial and Government Entity code and unique entity identifier (if known), that supplied or supplies the covered article or the product or service to the Offeror;

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- (D) Brand;
- (E) Model number (original equipment manufacturer number, manufacturer part number, or wholesaler number);
- (F) Item description;
- (G) Reason why the applicable covered article or the product or service is being provided or used;

(ii) *Executive agency review of disclosures.* The contracting officer will review disclosures provided in paragraph (b)(5)(i) to determine if any waiver is warranted. A contracting officer may choose not to pursue a waiver for covered articles or sources otherwise covered by a FASCSA order and to instead pursue other appropriate action.

(c) *Notice and reporting requirement.* (1) During contract performance, the Contractor shall review *SAM.gov* at least once every three months, or as advised by the Contracting Officer, to check for covered articles subject to FASCSA order(s), or for products or services produced by a source subject to FASCSA order(s) not currently identified under paragraph (b) of this clause.

(2) If the Contractor identifies a new FASCSA order(s) that could impact their supply chain, then the Contractor shall conduct a reasonable inquiry to identify whether a covered article or product or service produced or provided by a source subject to the FASCSA order(s) was provided to the Government or used during contract performance.

(3)(i) The Contractor shall submit a report to the contracting office as identified in paragraph (c)(3)(ii) of this clause, if the Contractor identifies, including through any notification by a subcontractor at any tier, that a covered article or product or service produced or provided by a source was provided to the Government or used during contract performance and is subject to a FASCSA order(s) identified in paragraph (b) of this clause, or a new FASCSA order identified in paragraph (c)(2) of this clause. For indefinite delivery contracts, the Contractor shall report to both the contracting office for the indefinite delivery contract and the contracting office for any affected order.

(ii) If a report is required to be submitted to a contracting office under (c)(3)(i) of this clause, the Contractor shall submit the report as follows:

(A) If a Department of Defense contracting office, the Contractor shall report to the website at <https://dibnet.dod.mil>.

(B) For all other contracting offices, the Contractor shall report to the Contracting Officer.

(4) The Contractor shall report the following information for each covered article or each product or service produced or provided by a source, where the covered article or source is subject to a FASCSA order, pursuant to paragraph (c)(3)(i) of this clause:

(i) Within 3 business days from the date of such identification or notification:

- (A) Contract number;
- (B) Order number(s), if applicable;
- (C) Name of the product or service provided to the Government or used during performance of the contract;
- (D) Name of the covered article or source subject to a FASCSA order;
- (E) If applicable, name of the vendor, including the Commercial and

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Government Entity code and unique entity identifier (if known), that supplied the covered article or the product or service to the Contractor;  
(F) Brand;  
(G) Model number (original equipment manufacturer number, manufacturer part number, or wholesaler number);  
(H) Item description; and  
(I) Any readily available information about mitigation actions undertaken or recommended.

(ii) Within 10 business days of submitting the information in paragraph (c)(4)(i) of this clause:

(A) Any further available information about mitigation actions undertaken or recommended.  
(B) In addition, the Contractor shall describe the efforts it undertook to prevent submission or use of the covered article or the product or service produced or provided by a source subject to an applicable FASCSA order, and any additional efforts that will be incorporated to prevent future submission or use of the covered article or the product or service produced or provided by a source that is subject to an applicable FASCSA order.

(d) *Removal.* For Federal Supply Schedules, Governmentwide acquisition contracts, multiagency contracts or any other procurement instrument intended for use by multiple agencies, upon notification from the Contracting Officer, during the performance of the contract, the Contractor shall promptly make any necessary changes or modifications to remove any product or service produced or provided by a source that is subject to an applicable FASCSA order.

(e) *Subcontracts.* (1) The Contractor shall insert the substance of this clause, including this paragraph (e) and excluding paragraph (c)(1) of this clause, in all subcontracts and other contractual instruments, including subcontracts for the acquisition of commercial products and commercial services.

(2) The Government may identify in the solicitation additional FASCSA orders that are not in SAM, which are effective and apply to the contract and any subcontracts and other contractual instruments under the contract. The Contractor or higher-tier subcontractor shall notify their subcontractors, and suppliers under other contractual instruments, that the FASCSA orders in the solicitation that are not in SAM apply to the contract and all subcontracts.

(End of clause)

### F. FAR 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

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extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 15 **calendar days of contract expiration**.

(End of clause)

### G. FAR 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 15 **calendar days**; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 15 calendar 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 **ten (10) years (ten years plus an additional six months if the Option to Extend Services is exercised)**.

(End of clause)

### H. CONTRACT CLAUSE 1 – OPTION FOR ADDITIONAL LEVEL OF EFFORT

The Government may increase the level of effort/hours, identified in the Schedule as an Additional Level of Effort option item, in accordance with the quantity and associated price stated in the Schedule. The Contracting Officer may unilaterally exercise the option by written notice to the Contractor at least 15 calendar days prior to exercise of the option.

### I. FAR 52.222-35 EQUAL OPPORTUNITY FOR VETERANS (JUN 2020)

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

"Active duty wartime or campaign badge veteran," "Armed Forces service medal veteran," "disabled veteran," "protected veteran," "qualified disabled veteran," and "recently separated veteran" have the meanings given at Federal Acquisition Regulation (FAR) [22.1301](#).

- (b) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60-300.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified protected veterans, and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans.
- (c) Subcontracts. The Contractor shall insert the terms of this clause in subcontracts valued at or above the threshold specified in FAR [22.1303](#)(a) on the date of subcontract award, unless exempted by rules, regulations, or orders of the Secretary of Labor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance

Programs, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate to identify properly the parties and their undertakings.

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(End of clause)

### J. FAR 52.222-36 EQUAL OPPORTUNITY FOR WORKERS WITH DISABILITIES (JUN 2020)

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

"Active duty wartime or campaign badge veteran," "Armed Forces service medal veteran," "disabled veteran," "protected veteran," "qualified disabled veteran," and "recently separated veteran" have the meanings given at Federal Acquisition Regulation (FAR) [22.1301](#).

(b) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60-300.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified protected veterans, and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans.

(c) Subcontracts. The Contractor shall insert the terms of this clause in subcontracts valued at or above the threshold specified in FAR [22.1303](#)(a) on the date of subcontract award, unless exempted by rules, regulations, or orders of the Secretary of Labor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate to identify properly the parties and their undertakings.

(End of clause)

### K. FAR 52.243-2 CHANGES – COST REIMBURSEMENT ALTERNATE V (DEVIATION JULY 2025)(RFO JUN 2025)

(a) (1) At any time, the Contracting Officer may issue a written order to make changes within the scope of this contract in any one or more of the following:

- (i) Drawings, designs, or specifications.
- (ii) Method of shipment or packing.
- (iii) Place of inspection, delivery, or acceptance.

(2) If there are any sureties, the Contracting Officer does not need to notify them of a written order.

(b) If any such change causes an increase or decrease in the estimated cost of, or the time required for, performance of any part of the work under this contract, whether or not changed by the order, or otherwise affects any other terms and conditions of this contract, the Contracting Officer shall make an equitable adjustment in the:

- (1) Estimated cost, delivery or completion schedule, or both;
- (2) Amount of any fixed fee; and
- (3) Other affected terms and shall modify the contract accordingly.

(c) The Contractor must assert its right to an adjustment under this clause within 30 days from the date of receipt of the written order. However, if the Contracting Officer decides that the facts justify it, the Contracting Officer may receive and act upon a proposal submitted before final payment of the contract.

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(d) Failure to agree to any adjustment shall be a dispute under the Disputes clause. However, nothing in this clause shall excuse the Contractor from proceeding with the contract as changed.

(e) Notwithstanding the terms and conditions of paragraphs (a) and (b) of this clause, the estimated cost of this contract and, if this contract is incrementally funded, the funds allotted for the performance of this contract, shall not be increased or considered to be increased except by specific written modification of the contract indicating the new contract estimated cost and, if this contract is incrementally funded, the new amount allotted to the contract. Until this modification is made, the Contractor shall not be obligated to continue performance or incur costs beyond the point established in the Limitation of Cost or Limitation of Funds clause of this contract.

(End of clause)

### **L. FAR 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):

<https://www.acquisition.gov/>

(End of clause)

### **M. HHSAR 352.232-70 INCREMENTAL FUNDING (DEC 2015)**

The Government intends to negotiate and award a cost-reimbursement contract using incremental funding as described in the clause at FAR 52.232-22, "Limitation of Funds". The initial obligation of funds under the contract is expected to cover TBD (if the Base Period is incrementally funded, the appropriate increment of performance will be inserted at time of award). The Government intends to obligate additional funds up to and including the full estimated cost of the contract for the remaining periods of performance by unilateral contract modification. However, the Government is not required to reimburse the Contractor for costs incurred in excess of the total amount obligated, nor is the Contractor required to perform beyond the level supported by the total amount obligated.

(End of provision)

### **N. HHSAR 352.231-70 SALARY RATE LIMITATION (DEC 2015)**

(a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated.

(b) For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary," have the same meaning and are collectively referred to as "direct salary," in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization may



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pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with contract funds.

- (c) The salary rate limitation also applies to individuals under subcontracts.
- (d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.
- (e) See the salaries and wages pay tables on the Office of Personnel Management Web site for Federal Executive Schedule salary levels.

(End of clause)

### **O. HHSAR 352.232-71 ELECTRONIC SUBMISSION OF PAYMENT REQUESTS**

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

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

- (b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at [www.ipp.gov](http://www.ipp.gov) or any successor site.
- (c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.
- (d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request.

(End of Clause)

### **P. LEVEL OF EFFORT—COST-REIMBURSEMENT CONTRACT (OCT 2024)**

- (a) The Contractor shall perform all work and provide all required reports within the level of effort specified. The Government's best estimate of the level of effort to fulfill these requirements is provided for advisory and estimating purposes. The Government is only obligated to pay for direct labor hours ordered and corresponding fixed fee for labor hours completed.
- (b) Direct labor includes professional and technical personnel, and not support personnel such as company management or data entry/word processing/accounting personnel even though such support personnel are normally treated as direct labor by the Contractor. The level of effort specified in

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paragraph (a) of this section includes Contractor, subcontractor, and consultant nonsupport labor hours.

- (c) If the Contractor provides less than 90 percent of the level of effort specified for the base period or any optional period exercised, an equitable downward adjustment of the fixed fee, if any, for that period will be made on an annual basis. The downward adjustment will reduce the fixed fee by the percentage by which the total expended level of effort is less than 100% of that specified in paragraph (a). (For instance, if a hypothetical base-period LOE of 100,000 hours is being reduced to 70,000, the fixed fee shall also be reduced by the same 30%. Using a corresponding hypothetical base-period fixed fee pool of \$300,000, the reduced fixed-fee amount is calculated as:  $\$300,000 \times (70,000 \text{ hours} / 100,000 \text{ hours}) = \$210,000$ .)
- (d) The Government may require the Contractor to provide additional effort up to 110 percent of the level of effort for any period until the estimated cost for that period has been reached. However, this additional effort shall not result in any increase in the fixed fee, if any.
- (e) If the level of effort specified to be ordered during a given base or option period is not ordered during that period, that level of effort may not be accumulated and ordered during a subsequent period.
- (f) These terms and conditions do not supersede the requirements of either the “Limitation of Cost” or “Limitation of Funds” clauses.

(End of Clause)

## **PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS**

### **SECTION J - List of Documents, Exhibits and Other Attachments**

The following documents are incorporated into this RFP:

#### **SOLICITATION ATTACHMENTS**

<b>Attachment No.</b>	<b>Title</b>
Attachment 1:	Proposal Intent Response Sheet
Attachment 2:	Statement of Work (includes Appendix A HHS SECURITY AND PRIVACY LANGUAGE, and Government Furnished Property Tracker Template)
Attachment 3:	Sec. 508 Voluntary Product Accessibility Template (VPAT)
Attachment 4:	Section K - Representations, Certifications, and Other Statements of Offerors
Attachment 5:	Summary of Related Activities
Attachment 6:	Sample Research Outlines
Attachment 7:	Corporate Experience Project Data Form
Attachment 8:	Biographical Sketch Form
Attachment 9:	Past Performance Questionnaire
Attachment 10:	Proposal Summary and Data Record, NIH-2043
Attachment 11:	Business Proposal Template (MS Excel) – use to prepare/submit budget proposal
Attachment 12:	Offeror's Points of Contact
Attachment 13:	Disclosure of Lobbying Activities, OMB Form SF-LLL
Attachment 14:	Instructions for Completing Form NIH 2706
Attachment 15:	Financial Report of Individual Project/ Contract NIH 2706
Attachment 16:	Invoice/Financing Request Instructions-CR-NIH(RC)-1

## **PART IV - REPRESENTATIONS AND INSTRUCTIONS**

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

#### **IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST:**

1. Go to the **System for Award Management (SAM)** and complete the Representations and Certifications. The SAM website may be accessed at: <https://www.sam.gov/content/home> ; and
2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**

**SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS** which is included as an Attachment in Section J- LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation.

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

#### CLAUSES INCORPORATED BY FULL TEXT:

FAR 52.204-19 INCORPORATION BY REFERENCE OF REPRESENTATIONS AND CERTIFICATIONS (DEC 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)

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### SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

#### **ARTICLE L.0. PROPOSAL INTENT**

Please review this Request for Proposal (RFP). Furnish the information requested in Attachment 1, Proposal Intent Response Form, and return the page to the Contract Specialist identified on Section A-Solicitation/Contract Form by the date listed in the attachment. This form is optional. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

#### **ARTICLE L.1. GENERAL**

##### **a. 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.

##### **b. NOTICE OF SMALL BUSINESS SET-ASIDE**

**General.** Offerors are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.

**Definitions.** The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the size standards in this solicitation. In addition to meeting these criteria, a small business concern submitting an offer in his own name shall furnish, in the performing the contract, only end items manufactured or produced by small business concerns in the United States or its outlying areas, provided that this additional requirement does not apply in connection with construction or service contracts.

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

1. It is anticipated that one award will be made from this solicitation and that the award(s) will be made on/about June 1, 2026.
2. It is anticipated that the award(s) from this solicitation will be a multiple-year Cost-Reimbursement type Level of Effort contract with a term of one base year and nine (9) option years, and that incremental funding may be used.
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.4. Proposal Submittal Requirements - A. Business Proposal in this solicitation for additional information about this certification.

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### d. LEVEL OF EFFORT

The Government's requirement for the work set forth in the Statement of Work of this solicitation is shown below. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

#### Labor Hours

Period	Level of Effort (Hours)
Base Period	35,470
Option Period 1	35,470
Option Period 2	35,470
Option Period 3	35,470
Option Period 4	35,470
Option Period 5	35,470
Option Period 6	35,470
Option Period 7	35,470
Option Period 8	35,470
Option Period 9	35,470
Option to Extend Services up to 6-months IAW FAR 52.217-8	22,430 (assumes ADDITIONAL LOE OPTION for Option Period 9 is exercised)
ADDITIONAL LEVEL OF EFFORT (LOE) OPTIONS, by Period	Level of Effort (Hours)
ADDITIONAL LOE OPTION -- Base Period	9,390
ADDITIONAL LOE OPTION -- Option Period 1	9,390
ADDITIONAL LOE OPTION -- Option Period 2	9,390
ADDITIONAL LOE OPTION -- Option Period 3	9,390
ADDITIONAL LOE OPTION -- Option Period 4	9,390
ADDITIONAL LOE OPTION -- Option Period 5	9,390
ADDITIONAL LOE OPTION	9,390

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-- Option Period 6	
ADDITIONAL LOE OPTION -- Option Period 7	9,390
ADDITIONAL LOE OPTION -- Option Period 8	9,390
ADDITIONAL LOE OPTION -- Option Period 9	9,390
Total Base Period and All Possible Options	470,605

### **e. COMMITMENT OF PUBLIC FUNDS**

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

### **f. COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

### **g. RELEASE OF INFORMATION**

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

### **h. PREPARATION COSTS**

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

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

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

### **j. 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

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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.

### k. 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.



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- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

### I. SELECTION OF OFFERORS

- a. The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal found to be technical acceptable will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -
  1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

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

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

While it is 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/content/home>

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### **m. 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>

### **n. 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.

### **ARTICLE L.2. PRE-AWARD INQUIRIES/REQUEST FOR PROPOSALS (RFP) INFORMATION/ CLARIFICATIONS/QUESTIONS**

Contractors are required to review the entire solicitation package before submitting questions. Submit all questions via one document using the format below, by E-mail to [jason.williams2@nih.gov](mailto:jason.williams2@nih.gov) and [lisa.schaupp@nih.gov](mailto:lisa.schaupp@nih.gov) no later than fifteen (15) days prior to the RFP due date by 5pm Eastern Standard Time. This is the most efficient way to ensure all questions are addressed in a timely manner.

RFP Page Number	Section	Paragraph	Question

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### *ARTICLE L.3 SUBMITTING YOUR PROPOSAL*

#### **Packaging and Delivery of Proposals for Use with the NIH electronic Contract Proposal Submission (eCPS) Website**

##### **I. PROPOSAL SUBMISSION**

###### **A. eCPS**

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

###### **B. Creating and Naming Files:**

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.

1. **Create one PDF file of your Technical Proposal, including all attachments:** The Technical Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned but must be merged into the Technical Proposal PDF file.
2. **Create one PDF file of your Business Proposal, including all attachments:** The Business Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned but must be merged into the Business Proposal PDF file. All attachments must be included in the Business Proposal except Attachment 11, the “Business Proposal Template” (MS Excel).
3. **Create your Business Document Excel.** The Excel file should be the “Business Proposal Template” (MS Excel) (Attachment 11) in its original Excel format, not PDF. Multiple Excel files may be included, as necessary. Do not print the Excel file to PDF.

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4. Each of the proposals, Technical and Business, must be separate and complete in itself. Do not reference one proposal in another.
5. File naming convention: It is requested that the filenames for your Technical Proposal, Business Proposal, and Excel Workbook include the name of the offeror, the solicitation number and the type of proposal (i.e., Technical, Business, or Excel Workbook).

Examples:

Technical Proposal: *XYZ Company\_NIHAI2012001\_Technical.pdf*

Business Proposal: *XYZ Company\_NIHAI2012001\_Business.pdf*

Excel Workbook: *XYZ Company\_NIHAI2012001\_Business.xlsx*

## II. FORMATTING AND PAGE LIMITATIONS:

### A. Formatting for proposals

1. Proposal page layout shall be letter size 8.5" x 11" for all pages, unless otherwise specified.
2. Proposals shall not include links to internet web site addresses (URLs) or otherwise direct readers to alternate sources of information.
3. Proposals shall not include audio or video files of any type.
4. Font size must be 12 points.
5. Spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
6. Margins must be at least one-inch on all sides.
7. **Failure to adhere to the formatting requirements above may impact whether your proposal is reviewed in its entirety.**

### B. Page limitations:

1. Please refer to page limitations for each Factor in Section L.
2. **Pages exceeding limitations will be removed from the proposal and will not be considered.**

Elaborate brochures or other presentations beyond that sufficient to present a complete and effective proposal are not desired. Elaborate artwork and expensive visual or other presentation aids are not necessary. Organization, clarity, accuracy of information, relevance, and completeness are of prime importance.

## ARTICLE L.4. PROPOSAL SUBMITTAL REQUIREMENTS

### L.4 A. Business Proposal

#### a. 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.

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### L.4.A1 Mandatory Criteria

- a. Tab A. Cover Page and Table of Contents. The following information shall be provided on the first page of your pricing proposal:
- Solicitation, contract, and/or modification number;
  - Name and address of Offeror;
  - Name and telephone number of point of contact;
  - Name, address, and telephone number of Contract Administration Office, (if available);
  - Name, address, and telephone number of Audit Office (if available);
  - Proposed cost and/or price; profit or fee (as applicable); and total;
  - The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
  - Date of submission; and
  - Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with FAR 15.406-2.

- b. Tab B. Completed and signed Standard Form 33 (SF-33). 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.
- c. Tab C. Acknowledgement of all solicitation amendment(s) (SF-30's) related to this RFP.
- d. 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).
- e. **CONFORMANCE TO SECTION 508 STANDARDS**

Submit Section 508 accessibility compliance information using the Voluntary Product Accessibility Template (VPAT) (**Attachment 3**)

***The following Section 508 accessibility technical standards apply to this contract:***

***E205.1 General Electronic content shall comply with E205***

Electronic documents and reports are anticipated to be included in the deliverables of the resultant contract. When acquiring Electronic and Information Technology (EIT), the government is obligated to meet the accessibility standards at 36 CFR Part 1194 and Section 508 of the Rehabilitation Act of 1973. Section 508 service requirements for Information Content are applicable for this requirement and must address 36 CFR Part 1194, Subpart D, Information, Documentation and Support. Information about Section 508 is available at

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<http://www.section508.gov/>. Organizations submitting proposals will be required to demonstrate compliance with the established EIT accessibility standards by preparing an HHS Section 508 Product Assessment Template which can be found here:

<http://www.hhs.gov/web/508/contracting/technology/vendors.html>. Draft reports do not need to be Section 508 compliant.

### **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.

- f. Submit Representations & Certifications (See Section K of this RFP and Attachment 4):

#### **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.

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

- g. **Total Compensation Plan**

Provide a total compensation plan in accordance with FAR 52.222-46, Evaluation of Compensation for Professional Employees (FEB 1993), setting forth salaries and fringe benefits proposed for the professional employees who will work under the contract. Advise if you have different compensation plans for various skill levels. Although this information is required to be submitted with your firm's business proposal, this information will not be evaluated as part of the price proposal. This information will be utilized as additional basis of your responsibility determination should your firm be considered for award.

#### **a. Instructions**

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by re-competition 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

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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.

### **h. 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:

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- a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
- b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

### 2. Government Property

The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

- a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);
- b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
- c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and
- d. A description of the offeror's property management system, plan, and any customary commercial practices, voluntary consensus standards, or industry-leading practices and standards to be used in the offeror in managing Government property.

**NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from an offeror or Contractor possessing Government property. This will be done by adjusting the offers by applying, for evaluation purposes only, a rental equivalent evaluation factor, as specified in FAR 52.245-9.**

### 3. Government-Furnished Property

A Listing of Government Furnished Property in the Statement of Work (see Section J – Solicitation Attachment 2 of this solicitation).

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "Appendix Q, HHS Contracting Guide for Contract of Government Property," which can be found at:  
[https://oamp.od.nih.gov/sites/default/files/DGS/HHS Contracting Guide for Contract of Government Property-Appendix Q.pdf](https://oamp.od.nih.gov/sites/default/files/DGS/HHS%20Contracting%20Guide%20for%20Contract%20of%20Government%20Property-Appendix%20Q.pdf).

- i. **Financial Capacity:** The offeror shall submit a statement indicating 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.

### j. 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.



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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.

**k. Facilities Capital Cost Election:**

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.

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**[ ] 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.

- l. **Proposer's Annual Financial Report:** A copy of the organization's most recent annual report must be submitted as part of the business proposal.
- m. **Disclosure of Lobbying Activities, OMB Form:** Submit the form using **Attachment 13**.
- n. **Form NIH 2706 Financial Report of Individual Project/Contract:** Submit this form using **Attachments 15 and 16**.
- o. **HHS Security and Privacy Language For Information and IT Procurements**

HHS Security and Privacy Language for Information and Information Technology Procurements is applicable to this solicitation and the following information is provided to assist in proposal preparation.

**IMPORTANT NOTE TO OFFERORS:** The information in Appendix A of the Statement of Work shall be addressed in a separate section of the Business Proposal entitled "Information Security."

The Homeland Security Presidential Directive (HSPD)-12 and the Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, Contractor (including subcontractor), or other source.

- p. **Submission of Electronic Funds Transfer Information with Offer, FAR Provision 52.232-38 (Jul 2013).**

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this solicitation. This submission satisfies the requirement to provide EFT information under paragraphs (b)(1) and (j) of the clause at 52.232 34, Payment by Electronic Funds Transfer Other than System for Award Management.

- (1) The solicitation number (or other procurement identification number).
- (2) The offeror's name and remittance address, as stated in the offer.
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
- (4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.
- (5) The offeror's account number and the type of account (checking, savings, or lockbox).
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.

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(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

(End of provision)

### L.4.A.2 Factor

a. Cost:

- (1) Solicitation Submittal Requirements: The Offeror shall use the Microsoft Excel **Attachment 11-Business Proposal Template** to prepare a cost estimate proposal as follows:
  - The “Instructions Tab” details how the Offeror is to use the workbook.
  - Offeror is required to fill in applicable indirect rates in the yellow boxes on the “Rates” tab.
  - The Offeror will only fill in the estimated amounts for the base period for all costing items. The Optional Periods will apply the proposed escalation percentage from the rates tab to the related base period to come up with costs for each option period.
  - Offeror shall propose on the Contract Administration hours to be used for activities associated with overall contract management and coordination, such as preparing task status updates and semi-annual reports, maintaining contract records, onboarding/offboarding Contractor staff, etc. Offeror is required to fill in applicable estimated hours, labor rates, any applicable other direct costs, and any applicable material/supply costs in the yellow boxes on the “Admin RO” tab.
  - For the remaining Research Outlines in the proposal template workbook, the Offeror is required to fill in applicable estimated hours, labor rates, any applicable other direct costs, and any applicable material/supply costs in the yellow boxes on the related workbook tab. The number of activities that is to be assumed in the proposal is included in the excel template and should not be modified. All costing information related to these ROs are provided below.

The below instructions are for cost information related to all services requested under this solicitation. Offerors are required to submit cost information for the required services (the base work plus the option for the additional effort).

#### Base, Option Periods and Optional Level of Effort (LOE)

Seven sample Research Outlines (RO I, II, III, IV, V, VI, VII) are included in **Attachment 6** to provide Offerors example research activities that might be conducted under the contract. When the actual contract award is made, the type and number of studies may vary from the Sample ROs, and options may be unilaterally exercised by the Government at any time during the contract. Table 1 lists the activities that the Offeror shall assume will be conducted during the base optional periods (assumes Option Years to extend the period of performance is exercised each year of the contract) and during the option to add labor hours

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(Option 1 – Additional Level of Effort Options). Option 1 can be exercised at any time for level of effort (LOE) up to a ceiling defined by costing assumption listed in Table 1. Some of these activities are associated with sample research outlines. For selected activities that are not associated with a sample research outline, detailed costing assumptions are provided in sections below. To estimate the total effort and cost over the 10-year period of the contract, Offerors are to assume that the sample ROs in Table 1, except for RO III, will be conducted (in full) in the contract year listed (assume a starting date of June 1, 2026). Sample RO III has been divided by Phases I and II in Table 1 such that the assigned work can be conducted within a period of performance of one year or less.

There should also be an administrative RO to be used for activities associated with overall contract management and coordination, such as preparing monthly status report, monthly budget summary report, invoice and annual report, planning for attending periodic progress meetings with the Government, maintaining contract and research records, onboarding/offboarding Contractor staff, etc.

**(Option 2 – Option to Extend Services up to 6 months IAW FAR 52.217-8)**

An Option to Extend Services up to 6-months may be exercised up to 15 calendar days prior to the end of the contract period of performance to allow for continuity services – see FAR 52.217-8, provided in full text in Section I of this RFP. The provided effort estimate in Article L.1.d. assumes the ADDITIONAL LOE OPTION is exercised during the final year of performance.

**Table 1. Assumptions for Annual Activities**

Required Capability Areas		Number of Activities Per Year for Base (Year1) and Option Years (Year 2-10)	Number of Activities Per Year for Option 1 (Year 1-10)
<i>Activities captured by the RO</i>			
<b>RO I.</b> Mining ICE for Chemical or Class Specific Information		10	3
<b>RO II.</b> Pathway-Based Predictive Approaches for Cardiovascular Toxicity Assessment		9	2
<b>RO III.</b> Inter-laboratory Study on Human Induced Pluripotent Stem Cell (iPSC)-derived Microglia Model for Developmental Neurotoxicity Screening – Phase I		2	0
<b>RO III.</b> Inter-laboratory Study on Human Induced Pluripotent Stem Cell (iPSC)-derived Microglia Model for Developmental Neurotoxicity Screening – Phase II		2	0
<b>RO IV.</b> Development of NAM Sets for Evaluation of Emerging Contaminants to Inform Human and Environmental Health Issues		6	1
<b>RO V.</b> Structural- and Functional Pharmacokinetic-Based Prediction of Population Variability-related Toxicity Screening		10	2
<b>RO VI.</b> Development of AI-Powered Liver Fibrosis Prediction Tool		2	1

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<b>RO VII. Planning for Workshop</b>	3	1
<i>Activities not captured by the RO</i>		
<i>Meeting Support and Event Hosting</i>		
• Specific Scientific Meetings	16	4
• Expert Group Meetings	2	1
• Professional Meetings	6	2
<i>Communication Management</i>		
• Website Maintenance	3	1
• Training support	2	1

### Description of Cost and Effort Summaries

The **Attachment 11 – Proposal Template** submitted by the Offeror includes an “Overall Summary” tab. This tab sums into Row 4 of the worksheet all of the proposed costs for base services and optional level of effort increases for the base year period of performance from the Research Outline and Travel workbook tabs. Rows 5-14 assume an escalation based on a percentage entered into the “Rates” tab and the row above it.

Offerors shall fill out the **Attachment 11** Business Proposal to have detailed effort and cost breakdowns following the instructions provided for:

- Administrative RO
- Each sample RO and activities not captured in a sample RO in Table 1.
- Overall summary cost estimate (base year + 9 optional years + options to add labor hours) for all research activities, including those captured in sample ROs and those not captured in sample ROs.

### Costing Assumptions

- (i) Research Outline (RO) III: Inter-laboratory Study on Human Induced Pluripotent Stem Cell (iPSC)-derived Microglia Model for Neurodevelopmental Toxicity Screening
  - a) Government will provide chemicals, along with identity and purity information. Any bulk chemical reanalysis will also be performed by the Government.
  - b) For the purpose of costing, assume the human iPSC cell lines are purchased from the commercial company (e.g., Applied StemCell, Inc, Milpitas, CA).
  - c) For the purpose of costing, assume 6 key endpoints (3 for differentiation, 3 for activation processes) will be examined for phase I.
- (ii) Research Outline (RO) IV: Development of NAM Sets for Evaluation of Emerging Contaminants to Inform Human and Environmental Health Issues
  - a) For the purpose of costing, assume one type of emerging contaminants to include up to 5 chemicals.
- (iii) Research Outline (RO) VI: Development of AI-Powered Liver Fibrosis Prediction Tool
  - a) All data sets to be incorporated into database shall be publicly assessable.

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- (iv) Research Outline (RO) VII: Planning for Workshop
  - a) This RO is intended to be used as an example to estimate the labor hours and cost to provide administrative and technical support for various types of meetings.
  - b) For the purpose of costing, assume same labor hours can be applied to all other types of meeting support (Expert Group meetings, workshop, etc).
  - c) The Offeror shall anticipate Contract Staff travel (local, domestic, and/or foreign) to support meetings. However, for the purpose of costing, contractor travel and other travel cost for participants are excluded in this RO (see below section for meeting and travel cost).
- (v) Meeting and travel cost
  - a) For the purpose of costing, Offerors shall use the information in Table II.
  - b) Meeting costs shall include costs for web-based conferencing (virtual), in person or hybrid environment (both in-person and webcast) as indicated. For the purpose of estimating Webcast costs, assume Webcast Capacity for 50.
  - c) Contractor travel costs shall be separated from participant travel costs.
  - d) For the purpose of estimating Contractor Travel for administrative and technical support for the in-person meetings, assume two contract staff shall be traveling to include travels for specific scientific meetings, Expert Group meetings, and workshop/symposiums/seminar.
  - e) Other travel cost shall include participant travel (e.g., airfare, lodging, baggage, etc.) and meeting equipment rental/supply costs for Expert Group meetings and workshop/symposiums/seminar/webinar.
  - f) To follow government travel regulations, airline tickets shall be refundable.
  - g) For the purpose of estimating Domestic travel costs for participants, assume flights from a major airline hub (e.g., United Airline) in the center of the United States (e.g., Dallas, TX).
  - h) For foreign Travel to Expert Group Meeting, assume one participant each from Tokyo, Japan; Seoul, Korea; Rome, Italy; Paris, France, and Ottawa, Canada. For other foreign travel support, average flight costs of the Expert Group Meeting travelers to estimate individual flights.
  - i) 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.
  - j) 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.

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**Table II: Assumptions for Meeting Support**

Meeting	# of Contract Staff to Travel	# of Domestic Participants to Travel	# of Foreign Participants to Travel	Length of Meeting (days)	# of Travel Days	# of Meetings/ Year	Locations
Specific Scientific Meeting	2	-	-	1	2	In-person 2; Teleconference 18	Virtual or Federal Facility (Washington, DC)
Workshops; Symposiums; Seminar; Webinar	2	9	3	1.5	4	4	Federal Facility (Washington, DC) with webcast
Expert Group meeting	2	10	5	2	4	3	Federal Facility (Durham, NC) with webcast

(vi) Contractor Travel for professional meetings

- The Offeror shall anticipate that Contract staff may be required to travel to participate in professional meetings (e.g., the annual Society of Toxicology [SOT] meeting and the biannual/triannual World Congress on Alternatives and Animal use in Life Sciences [WC]) to give poster and/or oral presentations on study results.
- For the purposes of determination of costs, assume the number of staff, the number of travel days, and the number of meetings per year as cited in Table III below. Use the costs for the 2023 SOT meeting held in Nashville, Tennessee as a basis for the Domestic Professional meetings and costs for the 12<sup>th</sup> WC meeting held in Niagara Falls, Canada as the basis for Foreign Professional Meetings. Only registration is covered for local professional meetings and use the registration fee for 2023 SOT as a basis.
- Each Contractor Travel shall not exceed \$30,000 to comply with The 21st Century Cures Act.

**Table III: Assumptions for Contractor Travel to Professional Meetings**

	# of Contract Staff	Length of Meeting (days)	# of Travel Days	# of Meetings/Year
Domestic Professional Meetings	9	5	6	4 (3 annually for each 12-month period of performance / 1 annually for each annual Additional Level of Effort Option)
Local meeting, registration only	12	1.5	-	3

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				(2 annually for each 12-month performance period / 1 annually for each annual Additional Level of Effort Option)
Foreign Professional Meeting	9	7	7	1 (1 annually for each 12-month performance period / 0 annually [none] for each annual Additional Level of Effort Option)

(vii) Website maintenance

- a) For the purpose of costing, assume four times major updates on NIEHS website contents will be needed per year.
- b) Reference to the Statement of Work for the requirements on website maintenance.

(viii) Training support

- a) For the purpose of costing, assume two education and training opportunities will be provided per year for training support. One is to coordinate a webinar for a demo session, and the other is to organize a virtual training session.
- b) For the webinar demo session, assume the topic on utilizing liver fibrosis web tool (RO VI) with the capacity of 50 attendees. Include the budget for generating training materials (e.g., handouts and presentations), video production, technical support, information sharing and gathering feedback from the participants.
- c) For the virtual training session, assume the topic on one of the accepted alternative methods with the capacity of 50 attendees. Include the budget for identifying relevant courses, generating training materials (e.g., handouts and presentations), video production, technical support, information sharing and gathering feedback from the participants.

### L.4.B. Technical Proposal

#### L.4.B.1 Mandatory Criteria

- a. Cover Page: Identify the Company profile to include, the Offeror's name, address, names of two (2) points of contact (including title, phone number and email address), the UEI number). Additionally include a table of contents
- b. Obtaining and Disseminating Biomedical Research Resources



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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>.

### b. Sharing of Model Organisms for Biomedical Research

The NIH Research Tools Policy ( <https://grants.nih.gov/policy/sharing.htm>) also referred to as NIH Principles and Guidelines for Sharing of Biomedical Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042 at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html> ), dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066 at:

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(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html> ), the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains. Offerors must include in their technical proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR provide appropriate reasons why such sharing is restricted or not possible. A reasonable time frame for periodic disposition of material and associated data must be specified in the proposal. In addition, the plan must address if, or how, offerors will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following:

1. Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) at: <https://www.ott.nih.gov/sites/default/files/documents/pdfs/slaform.pdf>; for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) ( <https://autm.net/surveys-and-tools/agreements/material-transfer-agreements/mta-toolkit/uniform-biological-material-transfer-agreement>)
2. How will inappropriate "reach-through" requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?
3. How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

Offerors may request funds in their cost proposal to defray reasonable costs associated with sharing materials or data or transfer of model organisms and associated data to appropriate repositories.

### L.4.B.2 Technical Factors

The solicitation requires the evaluation of cost and the following non-cost/price factors:

- Factor 1 – Experience
- Factor 2 – Program and Project Management and Coordination
- Factor 3 – Technical Approach and Sample Research Outlines
- Factor 4 – Personnel
- Factor 5 – Environment – Facilities, Equipment, and Security
- Factor 6 – Past Performance on Recent, Relevant Projects

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The distinction between experience and past performance is that experience pertains to the volume of work completed by a contractor that are comparable to the types of work described under the definition of recent, relevant projects, in terms of size, scope, and complexity. Past performance pertains to both the relevance of recent efforts and how well a contractor has performed on the contracts.

In order to be considered for award, Offerors must clearly demonstrate that the following mandatory requirement can be met by the time of contract award. Offerors shall include all information that documents and/or supports the qualification criterion in one clearly marked section of the Technical Proposal. Basis of Evaluation and Submittal Requirements for Each Factor.

### (1) **Factor 1 Experience:**

- (i) **Solicitation Submittal Requirements:** The offeror shall provide a minimum of one (1) and a maximum of three (3) examples of recent and relevant contract actions to be documented through use of Corporate Experience Project Data Form (**Attachment 7**). The offeror shall clearly demonstrate past experience to perform the services described in the Statement of Work. Examples submitted shall be recent and relevant contract actions that were similar in size (no less than \$150,000), scope, and complexity to the requirements described in the Statement of Work (SOW) completed within the last five (5) years preceding the release date of the solicitation. To meet the minimum standard acceptable for this evaluation, offerors shall demonstrate through their examples experience in items one (1) through four (4) either separately or combined to demonstrate relevancy:

1. Research, Development, and Validation of Computational Toxicological Approaches
2. Research, Development, and Validation of Alternative Test Methods
3. Meeting Support and Event Hosting
4. Communication Management, to include the following items:
  - Website maintenance
  - Database and information support
  - Training support

Offerors that demonstrate through their experience an understanding and proficiency working with NIEHS Database Systems may be viewed more favorably than offerors without such experience.

Relevant experience performed by the Offeror as a prime contractor may be considered more favorably than experience performed by the Offeror as a subcontractor.

If the Offeror is a Joint Venture (JV), and the JV has shared relevant experience, at least one of the relevant projects should be submitted for the JV entity. If the JV does not have shared relevant experience, at least one project shall be submitted for each JV partner. If a project was performed by a JV, and not all partners from that JV are on the JV proposed for this contract, the offeror shall clearly demonstrate what portion of the work was performed by the JV partner offering on this contract and shall not include work performed by the JV as a whole. If the Offeror does not specifically address what portion

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of the work under the submitted project was performed by the JV member offering on this contract, the project will not be evaluated.

For each contract action the offeror shall complete the Corporate Experience Project Data Form included as **Attachment 7**. All information shall be provided as requested on the form.

If the offeror uses affiliates/subsidiaries/parent/LLC/LTD member companies or subcontractors to demonstrate corporate experience, the offeror shall clearly demonstrate that the affiliates/subsidiaries/parent/LLC/LTD member companies or subcontractors will have meaningful involvement in the performance of this contract.

**IMPORTANT:** It is the offeror's responsibility to clearly explain and demonstrate to the Government how its work experience, and the experience of each teaming partner (if applicable) in each submitted contract action is relevant to the contract requirements in this solicitation. If the offeror does not clearly explain how its experience(s) are relevant to the contract requirements in this specification, the Government may determine that the submitted contract experience is not relevant.

### (2) **Factor 2, Program and Project Management and Coordination**

- (i) **Solicitation Submittal Requirements:** The contract requires a Principal Investigator (PI) and Program Manager (PM), both as key personnel. The offerors shall propose a delineation of the day-to-day roles and responsibilities of the PI/PM. Collectively, the PI and PM are expected to be knowledgeable and involved in all aspects of the contract, including project status, record keeping, reporting, and detailed analysis of budget for all contract functions. The Offeror shall submit a detailed plan, not to exceed 100 pages (two (2) page maximum for the PI; and two (2) pages maximum for the PM), addressing all areas below. Any information submitted in excess of the 100 page limit for this factor will not be considered in the evaluation. This 100 page limit does not include the Quality Management Plan, the Biographical Sketches, or the Information Technology Security Plan described below.

#### *1. Management Plan and Approach*

1.1 Discussion of proposed approach to program and project management.

1.2 A functional organization chart, including lines of reporting.

1.3 A Quality Management Plan (submit as an appendix to this factor, not to exceed 50 pages). A QMP identifies the organizational structure, policy and procedures, functional responsibilities of management and staff, lines of authority, and its processes for planning, implementing, documenting, and assessing all activities conducted under the organization's quality system. Discuss within the QMP a process for assessing possible conflicts of interest. For additional information on QMPs, see <https://www.epa.gov/irmpoli8/quality-management-plan-qmp-standard>.

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- 1.4 Document the proposed project staff working together as a team and describe how daily interaction and coordination of efforts will be accomplished.
- 1.5 Approach for communication among project staff and with Government staff.
- 1.6 Details on the scope of the program, how work will be scheduled, how progress will be monitored, and how project status will be communicated to the Government.
- 1.7 Summary of Corporate experience in the conduct and management of programs and projects of similar size, scope, and complexity, including those of any proposed subcontractors, to those described in the SOW.
- 1.8 Documentation of offeror's flexibility to perform multidisciplinary assignments. Note that these assignments may occur simultaneously on occasion. Describe how staffing will be handled during periods of peak activity (e.g., close to deadline) to ensure continued progress on all ongoing assignments.
- 1.9 Documentation of procedures for acquisition and oversight of any proposed subcontractors/consultants. If any subcontractors/consultants are proposed, the offeror must clearly define how any proposed subcontract/consultant arrangements would meet program needs. A letter of commitment from each subcontractor/consultant must be provided. If subcontracting is proposed, details must be given as to how this would be structured, organized, managed, and monitored. Please include a 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.

### *2. Principal Investigator and Program Manager*

- 2.1 Provide a description (limited to 2 pages for each personnel) to be included in the proposal body.
- 2.2 Provide a biographical sketch for the Principal Investigator and Program Manager (submit using **Attachment 8**; limited to 5 pages per person). Include information to document relevant education, training, experience, scientific expertise, accomplishments, and competency including selected references for publications relevant to the scope of the project, necessary for the successful completion of all contract requirements.

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- 2.3 Provide detail on specific duties on the proposed project, and availability to the project.
- 2.4 For Principal Investigator, provide detail on experience in the conduct and reporting of toxicology studies using computational and/or alternative methods of similar scope, size and complexity and provide selected references for publications relevant to the scope of the RFP. The Principal Investigator shall be an employee of the contractor and designated as key personnel, considered essential to the contract. General qualifications expected of a Principal Investigator include: a Doctorate, or the equivalent relevant experience in Life Sciences or Chem/Bio-informatics, with demonstrated experience in Chem/Bio-informatics and/or Toxicology; demonstrated knowledge of toxicology, validation of alternate toxicological test methods, and the use of in vitro and in silico testing methods as they relate to the assessment of hazard and safety of chemicals and other agents to human health as well as the development of adverse outcome pathways and integrated approaches to testing and assessment; demonstrated organizational and communication skills.
- 2.5 For Program Manager, provide detail on experience with program management and coordination of multidisciplinary projects similar to those described in the SOW. The Program Manager shall be an employee of the contractor and designated as key personnel. General qualifications expected of a Program Manager include: a Master's degree, or the equivalent, and relevant work experience in managing large-scale research programs requiring all disciplines; demonstrated capability for effective written and oral communication.

### 3. *Quality Control and Quality Assurance*

- 3.1 Document the proposed approach and procedures for quality control and quality assurance, including details of the organization and operating procedures of the Quality Assurance Unit and evaluation of the offeror's schedule for quality assurance inspections.
- 3.2 Document relevant training, experience, and competency of the proposed Quality Assurance Officer (using the biographical sketch **Attachment 8**, not to exceed 5 pages per person) and support staff, including proposed specific duties and effort on the project.

### **(3) Factor 3, Technical Approach and Sample Research Outlines:**

- (i) Solicitation Submittal Requirements: The criteria described here apply to both the overall technical approach as demonstrated in response to the SOW and the required capabilities, in addition to proposals for the specific requirements outlined in each of the Sample Research Outlines (**Attachment 6**). The responses to Research Outlines 1- 6 should be very detailed and describe how all aspects of the work would be conducted. The response to Research Outline 7 should not include technical detail but focus on the thought process in developing a research program to meet the described

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objectives. Offeror may propose alternative milestones for Research Outlines if, based on the proposal, the milestone timeframes are not feasible. The Offeror shall submit a detailed plan, not to exceed 200 pages, addressing all areas below. Any information submitted in excess of the 200 page limit for this factor will not be considered in the evaluation.

### *1. Project Approach*

- 1.1. Describe the overall strategy to accomplish the goals of the SOW and for each of the Sample Research Outlines.
- 1.2. Identify potential problems that may be encountered during performance of work under the contract and solutions to these problems.
- 1.3. Identify alternative strategies to accomplish the goals of the project; identify benchmarks for success under the project.

### *2. Overall Technical Approach*

- 2.1. Demonstrate technical capability applicable to conduct computational toxicology studies to include chem/bioinformatics-based model development, hazard identification, read-across prediction, quantitative analysis; develop and validate in vitro and alternative methods to include bioreactivity screening, complex in vitro, high-throughput screening and high-content data management; integrate in vitro and in vivo toxicological data for use in translation to human health.
- 2.2. Include detail and provide documentation to demonstrate how all aspects of the work will be implemented, including methodologies, analyses, technologies, and services to meet the goals of the program, including those that are novel or innovative; including work to be performed by contractor staff and any proposed subcontractors/consultants.

### *3. Organizational details*

- 3.1. Include organizational details for how projects will be staffed, managed, and organized, and details for submission of all reports/deliverables.
- 3.2. Describe how work will be coordinated between the contractor and proposed subcontractors

## **(4) Factor 4, Personnel:**

- (i) Solicitation Submittal Requirements: The Offeror shall address the areas below by submitting a detailed plan not to exceed one (1) page for additional critical personnel; ½ page for other professional personnel; two (2) pages by job function (e.g. computational toxicologists, toxicology data analysts, chem/bio-informaticists) for technical personnel. Tables summarizing personnel and years of experience are not limited.

NOTE: The Offeror must immediately notify the contracting officer when a key personnel designated in their proposal becomes unavailable to work on the contract prior to the formal award of the contract. The Offeror must replace key

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personnel with an individual with equal or better capability. The replacement of key personnel should only occur under circumstances where the Offeror can demonstrate a compelling reason for such substitution, and any proposed replacements must meet the qualifications and standards specified in the original proposal. This requirement is essential to ensure the continuity, expertise, and competence necessary for successful execution of the contracted project. Failure to comply with this mandate may result in disqualification for award or the termination of the contract.

**NOTE: 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. Professional Personnel*

- 1.1. For professional staff, provide a table of proposed staff that will work on the contract, including major roles/disciplines and qualifying criteria (e.g. years of experience, skill sets appropriate for the contract), and proposed level of effort on and availability to the project. The SOW designate which staff members are to be considered key personnel and professional staff and what the qualifying criteria are for each position.
- 1.2. Provide a description (limited to 1 page for critical personnel, ½ page for other professional personnel) to be included in the proposal body. If key personnel are committed to other government-supported projects, include their time commitment to these projects.
- 1.3. Provide a biographical sketch for all personnel (submit using **Attachment 8**; limited to 5 pages per person) with a Master's or Doctorate degree, or the equivalent in experience and/or responsibility. Include information to document relevant education, training, experience, scientific expertise and competency including selected references for publications relevant to the scope of the project, necessary for the successful completion of all contract requirements.
- 1.4. For Principal/Senior Toxicologist, provide demonstrated knowledge and experience in the development, validation, evaluation and regulatory acceptance of new toxicological testing methodologies in at least one of the following areas: population susceptibility; inhalation toxicity; acute/chronic systemic toxicity testing; ocular and dermal toxicity testing; developmental and reproductive toxicology; carcinogenicity. Describe experience with projects of similar scope, size and complexity.
- 1.5. Subcontractors/consultants shall be described similarly to contractor staff and designated as such.



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- 1.6. Document specific duties on the proposed project, and availability to the program (percent time).

### 2. *Technical Personnel*

- 2.1. Provide total effort to the program by job function (e.g. bioinformatician, computational chemists, data analyst, Project Coordinator).
- 2.2. Provide a description (two pages) of each technical group by function to be included in the proposal body. Include information to document relevant education, training, experience, and competency necessary for the successful completion of all contract requirements; these should be separated by job function. Provide demonstrated experience in the evaluation and validation of alternative toxicological test methods; understanding of mechanisms of toxicity; assessment of endocrine active substances, bioreactivity screening, and/or vaccines and other biologics; development of integrated approaches to assess adverse outcome pathways; development of computational models and prioritization tools to predict potential human toxicity of chemicals using data from HTS bioassay data, problem evaluation and critical assessment of new test method performance characteristics; creation/utilization of databases, algorithms, computational and statistical techniques; computational screening of in silico compound libraries to identify members likely to possess desired properties such as biological activity against a given target.
- 2.3. Subcontractors/consultants shall be described similarly to contractor staff and designated as such.
- 2.4. Document specific duties on, and availability to the program.

## (5) **Factor 5, Environment – Facilities, Equipment, and Security:**

- (i) Solicitation Submittal Requirements: The Offeror shall address the areas below. There is no page limit for this factor.

### 1. *Facilities*

- 1.1. Provide detailed information that demonstrates adequate work environment for employees and equipment. Describe available space for the performance of work. Include all disciplines relevant to the project (e.g. in vitro validation, computational modeling) with clear labels as to the location of equipment and function/use of all rooms. Document compliance with all applicable Federal and state regulations and guidelines for all aspects of the validation study if applicable. Include the above for any proposed subcontractors/consultants as appropriate.

### 2. *Equipment and Physical Resources, Policies, Procedures, and IT Processes.*

- 2.1. Provide a list of equipment available on site for use in performance of the work identified herein. Demonstrate the ability to obtain any other

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necessary equipment in support of the work identified herein.

- 2.2. Provide information to document policies and procedures surrounding data collection, management, and security.
- 2.3. Provide a draft Information Technology Security Plan (submit as an appendix to this factor, not to exceed 50 pages) for ensuring integrity and security of information.
- 2.5. Document relevant training, experience, and competency of the proposed Information Technology professional (as demonstrated in the biographical sketch) and support staff, including proposed specific duties and effort on the project.

### **(6) Factor 6, Past Performance:**

- (i) Solicitation Submittal Requirements: Submit a completed CPARS evaluation for each project submitted under Factor 1, Experience. If there is not a completed CPARS evaluation, the Past Performance Questionnaire (PPQ) included in the solicitation is provided for the offeror or its team members to submit to the client for each contract the offeror includes in its proposal for Factor 1 – Corporate Experience. AN OFFEROR SHALL NOT SUBMIT A PPQ WHEN A COMPLETED CPARS IS AVAILABLE.

IF A CPARS EVALUATION IS NOT AVAILABLE, ensure correct phone numbers and email addresses are provided for the client point of contact. Completed PPQs should be submitted with your proposal. If the offeror is unable to obtain a completed PPQ from a client for a project(s) before proposal closing date, the offeror should complete and submit with the proposal the first page of the PPQ (**Attachment 9**), which will provide contract and client information for the respective contract(s). Offerors should follow-up with clients/references to ensure timely submittal of questionnaires. If the client requests, questionnaires may be submitted directly to the Government's point of contact, Megan Bang, via email at [megan.bang@nih.gov](mailto:megan.bang@nih.gov) prior to proposal closing date. Offerors shall not incorporate by reference into their proposal PPQs or CPARS previously submitted for other RFPs. However, this does not preclude the Government from utilizing previously submitted PPQ information in the past performance evaluation.

Also include performance recognition documents received within the last 5 (five) years such as awards, award fee determinations, customer letters of commendation, and any other forms of performance recognition. For performance recognition documents to be considered under this factor, they are required to be dated and contain the signature and position of the individual signing. Further, performance recognition documents solicited especially for the purposes of this factor may be considered less favorably than documents contemporaneously received for the work performed.

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In addition to the above, the Government may review any other sources of information for evaluating past performance. Other sources may include, but are not limited to, past performance information retrieved through the Contractor Performance Assessment Rating System (CPARS) using all CAGE/UEI numbers of team members (partnership, joint venture, teaming arrangement, or parent company/subsidiary/affiliate) identified in the offeror's proposal, inquiries of owner representative(s), Federal Awardee Performance and Integrity Information System (FAPIS), Electronic Subcontract Reporting System (eSRS), and any other known sources not provided by the offeror.

While the Government may elect to consider data from other sources, the burden of providing detailed, current, accurate and complete past performance information rests with the Offeror.

A copy of the blank Past Performance Questionnaire to be used for requesting client references is included as **Attachment 9**.

The definition of a recent, relevant project is a contract that has been completed in the past five (5) years with services similar to those described in the attached statement of work.

### ***ARTICLE L.5. PROVISIONS AND CLAUSES***

#### **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement completion/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.

#### PROVISION INCORPORATED BY REFERENCE:

Database	Number	Title	Date
FAR	52.204-7	System for Award Management	OCT 2018
FAR	52.204-22	Alternative Line Item Proposal	JAN 2017
FAR	52.207-1	Notice of Standard Competition	MAY 2006
FAR	52.215-22	Limitations on Pass-Through Charges—Identification of Subcontract Effort	OCT 2009
FAR	52.222-24	Preaward On-Site Equal Opportunity Compliance Evaluation	FEB 1999
FAR	52.222-46	Evaluation of Compensation for Professional Employees	FEB 1993
FAR	52.237-10	Identification of Uncompensated Overtime	MAR 2015

#### PROVISION INCORPORATED BY FULL TEXT:

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### FAR PROVISION 52.215-1 INSTRUCTIONS TO OFFERORS—COMPETITIVE ACQUISITION (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

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(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

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at [52.215-5](#), Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

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

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

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

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

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

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

(e) *Restriction on disclosure and use of data.* Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall-

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

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

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

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

(f) Contract award.

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

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

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- (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.

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(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)

### FAR 52.215-16 FACILITIES CAPITAL COST OF MONEY (JUN 2003)

(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)

### FAR 52.216-1 TYPE OF CONTRACT (APR 1984)

The Government contemplates award of a Cost-Reimbursement Level-of-Effort contract resulting from this solicitation.

(End of provision)

### FAR 52.233-2 SERVICE OF PROTEST (SEP 2006)

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

Contracting Officer  
National Institutes of Health, DHHS  
NICHD Office of Acquisitions, ARB  
NIAAA and NIEHS Team  
6700B Rockledge Dr., Rm. 1310  
Bethesda, MD 20817

(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)

### FAR 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



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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):

<https://www.acquisition.gov/>

(End of provision)

### FAR 52.252-5 AUTHORIZED DEVIATIONS IN PROVISIONS (NOV 2020)

(a) The use in this solicitation of any Federal Acquisition Regulation (48 CFR Chapter 1) provision with an authorized deviation is indicated by the addition of "(DEVIATION)" after the date of the provision.

(b) The use in this solicitation of any Health and Human Services Acquisition Regulation provision with an authorized deviation is indicated by the addition of "(DEVIATION)" after the name of the regulation.

(End of provision)

### HHSAR 352.215-70 LATE PROPOSALS AND REVISIONS (DEVIATION) (DEC 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 advantage 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)

### HHSAR 352.219-70 Mentor-Protégé Program (DEC 2015)

(a) Large business prime contractors serving as mentors in the HHS Mentor-Protégé 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-protégé agreements as part of their offers. The amount of credit provided by the Contracting Officer to a mentor firm for protégé firm developmental assistance costs shall be calculated on a dollar for dollar basis and reported by the mentor firm in the Summary Subcontract Report via the Electronic Subcontracting Reporting System (eSRS) at [www.esrs.gov](http://www.esrs.gov). The mentor firm and protégé 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 protégé 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:

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(i) Demonstrate the interest, commitment, and capability to provide developmental assistance to small business protégé firms; and

(ii) Have a Mentor-Protégé agreement approved by HHS' OSDDBU;

(2) Protégé 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-Protégé agreement approved by HHS' OSDDBU; and

(3) Mentor-Protégé agreements - joint agreements, approved by HHS' OSDDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

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### SECTION M - EVALUATION FACTORS FOR AWARD

#### *ARTICLE M.1 BASIS FOR AWARD*

1. 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.
2. The Government reserves the right to eliminate from consideration for award any or all offers at any time prior to award of the contract; to negotiate with offerors in the competitive range; and to award the contract to the offeror submitting the proposal determined to represent the best value—the proposal most advantageous to the Government, price and other factors considered.
3. As stated in the solicitation, the Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. In addition, 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.
4. The tradeoff process is selected as appropriate for this acquisition. The Government considers it to be in its best interest to allow consideration of award to other than the lowest priced offeror or other than the highest technically rated offeror.
5. As stated in the solicitation, all technical factors when combined are of equal importance to the performance confidence assessment (past performance) rating; and all technical factors and the performance confidence assessment (past performance) rating, when combined are significantly more important than cost.
6. Any proposal found to have a deficiency in meeting the stated solicitation requirements or performance objectives will be considered ineligible for award, unless the deficiency is corrected through discussions. An Unacceptable rating in any of the non-cost/price factors will result in an overall rating of “Unacceptable” for the non-cost/price factors, unless corrected through discussions. Proposals may be found to have either a significant weakness or multiple weaknesses that impact either the individual factor rating or the overall rating for the proposal. The evaluation report must document the evaluation board’s assessment of the identified weakness(s) and the associated risk to successful contract performance resulting from the weakness(s). This assessment must provide the rationale for proceeding to award without discussions.
7. The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the SOLICITATION. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the SOLICITATION. Offerors must submit information sufficient to evaluate their proposals based on the detailed factors listed below.

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### ***ARTICLE M.2 MANDATORY QUALIFICATION CRITERIA***

Listed below are mandatory qualification criteria. THE OFFEROR SHALL PROVIDE AN INDEX WITHIN ITS PROPOSAL AS STATED BELOW WHICH DIRECTS THE REVIEWER(S) TO THE SPECIFIC AREA(S) OF THE PROPOSAL THAT ADDRESS A PARTICULAR MANDATORY QUALIFICATION (as listed in Section L). The qualification criteria establishes conditions that must be met at the time of receipt of Proposals by the Contracting Officer in order for your proposal to be considered any further for award.

Each mandatory requirement submitted by an Offeror shall be assessed for appropriateness, adequacy, reasonableness, or state appropriate reasons why submittal is not possible. If an Offeror's proposal mandatory requirement is considered "unacceptable," and the Government includes Offeror's proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), the Offeror will be afforded the opportunity to further discuss, clarify, and/or modify its Plan during discussions and in its Final Proposal Revision (FPR). However, if the requirement is still considered "unacceptable" by the Government after discussions, or your justification for restricting sharing is still considered inappropriate by the Government after discussions, the Offeror may not be further considered for award.

### **CONFORMANCE TO SECTION 508 STANDARDS**

Electronic documents and reports are anticipated to be included in the deliverables of the resultant contract. Requirements for accessibility based on Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 (P.L. 105-220) will apply to this procurement. Products, platforms, and services delivered as part of this work statement that are identified as Information and Communication Technology (ICT), or contain ICT, must conform to the Revised 508 Standards, which are located at 36 C.F.R. § 1194.1 & Apps. A, C & D, and available at 508 Standards and Guidelines.

Organizations submitting proposals will be required to demonstrate compliance with the established ICT accessibility standards by preparing an Accessibility Conformance Report (ACR) using the Voluntary Product Accessibility Template (VPAT) (Version 2.1 or later) <https://www.itic.org/policy/accessibility/vpat> or HHS Conformance Checklists available at (<https://www.hhs.gov/web/section-508/accessibility-checklists/index.html>). The VPAT is provided as **Attachment 9** and will be used to complete the ACR. Additional information about the VPAT can be found at: <https://www.itic.org/policy/accessibility/vpat-training>

Offerors that do not submit the required Section 508 documentation with proposals will be considered non-responsive.

NOTE: Draft reports do not need to be Section 508 compliant

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

If your proposal does not include a completed Accessibility Conformance Report (ACR) via VPAT© or HHS Conformance Checklist(s) which demonstrates that EIT products and services proposed support

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applicable Section 508 accessibility standards, or, if the completed "Template" included in your proposal is considered "noncompliant," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify the "Template" during discussions and in your Final Proposal Revision (FPR). If your "Template" is still considered "noncompliant" by the Government after discussions, your proposal may not be considered further for award.

The following Section 508 Standards apply to this requirement:

**E205.1 General Electronic content shall comply with E205**

### **EVALUATION OF DATA MANAGEMENT AND SHARING PLAN**

An Offeror's plan for the management and sharing of final research data (Data Management and Sharing Plan) shall be assessed for appropriateness, adequacy, and reasonableness.

If an Offeror's proposal does not include a Data Management and Sharing Plan (Plan) or if the Plan in an Offeror's proposal is considered "unacceptable," and the Government includes Offeror's proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), the Offeror will be afforded the opportunity to further discuss, clarify, and/or modify its Plan during discussions and in its Final Proposal Revision (FPR). However, if the Plan is still considered "unacceptable" by the Government after discussions, the Offeror may not be further considered for award.

### **EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH**

The offeror's proposal must address the plans for sharing model organisms, OR state appropriate reasons why such sharing is restricted or not possible. Offerors must also address as part of the sharing plan if, or how, they will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. The discussion areas regarding intellectual property outlined in Section L should be addressed.

If your proposal does not include a plan, appropriate reasons for restricting sharing, or, if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan for sharing model organisms during discussions and in your Final Proposal Revision (FPR). If your plan for sharing model organisms is still considered "unacceptable," or your justification for restricting sharing is still considered inappropriate by the Government after discussions, your proposal may not be considered further for award.

### **ARTICLE M.3 EVALUATION FACTORS CRITERIA**

#### **(a) Cost (Business Proposal)**

- (1) Basis of Evaluation: Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would

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pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in FAR 15.404.

Cost Realism: The specific elements of each offeror(s) proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in the offeror(s) technical proposal.

Cost Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal. Cost realism analysis will be conducted in accordance with FAR 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value tradeoff decision.

The Government will evaluate price based on the total price. Total price consists of the basic requirements and all option items (see Section B of the solicitation). The Government intends to evaluate all options and has included the provision FAR 52.217-5, Evaluation of Options (JUL 1990) in Section M of the solicitation. The Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. In accordance with FAR 52.217-5, evaluation of options will not obligate the Government to exercise the option(s). Analysis will be performed by one or more of the following techniques to ensure a fair and reasonable price:

- i. Comparison of proposed prices received in response to the RFP.
- ii. Comparison of proposed prices with the IGCE.
- iii. Comparison of proposed prices with available historical information.
- iv. Comparison of market survey results.

### **(b) Non-cost/price Factors (Technical Proposal):**

#### **(1) Factor 1 Experience:**

- i. Basis of Evaluation: Offeror demonstrates experience in performing work of similar size, scope and complexity to this requirement. The assessment of the offeror's recent and relevant experience will be used as a means of evaluating the capability of the offeror to successfully meet the requirements of the RFP. At a minimum, the offeror must submit contract actions demonstrating experience: 1. Research, Development, and Validation of Computational Toxicological Approaches; 2. Research, Development, and Validation of Alternative Test Methods; 3. Meeting Support and Event Hosting; and 4. Communication Management (to include the following items: website maintenance, database and information support, and training support). The Government will review only the first three (3) contract actions submitted. Any contract actions submitted in excess of the three (3) contract action limit will not be considered in the evaluation.

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Offerors that demonstrate through their experience an understanding and proficiency working with NIEHS Database Systems may be viewed more favorably than offerors without such experience.

Offerors that submit contract actions demonstrating experience performing the other requirements outlined in the Statement of Work that are above and beyond those required to meet the minimum standard may be rated more favorably than offerors who only meet the minimum standard.

### (2) **Factor 2, Program and Project Management and Coordination**

- i. Basis of Evaluation: Each offeror will be evaluated on the extent to which the offeror demonstrates an understanding of the three (3) below areas:

*1. Management Plan and Approach*: Appropriateness of the proposed approach to program and quality management strategy, including: functional organization chart; Quality Management Plan; management of staff, experience of staff working together as a team, and communication between the project staff and Government staff; details of project scope; scheduling and monitoring of progress; relevancy of corporate experience in projects of similar size, scope and complexity; evaluation of the offeror's flexibility to perform various multidisciplinary assignments; adequacy of details for arrangement and oversight for any proposed subcontractors/consultants.

*2. Principal Investigator and Program Manager*: Appropriateness of the education, training, experience, scientific expertise, competency, and accomplishments of the proposed Principal Investigator (as demonstrated in the biographical sketch) familiar with in the management and coordination of multidisciplinary projects leading to the validation of alternative toxicological test methods, as well as demonstrated ability to analyze large disparate data sets and integrate in vivo, in vitro and in silico data into novel testing methods; proposed specific duties, effort on, and availability to the program. Appropriateness of the education, training, experience, scientific expertise, competency, and accomplishments of the proposed Program Manager (as demonstrated in the biographical sketch) familiar with the organization, management and coordination of scientific review and evaluation activities; proposed specific duties, effort on, and availability to the program.

*3. Quality Control and Quality Assurance*: Appropriateness of the proposed approach and procedures for quality control and quality assurance, including details of the organization and operating procedures of the Quality Assurance Unit and evaluation of the offeror's schedule for quality assurance audits and inspections. Appropriateness of the training, experience, and competency of the proposed Quality Assurance Officer (as demonstrated in the biographical sketch) and support staff, including proposed specific duties and effort on the program; include those of any proposed subcontractors/consultants.

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### (3) **Factor 3, Technical Approach and Sample Research Outlines**

- i. Basis of Evaluation: Each offeror will be evaluated on the extent to which the offeror demonstrates an understanding of the three (3) below areas:

*1. **Project Approach***: Appropriateness of the demonstrated understanding of how all aspects of the project will be achieved, including identification of problems, solutions, alternative strategies, and benchmarks for success.

*2. **Overall Technical Approach***: Appropriateness and feasibility of the demonstrated technical approach, including overall strategy, methodologies, analyses, technologies, and services, including those that are novel or innovative; technical capability in the conduct of toxicological testing using computational and alternative methods; including all aspects of the work performed by contractor staff and any proposed subcontractors or consultants. Appropriateness of the demonstrated understanding of the approach, analysis of the information provided in the Sample Research Outlines. Appropriateness of the identification of potential problems and solutions, and alternative strategies.

*3. **Organizational Details***: Appropriateness of organizational details, including how projects are staffed, managed, and organized, benchmarks for success and details for the submission of deliverables, including all aspects of the work to be performed by contractor staff and any proposed subcontractors/consultants.

### (4) **Factor 4, Personnel**

- i. Basis of Evaluation: Each offeror will be evaluated on the extent to which the offeror demonstrates an understanding of the two (2) below areas:

*1. **Professional Personnel***: Appropriateness of the education, training, experience, scientific expertise, and competency of the proposed additional professional personnel, including Principal and Senior Toxicologist familiar with toxicology and related fields (including but not limited to computational toxicology; developmental/reproductive toxicology; endocrine disruption; carcinogenicity; inhalation toxicology; acute/chronic systemic toxicity testing; ocular and dermal toxicity testing; chem/bio-informatics; regulatory testing methods and health hazard and safety assessment; and the development and/or validation of modern new approach methodologies, particularly Defined Approach [DA] and Integrated Approaches to Testing and Assessment [IATA]); proposed specific duties; effort on, and availability to the project; adequacy of experience with methods in large data sets analysis and/or software used for analysis; include those of any proposed subcontractors/consultants.

*2. **Technical Personnel***: Appropriateness of the education, training, experience, and competency of the proposed technical personnel with the knowledge and ability to conduct evaluation and validation of computational and/or alternative toxicological test methods; proposed specific duties, effort on, and availability to the project; include those of any proposed subcontractors/consultants.



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### (5) **Factor 5, Environment – Facilities, Equipment, and Security**

- i. **Basis of Evaluation:** Basis of Evaluation: Each offeror will be evaluated on the extent to which the offeror demonstrates an understanding of the two (2) below areas:

*1. **Facilities:*** Appropriateness of facilities for all aspects of the project, including available space for the performance of work; include those of any proposed subcontractors/consultants.

*2. **Equipment and Physical Resources, Policies, Procedures, and IT Processes:*** Appropriateness of equipment and physical resources for all aspects of the project, including descriptions and locations; include those of any proposed subcontractors/consultants. Appropriateness of the proposed policies and procedures relating to security of data management, including compliance requirements, data security, data storage, archiving, and transmission; adequacy of the proposed IT security plan. Appropriateness of the training, experience, and competency of the proposed IT professional (as demonstrated in the biographical sketch) and support staff, including proposed specific duties and effort on the project; include those of any proposed subcontractors/consultants.

### (6) **Factor 6, Past Performance:**

- i. **Basis of Evaluation:** The Government will evaluate how well the offeror performed on the recent and relevant contracts submitted under Factor 1 - Experience and on other recent and relevant contracts documented in known sources. There are three (3) aspects of the past performance evaluation: recency, relevancy, and quality. The first is to evaluate the recency of the offeror's past performance. The second aspect is to determine whether the offeror's performance is relevant or not relevant to the effort to be acquired. For purposes of this evaluation, a recent and relevant contract is a contract as defined in Factor 1, Corporate Experience. The third aspect of the evaluation is to establish the overall quality of the offeror's past performance and how well the contractor performed on the contracts. The past performance evaluation performed in support of a current source selection does not establish, create, or change the existing record and history of the offeror's past performance on past contracts; rather, the past performance evaluation process gathers information from customers on how well the offeror performed those past contracts.

The Government will also evaluate the degree to which past performance evaluations and all other past performance information reviewed by the Government (e.g., CPARS, Federal Awardee Performance and Integrity Information System (FAPIIS), Electronic Subcontract Reporting System (eSRS), performance recognition documents, and information obtained from any other source) reflect a trend of satisfactory performance considering:

- A pattern of successful completion of tasks;
- A pattern of deliverables that are timely and of good quality;
- A pattern of cooperativeness and teamwork with the Government at all levels (task managers, contracting officers, auditors, etc.); and

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- Recency of tasks performed that are identical to, similar to, or related to the task at hand.

In the case of offerors without a record of relevant past performance or for whom information on past performance is not available or so sparse that no meaningful past performance rating can be reasonably assigned, the offeror may not be evaluated favorably or unfavorably on past performance (see FAR 15.305(a)(2)(iv)), and will receive a Neutral Confidence Rating.

### ***ARTICLE M.4 ADJECTIVAL RATINGS/DESCRIPTIONS***

Proposals will be technically evaluated in accordance with the criteria set forth in this solicitation. The technical rating will reflect the degree to which the proposed approach meets or does not meet the minimum performance or capability requirements through an assessment of the strengths, weaknesses, significant weaknesses, deficiencies, and risks of a proposal. Adjectival ratings and rating descriptions will be used to assign an overall rating to each technical proposal and to assign a rating for each technical factor. Any aspect of an Offeror's proposal with merit or demonstration of exceeding a specified performance or capability requirement to the advantage of the Government during contract performance may receive favorable consideration.

#### **M.4.1. TECHNICAL EVALUATION (FACTORS 1-5):**

The technical rating reflects the degree to which the proposed approach meets or does not meet the minimum performance or capability requirements through an assessment of the strengths, weaknesses, significant weaknesses, deficiencies, and risks of a proposal.

- a. A combined technical/risk evaluation includes consideration of risk in conjunction with the significant strengths, strengths, weaknesses, significant weaknesses, uncertainties, and deficiencies in determining technical ratings shall be used. The technical risk evaluation shall utilize the combined technical/risk ratings listed in the following table. Adjectival ratings and rating descriptions will be used to assign an overall rating to each technical proposal and to assign a rating for each technical factor. Use upper case letter ratings for major technical factors as well as the overall rating. The addition of plus (+) or minus (-) to an adjective rating is not allowed.

<b>Table 1. Combined Technical/Risk Rating Method</b>	
<b>Adjectival Rating</b>	<b>Description</b>
Outstanding (O)	Proposal demonstrates an exceptional approach and understanding of the requirements and contains multiple strengths and/or at least one significant strength, and risk of unsuccessful performance is low.

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Good (G)	Proposal indicates a thorough approach and understanding of the requirements and contains at least one strength or significant strength, and risk of unsuccessful performance is low to moderate.
Acceptable (A)	Proposal meets requirements and indicates an adequate approach and understanding of the requirements, and risk of unsuccessful performance is no worse than moderate.
Marginal (M)	Proposal has not demonstrated an adequate approach and understanding of the requirements, and/or risk of unsuccessful performance is high.
Unacceptable (U)	Proposal does not meet requirements of the solicitation and, thus, contains one or more deficiencies and is unawardable unless corrected through discussions, and/or risk of performance is unacceptably high.

b. Definitions: The following definitions are provided to assist evaluators in the evaluation of each non-cost/price factor.

- (i). Significant Strength: An aspect of an Offeror's proposal with appreciable merit or will exceed specified performance or capability requirements to the considerable advantage of the Government during contract performance.
- (ii). Strength: An aspect of an offeror's proposal with merit or will exceed specified performance or capability requirements to the advantage of the Government during contract performance.
- (iii). Weakness: A flaw in the proposal that increases the risk of unsuccessful contract performance.
- (iv). Significant Weakness: A flaw that appreciably increases the risk of unsuccessful contract performance.
- (v). Uncertainty: any aspect of a non-cost/price factor proposal for which the intent of the offer is unclear (e.g., more than one way to interpret the offer or inconsistencies in the proposal indicating that there may have been an error, omission, or mistake).
- (vi). Deficiency: A material failure of a proposal to meet a Government requirement or a combination of significant weaknesses in a proposal that increases the risk of unsuccessful contract performance to an unacceptable level.

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### M.4.2. PAST PERFORMANCE EVALUATION (FACTOR 6):

- a. The past performance evaluation results in an assessment of the offeror's ability of meeting the solicitation requirements. The past performance evaluation considers each offeror's demonstrated recent and relevant record of performance in supplying products and services that meet the contract's requirements. The currency and relevance of the information, source of the information, context of the data, and general trends in contractor's performance shall be considered. These are combined to establish one performance confidence assessment rating for each offeror.
- b. There are three aspects to the past performance evaluation: recency, relevancy (including context of data), and quality (including general trends in contractor performance and source of information).

The first is to evaluate the recency of the offeror's past performance. The second is to determine how relevant a recent effort accomplished by the offeror is to the effort to be acquired through the source selection. The third is to establish the overall quality of the offeror's past performance. Recency is generally expressed as a time period during which past performance references are considered relevant, and is critical to establishing the relevancy of past performance information. In establishing what is relevant for the acquisition, consideration should be given to those aspects of an offeror's contract history that would give the greatest ability to measure whether the offeror will satisfy the current procurement. Common aspects of relevancy include, but are not limited to, the following: similarity of service/support, complexity, dollar value, contract type, use of key personnel (for services) and extent of subcontract/teaming. The third aspect of the past performance evaluation is to establish the overall quality of the offeror's past performance (see FAR 15.304[c][2]). The past performance evaluation conducted in support of a current source selection does not establish, create, or change the existing record and history of the offeror's past performance on past contracts; rather, the past performance evaluation process gathers information from customers on how well the offeror performed those past contracts. A separate quality assessment rating is not required; rather, the past performance rating using the confidence assessment rating, is based on the offeror's overall record of recency, relevancy, and quality of performance.

- c. This source selection will evaluate past performance relevancy in accordance with the ratings in the table below:

Past Performance Relevancy Rating Method	
Adjectival Rating	Description
Very Relevant	Present/past performance effort involved essentially the same scope and magnitude of effort and complexities this solicitation requires.
Relevant	Present/past performance effort involved similar scope and magnitude of effort and complexities this solicitation requires.
Somewhat Relevant	Present/past performance effort involved some of the scope and magnitude of effort and complexities this solicitation requires.
Not Relevant	Present/past performance effort involved little or none of the scope and magnitude of effort and complexities this solicitation requires.

- d. The evaluators will review all past performance information collected and determine the quality of the offeror's performance, general trends, and usefulness of the information and incorporate these into the performance confidence assessment. A separate quality assessment rating is not required; rather, the past

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performance confidence assessment rating is based on the offeror's overall record of recency, relevancy and quality of performance.

In the case of offerors for which there is no information on past contract performance or where past contract performance is not available, the offeror may not be evaluated favorably or unfavorably on the factor of past contract performance. In this case, the offeror's past performance is unknown and assigned a confidence rating of "neutral." Although the evaluators may not rate an offeror that lacks recent, relevant past performance favorably or unfavorably with regard to past performance, the Source Selection Authority may determine, that a "Substantial Confidence" or "Satisfactory Confidence" past performance rating is worth more than a "Neutral Confidence" past performance rating in a best value tradeoff as long as the determination is consistent with stated selection criteria.

e. Performance Confidence Assessment. This source selection requires a greater level of discrimination within the past performance evaluation, therefore, the evaluators shall use all confidence ratings identified in table below.

Performance Confidence Assessments	
Adjectival Rating	Description
Substantial Confidence	Based on the offeror's recent/relevant performance record, the Government has a high expectation that the offeror will successfully perform the required effort.
Satisfactory Confidence	Based on the offeror's recent/relevant performance record, the Government has a reasonable expectation that the offeror will successfully perform the required effort.
Neutral Confidence	No recent/relevant performance record is available or the offeror's performance record is so sparse that no meaningful confidence assessment rating can be reasonably assigned. The offeror may not be evaluated favorably or unfavorably on the factor of past performance.
Limited Confidence	Based on the offeror's recent/relevant performance record, the Government has a low expectation that the offeror will successfully perform the required effort.
No Confidence	Based on the offeror's recent/relevant performance record, the Government has no expectation that the offeror will be able to successfully perform the required effort.

### ***ARTICLE M.5 PROVISIONS AND CLAUSES***

#### **PROVISIONS INCORPORATED BY REFERENCE:**

Database	Number	Title	Date
FAR	52.217-5	Evaluation of Options	JUL 1990