SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1.Requisition or other Purchase Authority: Public Law 81-692 as amended		
2. **Request for Proposal (RFP) Number:** 75N93026R00005	3. **Issue Date:** 6/2/2026	4. **Set Aside:** [X] No [ ] Yes See Part IV Section L
5. Title: Radiological or Nuclear Medical Countermeasure Product Development Support (PDS)		
6. ISSUED BY: Office of Acquisition National Institute of Allergy and Infectious Diseases 5601 Fishers Lane Rockville, MD 20852		7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation. **Any solicitation questions must be submitted on or before 7/02/2026**
8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in **Attachment 1, "Packaging and Delivery of the Proposal,"** **until 3:00 pm Eastern Time on 8/31/2026.** Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.		
9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH [subparagraph (c)(3) of RFO Clause 52.215-1, Instructions to Offerors--Competitive Acquisition,"/HHSAR Clause 352.215-70, "Late Proposals and Revisions"] LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
10. Offeror must be registered in the System for Award Management (SAM) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at https://www.sam.gov/SAM/ .		
11. FOR INFORMATION CALL: Karen Telphia PHONE: 240-669-2960 e-mail: karen.telphia@nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
We strongly suggest that any questions regarding the solicitation be submitted by **3:00 PM EST, on July 2, 2026,** so that we can provide timely responses before proposals are due.		Karen Telphia Contracting Officer Office of R&D and Professional Services Contracts Office of Acquisitions & Logistics Management

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PART I - THE SCHEDULE

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

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The Contractor shall provide the facilities, expertise, and capabilities needed to develop additional radiological or nuclear medical countermeasures (MCMs) and support NIAID's biodosimetry efforts. One IDIQ contract will be awarded to an organization that can provide comprehensive product development services. NIAID will initiate, direct, and fund the work through Task Orders to support the research and development of radiological or nuclear MCMs and biodosimetry approaches along the drug or device development pathway to achieve approval, FDA licensure, or clearance. NIAID expects that the products for screening, testing, and development will come from industry, academia, and government agencies. Both the contractors and their collaborators are to have conducted some of the requested types of studies in accordance with Good Laboratory Practice (GLP) standards (21 CFR 58). Their extensive range of capabilities should include:

- Developing animal models and New Approach Methodologies (NAMs)
- Conducting efficacy tests in rodent and large [nonhuman primates (NHPs] animal models for H- and GI-ARS
- Assessing DEARE in rodent and large animal models (e.g., pigs and NHPs))
- Facilitating large animal sample distribution for testing candidate biodosimetry methods
- Evaluating radionuclide decorporation agents in rodent and canine models
- Performing animal safety studies, including pharmacokinetic and pharmacodynamic assessments
- Managing manufacturing and formulation processes
- Overseeing quality assurance activities
- Conducting Phase I Clinical Safety Studies

ARTICLE B.2. PRICES/COSTS

a. This is an Indefinite Quantity contract as contemplated by RFO 16.504. The Contractor shall be reimbursed by the Government in an amount not less than a total of $ 2,500(minimum) nor more than a total of $ 135,000,000 (maximum) for successful performance of this contract.

b. The costs set forth in this ARTICLE will cover the contract period 7/01/2027 through 6/30/2034.

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

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

Invoice Processing Platform (IPP)

NIH is using a phased transition approach from the NIH Office of Financial Management (OFM) Electronic Invoice Submission instructions to the Department of Treasury's Invoice Processing Platform (IPP). This award will transition to IPP in the future. The Contractor/Vendor shall use the attached NIH OFM Electronic Invoice Submission Instructions until the Contractor/Vendor has transitioned to IPP as specified on the OALM IPP website at https://oalm.od.nih.gov/IPP. It is the Contractor/Vendor's responsibility to periodically check the OALM IPP website and be prepared to transition to IPP on the designated transition date. Questions concerning the transition to IPP should be directed to NIH-IPPinvoicing@mail.nih.gov. Questions concerning this award should be directed to the NIH Contracting Officer.

All IPP invoices must contain a Unique Entity Identifier (UEI) which is located in the System for Award Management (SAM) and replaces the Dun & Bradstreet Data Universal Numbering System (DUNS) number.

Protection of Proprietary Data

The Government anticipates that the Contractor will be utilizing and evaluating materials developed at private expense and subsequently provided to the Government by a third-party Supplier. It is essential to include provisions that will protect the proprietary rights of the Supplier.

All information provided by the Supplier or COR should be assumed to be confidential unless specifically identified as non-confidential in writing by the COR. Confidential information may not be revealed without written permission. All materials supplied to the Contractor and all test results similarly are to be considered confidential. All materials supplied to the Contractor shall be utilized solely for contract-related research purposes and no unauthorized use or distribution of these materials will be permitted.

Any data generated under this contract must be submitted for review by the COR before submission for public presentation or publication. Contract support shall be acknowledged in all such publications. A 'publication' is defined as issue of printed material or a document produced electronically and offered for public distribution or any communication or oral presentation of information. The COR will review all submitted publications in a period of time not to exceed 90 calendar days from receipt, and will either agree to the publication/ disclosure, recommend changes or, as applicable, refer the document to the Supplier of the compound for their review. Information in any publication that is considered Confidential will be deleted by the COR and/or the Supplier prior to approval.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated December 12,2026 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."

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 only, it is estimated that one electronic version of the following reports will be required for any task orders:

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

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.

Annual Technical Progress Report for Clinical Research Study Populations

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

The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this contract.

In addition, the “NIH Policy and Guidelines on the Inclusion of Women and Members of Racial and/or Ethnic Minority Groups as Subjects in Clinical Research”, effective August 16, 2025 also applies. If this contract is for Phase III clinical trials, see Section B of these guidelines. The Guidelines may be found at the following website: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-131.html
For NIH-defined Phase III Clinical Trials: Include a description of the plans for valid analysis in the study design and outcomes. This includes designing the study in a manner that potential differences, as appropriate, by sex and/or racial/ethnic groups in the clinical trial protocol could be conducted. Also, provide a description of any analyses by sex , racial, and/or ethnic groups, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion

of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex, racial and/or ethnic groups.

c. **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/Hard Copy] format. Thereafter, reports shall be due in accordance with the regulatory compliance requirements in 45 CFR Part 94. 45 CFR Part 94 is available at: https://www.ecfr.gov/current/title-45/part-94.
   See Part 94.5, Responsibilities of Institutions regarding Investigator financial conflicts of interest for complete information on reporting requirements.

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

2. **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.

3. **REPORTING REQUIREMENTS FOR USE WITH THE ELECTRONIC REPORT DELIVERABLE SUBMISSION (eRDS) SITE**

   All reports required herein must be submitted in electronic format. All electronic contract deliverables must be submitted via the NIAID electronic Report Deliverable Submission (eRDS) Site, available at the following website: https://erds.niaid.nih.gov/ . All electronic reports submitted must 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."

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by [RFO Clause 52.227-11, Patent Rights-Ownership by the Contractor/RFO Clause 52.227-13, Patent Rights-Ownership by the Government] including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see RFO 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 August 1, 2028. Thereafter, reports shall be due on or before the 30th Calendar day following the reporting period of the contract. The final invention statement (see RFO 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
Office of Acquisition & Logistics Management,
Office of R&D and Professional Service Contracts, Division A
6701 Rockledge Drive
Bethesda, Maryland 20817

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

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

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

c. Inspection and acceptance will be performed at:
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Division of Allergy, Immunology, and Transplantation
5601 Fishers Lane
Rockville, MD 20852

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

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

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract shall be from 7/1/2027 through 6/30/2034.

ARTICLE F.2. DELIVERIES

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

a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in RFO 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified in each Task Order.

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

   All reports required herein shall be submitted in electronic format. All electronic contract deliverables shall be submitted via eRDS (NIAID's electronic Report Deliverable Submission), available at the following website: http://erds.niaid.nih.gov/. Attachment 29, eRDS Vendor Quick Reference is attached in Section J of the contract.

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

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

REVOLUTIONARY FAR OVERHAUL (RFO) (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989).

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

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER REPRESENTATIVE (COR)

The following Contracting Officer Representative (COR) will represent the Government for the purpose of this contract: **To be specified at the time of award**

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

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

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

The Government may unilaterally change its COR designation.

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

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

(End of clause).

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

Name	Title
To be specified at time of award	

ARTICLE G.3. TASK ORDER PROCEDURE

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

a. **General**

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

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

b. **Requesting Task Order Proposals.**

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

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

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

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

Contractors are not required to propose on all TORFPs. Those eligible Contractors that decide not to submit a proposal shall advise the Contracting Officer, in writing, of their intention not to submit a proposal on or before the closing date and time established in the TORFP. An election not to propose on a given TORFP will not negatively affect or prohibit a Contractor from competing on future TORFPs.

However, it may affect the Contractor's eligibility for continuations or extensions of the resultant Task Order.

c. **Competitive Ordering Process.**

1. All Contractors within a technical area will receive e-mail notification advising of the availability of each proposed task order requirement. All proposed task orders will incorporate all terms of this contract unless otherwise specified in the proposed task order.

2. Contractors will be provided an adequate time to prepare and submit responses based on the Contracting Officer's consideration of the estimated dollar value and complexity of proposed task order. Responses will not be considered a proposal as defined in RFO Part 15. However, the Contractor shall provide information sufficient for consideration in accordance with RFO Part 16. Each TORFP will indicate the criteria for the evaluation of proposals. The responses shall demonstrate capability for each criterion to be evaluated. Generally, the Contractor will be asked to demonstrate the following as appropriate:
    - Understanding of the requirements;
    - Experience and capability on similar tasks;
    - Technical approach, methods and procedures for satisfying the requirements with a discussion of potential problems to be encountered and proposed solutions and/or risk mitigation strategies;
    - Procedures for assuring quality of work, products, and deliverables;
    - Plan for managing the task order, including meeting requirements and schedules, and performance measures (if applicable);
    - Staffing plan with skill levels and level of effort for each individual proposed. Generally, resumes will be required for proposed personnel (if not previously submitted);
    - References to evaluate past performance; and
    - Cost/Price to perform the task order.

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

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

Upon completion of evaluations, the Contracting Officer will issue a task order to the <u>Contractor.</u> The Contracting Officer will notify the Contractor(s) of the selection decision in writing.

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

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

1. The Contractor must submit invoices to the Department of Treasury's Invoice Processing Platform (IPP) at https://www.ipp.gov mailto:with a copy to the approving official for approval, as directed below and in accordance with the definitions of timeliness set forth in the invoice instructions included as an attachment in Section J of this Solicitation/Contract.

   The contractor's failure to submit timely invoice(s) to the Government waives the contractor's rights to receive payment pursuant to this contract. In the event of this waiver, the Government is not obligated to make such payment, and the Contracting Officer shall have the authority to unilaterally deobligate the funds in accordance with the requirements at 31 U.S.C. 1552(a) and downwardly adjust the total amount of the award by the amount of the deobligation. The contractor shall be given an opportunity to request the excusal of a late invoice from the Contracting Officer. If excused, the Contracting Officer will respond in writing to confirm that the contactor's right to receive payment has not been waived.

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

   Official: Contracting Officer
   Name- TBD

   Contracting Officer Representative
   Name- TBD

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

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

2. In addition to the requirements specified in RFO 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 Office of Acquisition & Logistics Management, Research & Development and Professional Services, Division A.
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: Radiological or Nuclear Medical Countermeasure Product Development Support (PDS)

g. Contract Line Items as follows:

Line Item #	Line Item Description
To be determined at time of award.	

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

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

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

ARTICLE G.5. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, RFO 52.232-40 (Mar 2023).

(a) (1) In accordance with 31 U.S.C. 3903 and 10 U.S.C. 3801, within 15 days after receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

(2) The Contractor agrees to make such payments to its small business subcontractors without any further consideration from or fees charged to the subcontractor.

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

(c) Include the substance of this clause, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial products or commercial services.

(End of clause).

ARTICLE G.6. INDIRECT COST RATES

In accordance with Revolutionary FAR Overhaul (RFO) Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in this contract in PART II, SECTION I, the Cognizant Federal Agency Official (CFAO) responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director,
Division of Financial Advisory Services (DFAS)
Office of Acquisition Management and Policy
National Institutes of Health
6701 Rockledge Drive
4th Floor, MSC-7786
Bethesda, MD 20892-7786

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 DFAS Indirect Cost Branch's information package documents.

DFAS accepts only electronic submissions of indirect cost proposals. Go to the New Online Submission Guidance web page: https://oamp.od.nih.gov/division-of-financial-advisory-services/new%20-online-submission-guidance for guidance on submitting indirect cost rate proposals electronically to DFAS.

Billing (Provisional) Rates:

In accordance with RFO 42.504, billing (provisional) rates must be established by the CFAO on the basis of information resulting from recent reviews, previous rate audits or experience, or similar reliable data or experience of other contracting activities.

The Contractor is required to submit a billing rate proposal to the CFAO identified above for the purpose of establishing and/or renewing expiring billing rates. As an administrative requirement, such submission shall be made no later than five (5) business days following the expiration of each of the Contractor's fiscal years.

Failure to submit a timely billing rate proposal to the CFAO may result in establishment of billing rates unilaterally by the CFAO, based on audited historical data or other available data with unallowable costs excluded.

The contractor shall have an opportunity to request reasonable extensions in writing at least 30 days prior to the expiration of the active billing rate agreement. Requests may be granted in writing by the CFAO.

The contractor shall notify the CFAO if/when the current billing (provisional) rates are no longer representative of current conditions and need to be renegotiated. This notification should include a revised indirect cost proposal and complete financial documentation to support a significant change in circumstances that warrants renegotiation of the rates.

The contractor shall utilize the IDC Submission Checklist found at: https://oamp.od.nih.gov/division-of-financial-advisory-services/indirect-cost-branch/indirect-cost-submission for preparing the billing rate proposal.

Final Indirect Rates:

In accordance with RFO Clause 52.216-7 (d)(2), Allowable Cost and Payment incorporated by reference in PART II, SECTION I of this contract, the Contractor shall submit an adequate final indirect cost rate proposal to the Contracting Officer (or cognizant Federal agency official) and auditor **within the 6-month period following the expiration of each of its fiscal years**. Reasonable extensions, for exceptional circumstances only, may be requested in writing by the Contractor and granted in writing by the Contracting Officer.

FAR Clause 52.216-7 (d)(2) lists the full requirements for submission of an adequate final indirect cost rate proposal. In accordance with RFO 42.503-2(a), the Government must not accept a proposal or agree to establish final indirect cost rates unless the contractor certifies the costs are allowable. Failure to submit a certified final indirect rate proposal to the CFAO may result in establishment of final indirect rates unilaterally by the Government, based on audited historical data or other available data with unallowable costs excluded. These unilateral rates established by the Government shall be set low enough to ensure that unallowable costs will not be reimbursed (RFO 42.503-2(c)).

ARTICLE G.7. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with RFO Subpart 4211. 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 to coincide with the anniversary date of the contract.

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

Officer, whose decision will be final.

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

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 .

End of clause.

ARTICLE G.8. GOVERNMENT PROPERTY

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. NOTICE TO OFFERORS – PROTECTION OF HUMAN SUBJECTS HHSAR 352.270-70 (MAR 2026) (RFO DEVIATION)

(a) The Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR part 46, are available on the Office for Human Research Protections (OHRP) website at: http://www.hhs.gov/ohrp/index.html.

(1) These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of human subjects participating in research activities supported or conducted by HHS.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable public information through intervention or interaction with the individual, or identifiable private information. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. 45 CFR part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.

(c) Activities which involve human subjects in one or more of the categories set forth in 45 CFR 46.104(d)(1)-(8) are exempt from complying with 45 CFR part 46. See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal.

(e) In accordance with 45 CFR part 46, Offerors considered for award must file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board must ensure that: The risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111 for additional requirements regarding initial and continuing review. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP Web site (at http://www.hhs.gov/ohrp/assurances/index.html).

(f) Offerors may consult with OHRP only for general advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. ONLY the contracting officer may offer information concerning a solicitation.

(g) The Offeror must document in its proposal the approved or active FWA from OHRP, related to the designated Institutional Review Board (IRB) reviewing and overseeing the research.

(1) If the Offeror does not have an approved FWA from OHRP, the Offeror must obtain an FWA before the deadline for proposal submission.

(h) When possible, the Offeror must also certify the IRB's review and approval of the research. If the Offeror cannot obtain this certification by the time of proposal submission, they must include an explanation in their proposal.

(i) Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.

(End of provision)

Alternate I (MAR 2026) (RFO DEVIATION).

As prescribed in HHSAR 335.7004(a), substitute the following paragraph (g)(1) for paragraph (g)(1) of the basic clause.

(1) If the Offeror does not have an active FWA from OHRP, the Offeror must take all necessary steps to obtain an FWA prior to the proposal submission deadline. If the Offeror cannot obtain an FWA before the proposal submission deadline, the proposal must indicate the steps/actions the Offeror will take to obtain OHRP approval prior to the contract award. Upon obtaining FWA approval, submit the approval notice to the Contracting Officer.

ARTICLE H.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated August 25, 2000 at the following website:

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

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

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

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design

and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.3. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

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

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

The Contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.
Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.
The Data and Safety Monitoring [Board/Plan/Board and Plan/Board and/or Plan] shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H.4. GOOD CLINICAL PRACTICE TRAINING FOR NIH AWARDEES INVOLVED IN NIH-FUNDED CLINICAL TRIALS

All NIH-funded investigators and staff who are involved in the conduct, oversight, or management of clinical trials should be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R2). GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. GCP training should be refreshed at least every three years to remain current with regulations, standards and guidelines. The Contractor shall provide completion of training documentation to the Contracting Officer's Representative (COR).

Investigator: The individual responsible for the conduct of the clinical trial at a trial site. If a clinical trial is conducted by a team of individuals at a trial site, the investigator is the responsible leader of the team and may be called the principal investigator.

Clinical Trial Staff: Individuals, identified by the investigator, who are responsible for study coordination, data collection and data management. Clinical trial staff may also be called the research coordinator, study coordinator, research nurse, study nurse or sub-investigator.

ARTICLE H.5. CLINICAL TRIAL REGISTRATION AND RESULTS INFORMATION SUBMISSION

The Contractor conducting clinical trials, funded wholly or partially through the NIH extramural and intramural programs, shall ensure that its NIH-funded clinical trials are registered at, and summary results information is submitted to, www.clinicaltrials.gov for public posting. See NIH Guide Notice NOT-OD-16-149 dated September 16, 2016.

All NIH- funded clinical trials shall be registered and results information submitted to www.clinicaltrials.gov regardless of study phase, type of intervention, or whether they are subject to the regulation 42 CFR Part 11. Clinical trials subject to the regulation are called " applicable clinical trials."

The Contractor must submit a plan with its proposal to meet the regulatory requirements of the dissemination of information of NIH-funded Clinical Trials. The Contractor and investigators are required to comply with all terms and conditions of award, including following their acceptable plan for the dissemination of NIH-funded clinical trial information.

The Contractor must register all NIH-funded clinical trials in www.clinicaltrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information from those trials must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of a new use is being sought. The Contractor shall include the trial registration number (NCT number) in the Technical Progress Report covering the period in which registration occurred, and as a standalone notification to the Contracting Officer within ten (10) calendar days of the registration. Each NIH-funded clinical trial must have only one entry in ClinicalTrials.gov that contains its registration and results information.

The Contractor shall include a specific statement in all informed consent documents relating to posting of clinical trials information to www.clinicaltrials.gov. The responsibilities of the Contractor will fall within one of the following three categories:

1. If the NIH-funded clinical trial is an applicable clinical trial under the regulation and the Contractor is the responsible party, the Contractor will ensure that all regulatory requirements are met.

2. If the NIH-funded clinical trial is an applicable clinical trial under the regulation but the Contractor is not the responsible party, the Contractor will coordinate with the responsible party to ensure that all regulatory requirements are met.

3. If the NIH-funded clinical trial is not an applicable clinical trial under the regulation, the Contractor will be responsible for carrying out the tasks and meeting the timelines described in NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information. Such tasks include registering the clinical trial in ClinicalTrials.gov and submitting results information to ClinicalTrials.gov.

Failure to comply with the terms and conditions of the award may provide a basis for enforcement actions. Identifying clinical trial record as non-compliant in ClinicalTrials.gov may lead to termination, consistent with 45 CFR 75.371 and/or other authorities, as appropriate. If the NIH-funded clinical trial is also an applicable clinical trial, non-compliance with the requirements specified in 42 USC 282(j) and 42 CFR Part 11 may also lead to the actions described in 42 CFR 11.66.

The Contracting Officer may take one or more of the following enforcement actions, if the Contractor fails to provide evidence of compliance within 30 days.

1. Temporary withhold payments pending correction of the deficiency;
2. Disallow all or part of the cost of the activity or action not in compliance;
3. Wholly or partly suspend or terminate the contract award;
4. Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and HHS awarding regulations at 2 CFR part 376;
5. Withhold further awards for the project and program;
6. Take other remedies that may be legally available.

ARTICLE H.6. CLINICAL TRIAL REGISTRATION AND RESULTS INFORMATION SUBMISSION PLAN

The special terms and conditions in the Contract Award that include a clinical trial:

1. The clinical trial(s) supported by this award is subject to the plan dated [DATE] submitted to NIH and the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. The plan must state that the clinical trial(s) funded by this award will be registered in ClinicalTrials.gov not later than 21 calendar days after enrollment of the first participant. The plan also must state that primary summary results shall be reported in ClinicalTrials.gov, including adverse event information, not later than one year after the primary completion date of the trial. The reporting of summary results is required by this term of award.

2. This award is subject to reporting requirements with each submission of the annual report. Contractor shall agree to the following annual certification. By affirming this annual certification:

The Contractor hereby certifies that all investigators conducting NIH-funded clinical trials under the NIH contract number which is to be determined are in compliance with the Contractor's plan addressing compliance with the NIH policy on Dissemination of NIH-Funded Clinical Trial Information. Any clinical trial funded wholly or partially under this award has been registered in ClinicalTrials.gov or will be registered not later than 21 calendar days after enrollment of the first participant. Primary summary results have been submitted to ClinicalTrials.gov or will be submitted not later than one year after the primary completion date of the trial.

ARTICLE H.7. CERTIFICATE OF CONFIDENTIALITY

Section 2012 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions governing the authority of the Secretary of Health and Human Services (Secretary) to protect the privacy of individuals who are the subjects of research, including significant amendments to the previous statutory authority for such protections, under subsection 301(d) of the Public Health Service Act.

Effective October 1, 2017, all research that was commenced or ongoing on or after December 13, 2016 and is within the scope of the NIH Policy for Issuing Certificate of Confidentiality (CoC) NOT-OD-17-109, the Contractor shall protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act as a term and condition of the contract. The certificate will not be issued as a separate document.

NIH considers research in which identifiable, sensitive information is collected or used, to include:

- Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research (except for human subjects' research that is determined to be

exempt from all or some of the requirements of 45 CFR 46) if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects);

- Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;
- Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

The Contractor shall not:

- Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

The Contractor is permitted to disclose only in below circumstances. The Contractor shall notify the CO minimum ten (10) calendar days prior to disclosure.

- Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding;
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

In accordance with 45 CFR Part 75.303(a), the Contractor shall maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal Statutes and regulations.

The recipient of CoCs shall ensure that any company/institution/individual not funded by NIH who receives a copy of identifiable, sensitive information protected by a Certificate understand that they are also subject to the requirements of subsection 301(d) of the Public Health Service Act. The Contractor shall ensure that Subcontractors who receive funds to carry out part of the Federal award understand they are also subject to subsection 301(d) of the Public Health Service Act and the NIH Policy for Issuing CoC.

ARTICLE H.8. SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)

For Institutional Review Board (IRB), the Contractor shall use the single Institutional Review Board (sIRB) of record for cooperative/multi-site research. All domestic sites participating in multi-site studies involving a non-exempt human subjects research funded wholly or partially by the National Institutes of Health (NIH) shall use a sIRB to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46 and the NIH Policy on the Use of Single Institutional Review Board for Multi-Site Research . Any IRB serving as the sIRB of record for NIH funded research shall be registered with the HHS Office for Human Research Protections (OHRP) and shall have membership sufficient to adequately review the proposed study. The Contractor shall provide to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 certifying IRB review and approval of the research that encompasses all sites of performance. *This paragraph applies only if the Government provided a sIRB through a separate entity as stated in section- C* . When the Government provided sIRB through a separate entity, the Contractor agrees to use of the sIRB. The Contractor shall provide to the Contracting Officer sIRB information and data in a timely manner as necessary to meet the policy and/or regulatory requirements of the Protection of Human Subjects at 45 CFR Part 46.

Exceptions to the NIH Single IRB Policy

The Contractor may request an exception in the following instances:

1. Where review by the proposed sIRB would be prohibited by Federal, state, or tribal laws, regulations or policies (policy-based exceptions);
2. *Other exceptions,* to be determined by NIH if there is a compelling justification; and
3. Time Limited Exception: ancillary studies to ongoing research without a sIRB- new multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use a sIRB of record until the parent study is expected to comply with the sIRB policy.
   Policy-based exceptions and time limited exceptions are automatically granted when identified in the sIRB Plan.

Other exceptions must be reviewed by NIH OD and are expected to be granted rarely. *Other exceptions* when Offeror believes that one or more research sites should be exempt from use of the single IRB of record to conduct local IRB review based on compelling justification-

1. Offerors should request an exception in the sIRB plan attachment within the contract proposal (section 3.2 in the Study Record: PHS Human Subjects and Clinical Trials Information form).
2. Offerors must include the name of the site(s) for which an IRB other than the sIRB of record is proposed to review the study for the sites(s).

3. Offerors must substantiate their exception request with sufficient information that demonstrates a compelling justification for *other exceptions* to the sIRB policy. The rationale should include why the sIRB of record cannot serve as the reviewing IRB for the site(s), and why the local IRB is uniquely qualified to be the reviewing IRB for the specific site(s).
   - For instance, the justification may consider ethical or human subjects protections issues, population needs, or other compelling reasons that IRB review for the site(s) cannot be provided by the single IRB of record.
4. Note that the proposed budget in the proposal must reflect all necessary sIRB costs without an approved *other exception.* The Offerors should not assume that *another exception* will be granted when considering what sIRB costs to include in the budget.

Post-Award Exception Requests

For any post-award changes that necessitate an exception request, such as the addition of a new domestic site that may be unable to use the sIRB Contractor shall contact their Contracting Officer (CO). For policy-based exceptions, the Contractor shall provide the appropriate citation to verify the requirement for local IRB review for the newly added site(s) to the CO. For *other exceptions*, the Contractor shall provide compelling justification to the CO to be reviewed by the NIH Exceptions Review Committee (ERC) (see **Steps to Request an Other Exception to the sIRB Policy** above). For time limited exceptions, Contractor shall provide the parent contract number to the CO. For time limited exceptions, Contractor shall provide the parent contract number to the CO.

Notice of Approval or Disapproval of *Other Exception* Requests

The sIRB exception requests will be considered after peer review for proposals in the competitive range. The decision of NIH OD is final. Offerors will be notified of the final decision by their CO prior to award. Approved exceptions will be incorporated as a term and condition in the contract award. Also, any exception requests submitted after award must be submitted to the CO and reviewed by the NIH ERC. No further revisions of the exception request will be accepted.
The award budget may need to be adjusted if an exception is granted.

Exception To the Revised Common Rule's Single IRB Review Requirement for Cooperative Research

NIH can only issue exceptions to the requirement at 45 CFR 46 that domestic sites participating in non-exempt human subjects research use a single IRB when authority to provide such exceptions is explicitly granted to NIH by the Office for Human Research Protections (OHRP).

ARTICLE H.9. IDENTIFICATION OF SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)

For this multi- site study, the TBD Contractor agrees to adhere to applicable single IRB review requirements specified in 45 CFR 46 and the NIH sIRB policy, and the TBD (IRB Name) IRB shall serve as the single IRB of record. All participating sites have agreed to rely on the TBD (IRB Name) IRB, and a written authorization/reliance agreement shall be developed. Any additional sites added after contract award shall also agree to rely on this study's single IRB of record. Communication plans for interactions between the sIRB and participating sites shall be described in the authorization/ reliance agreement. All participating sites shall, prior to initiating the study, sign the authorization/ reliance agreement that shall clarify the roles and responsibilities of the sIRB and participating sites. The TBD (Contractor

Name/ Name of the Coordinating Center or Contract Research Organization (CRO)) shall maintain records of the authorization/reliance agreements, including the communication plans. The name of the sIRB of record shall be incorporated as a term and condition of the award. Contractor shall provide any proposed updates/changes to the identity of the sIRB of record to the Contracting Officer, with a copy to the Contracting Officer Representative, at least thirty (30) calendar days prior to any proposed updates/changes to the sIRB, so the Government can review and approve any such proposed changes via formal modification of the contract.

Exceptions to the Single IRB Plan

The Contractor may request an exception to the sIRB plan under the following instances:

- Sites for which federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions)
  Review by a single IRB of record will not be possible for (***sites)*** *because of federal/state/tribal law, regulation, or policy* (***provide specific citation(s))***
- Other exceptions, to be determined by NIH if there is a compelling justification
  Review by a single IRB of record will not be possible for ***(this contractor)*** *because of* ***(provide compelling justification and rationale why local IRB is uniquely qualified to be the reviewing IRB for the specific site(s)).***
- Time Limited Exceptions: New multi- site non- exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use the sIRB of record until the parent study is expected to comply with the sIRB policy.
  Review by a single IRB of record will not be possible for ***(sites)*** *because of ongoing multi- site parent study* ***(provide parent contract number).***

ARTICLE H.10. INCLUSION OF WOMEN AND MEMBERS OF RACIAL AND/OR ETHNIC MINORITY GROUPS IN CLINICAL RESEARCH

NIH-conducted and supported clinical research must conform to the NIH Policy and Guidelines on the Inclusion of Women and Members of Racial and/or Ethnic Minority Groups as Subjects in Clinical Research in accord with Public Health Service Act sec. 492B, 42 U.S.C. sec. 289a-2. The policy requires that women and members of racial and/or ethnic minority groups and their subpopulations must be included in all NIH-conducted or supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant NIH Institute/Center (IC) Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an IC Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Members of Racial and/or Ethnic Minority Groups as Subjects in Clinical Research", published in the NIH Guide for Grants and Contracts, effective August 16, 2025, at the following website: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-131.html

When registering in Clincialtrials.gov, NIH-defined Phase 3 applicable clinical trials must specify outcomes on sex and race and/or ethnic group(s). For NIH-defined Phase 3 applicable clinical trials, submissions of results to ClinicalTrials.gov must include results of valid analyses by sex and race and/or ethnicity, as required based on prior evidence.

The NIH Inclusion Policy is complementary to requirements outlined in the Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11 and the accompanying NIH Policy on the Dissemination of NIH-Funded Clinical Trial Information (NO-OD-16-149). Applicable clinical trials are required to be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information generally must be submitted no later than one year after the primary completion date, unless a certification of delay was submitted, a request for an extension for good cause was granted, or a request for a waiver of the requirements for submission of results information was granted.

ARTICLE H.11. INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

Section 2038 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions requiring NIH to address the consideration of age as an inclusion variable in research involving human subjects, to identify criteria for justification for any age-related exclusions in NIH research, and to provide data on the age of participants in clinical research studies. The NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accordance with § 46.104 and 401(c) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects.

Effective on all solicitations issued on or after January 25, 2019, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

The Contractor must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. The Contractor must provide a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the contractor must provide acceptable justification for the exclusion.

The Contractor must submit cumulative data as prescribed in the Attachment Files - Section J "NIH Contracts Age Enrollment Report template" on participant age at enrollment in monthly progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual level participant data on sex, race, and/or ethnicity, and age at enrollment may be provided in progress reports. The Contractor must submit cumulative de-identified individual level participant data on sex, race, and/or ethnicity, and age at enrollment annually. The template used for these submissions is https://www.era.nih.gov/sites/default/files/2020-05/ParticipantLevelData-Template.CSV

ARTICLE H.12. POSTING CLINICAL TRIAL INFORMED CONSENT FORMS TO CLINICALTRIALS.GOV

The Revised Common Rule sections 46.102(b) and 46.116(h) requires Contractors to post one IRB-approved version of an Informed Consent Form that has been used to enroll participants on a public federal website designated for posting such Consent Forms. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database ClinicalTrials.gov . Note: ClinicalTrials.gov only accepts Informed Consent Forms written in English; non-English language forms must be submitted to Regulations.gov . The Informed Consent Form must be posted after recruitment closes, and no later than 60 days after the final study visit. The Contracting Officer (CO) and/or Contracting Officer Representative (COR) may permit or require redactions as appropriate.

ARTICLE H.13. REGISTRATION AND RESULTS REPORTING FOR APPLICABLE CLINICAL TRIALS IN CLINICALTRIALS.GOV

The Food and Drug Administration Amendments Act of 2007 (FDAAA) at: PUBLIC Law 110-085.PS, Title VIII, expands the National Institutes of Health's (NIH's) clinical trials registry and results database known as ClinicalTrials.gov and imposes new requirements that apply to specified "applicable clinical trials," including those supported in whole or in part by NIH funds. FDAAA requires:

- the registration of certain "applicable clinical trials" (see Definitions at: https://grants.nih.gov/grants/policy/nihgps/html5/section_1/1.2_definition_of_terms.htm) in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
- the reporting of summary results information (including adverse events) no later than 1 year after the completion date (See Definitions at link above) for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

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

The [Contractor is the Sponsor, therefore/Government is the Sponsor and delegates the Contractor's Principal Investigator as/Government is the Sponsor, therefore] the "Responsible Party" for the purposes of compliance with FDAAA which includes registration (and results reporting, if required) of applicable clinical trial(s) performed under this contract in the Government database,

ClinicalTrials.gov (https://www.ClinicalTrials.gov). The Contractor shall provide the "Responsible Party" with all essential data for timely compliance with ClinicalTrials.gov reporting requirements.

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

ARTICLE H.14. REPORTING IN ELECTRONIC RESEARCH ADMINISTRATION (eRA) SYSTEM

The Contractor shall submit data relevant to Human Subjects and Clinical Trial Information, including any required Inclusion Enrollment Reporting, into the NIH Electronic Research Administration (eRA) system.

More information is available at https://www.era.nih.gov/help-tutorials/era-training-hss.htm.

System Access

The eRA system website may be accessed at: https://public.era.nih.gov/commonsplus.

Please note that if your organization does not currently have an account in eRA Commons, you will first need to register your organization at https://public.era.nih.gov/commonsplus/public/registration/initRegistration.era.

Once your organization is registered, your signing official is then able to create new eRA system user accounts (such as for a Project Director/Principal Investigator).

For information on how to create/manage accounts in the eRA system, please refer to: https://www.era.nih.gov/register-accounts/create-and-edit-an-account.htm . [Note: You must be logged into the eRA system with appropriate role(s), in order to complete these activities.]

Refer to SECTION F - NOTIFICATION OF COMPLETION OF RESEARCH AND DEVELOPMENT DATA ENTRY IN ELECTRONIC RESEARCH ADMINISTRATION (eRA) SYSTEM for schedule and notification requirements related to data submission in the NIH eRA system.

ARTICLE H.15. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

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

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

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

ARTICLE H.16. PUBLIC HEALTH SURVEILLANCE EXCLUSION

The Contractor may request an exclusion from applicability of the "revised Common Rule"[1] if it believes that the NIH-funded or -conducted activities associated with this contract should be considered "public health surveillance activities deemed not to be research" for the purposes of the revised Common Rule. All requests for exclusion from the revised Common Rule for NIH-funded research-whether conducted or supported-must receive NIH approval, as per the process outlined below, to be considered a public health surveillance activity deemed not to be research under the revised Common Rule's Sections §46.102(k), Public health authority, and §46.102(l)(2), Public health surveillance activities. NIH expects that NIH-supported or -conducted research will be determined to be a public health surveillance activity only in extremely rare cases. **Please note that NIH will not consider any NIH-defined clinical trials for a public health surveillance exclusion request. In addition, NIH will not consider studies that contain any activity that does not meet the requirements for an exclusion for a public health surveillance determination, which includes any intent to store specimens and/or data for future use, for a request for exclusion.**

Contractor shall provide a compelling justification as to why NIH-funded or -conducted activities should be considered public health surveillance activities deemed not to be research for the purposes of the revised Common Rule, a template of which is included as an attachment in Section J, LIST OF ATTACHMENTS - CONTRACT, of this Contract.

Contractor shall complete and submit the PHS Human Subjects and Clinical Trials Information Form, following instructions in the solicitation or contract, as applicable. Contractor should not assume that approval of an exclusion will be granted when completing the PHS Human Subjects and Clinical Trials Information Form.

Note that the proposed budget in the proposal must reflect all necessary/required costs for the full and proper conduct of research involving human subjects, in complete compliance with all applicable laws, protocols, rules, and/or regulations at all levels, without approval of any exclusion. Contractor should not assume that approval of an exclusion will be granted when considering the costs to include in any proposed budget and therefore, must respond and price accordingly.

Notice of Approval or Disapproval of Request for Exclusion

Exclusion requests will be considered separate from the NIH peer review of technical proposals. Offerors will be issued written notification of approval or denial by the NIH Contracting Officer of any request(s) for exclusion prior to award. Any decision by NIH on an Offeror's request for a Public Health Surveillance Exclusion shall be final.

If a Public Health Surveillance exclusion is approved, the Contracting Officer shall request that the Contractor revise its proposed costs during negotiations, in order to reflect any associated decreases in estimated costs, as a result of the exclusion being granted. The Contracting Officer shall also determine if any changes to the terms and conditions of the contract, as applicable, need to be made, based on the exclusion.

The cost proposal will then be adjusted accordingly at award if approval of an exclusion is granted by NIH.

[1] Code of Federal Regulations (CFR) Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects, Revised 19 January 2017, Effective 19 July 2018, with a General Compliance Date of 21 January 2019 (45 CFR part 46)), and not its predecessor, the Pre-2018 Common Rule (Common Rule). The revised Common Rule is also known or referred to as the "2018 Requirements" or the "2018 Rule."

ARTICLE H.17. 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. More information is available at https://grants.nih.gov/policy/reproducibility/index.htm, including FAQs and a General Policy Overview.

ARTICLE H.18. 2024 NIH PUBLIC ACCESS POLICY

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) electronic versions of all Author Accepted Manuscripts arising from this contract in whole or in part, upon acceptance for publication. NIH defines the Author Accepted Manuscripts as the author's final version that has been accepted for journal publication and includes all revisions resulting from the peer review process, including all associated tables, graphics, and supplemental material. NIH-funded investigators shall notify their Contracting Officers and Contracting Officer Representatives upon the acceptance of an Author Accepted Manuscript resulting from the contract, even if co-authored with those not using contract funds. Through execution of this contract, contractor, and through implementation of this provision by contractor to each of contractor's investigators and subcontractor, and through implementation of this provision to each of subcontractor's investigators, conducting work under this contract or a subcontract, respectively, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this contract, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy. Upon receipt of a PMCID, investigators should report the PMCID to their Contracting Officers and Contracting Officer Representatives to demonstrate compliance with this term of the contract. The PMC archive will permanently preserve and retain these manuscripts for use by the public, health care providers, educators, scientists, and NIH. NIH Policy directs electronic submissions to the NIH/NLM/PMC: https://www.ncbi.nlm.nih.gov/pmc/.

Additional information is available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-047.html and https://grants.nih.gov/policy-and-compliance/policy-topics/public-access

ARTICLE H.19. NEEDLE EXCHANGE, HHSAR 352.35-72 (Mar 2026)(RFO DEVIATION).

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

(End of clause).

ARTICLE H.20. ACKNOWLEDGEMENT OF FEDERAL FUNDING

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

ARTICLE H.21. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.235-73 (Mar 2026)(RFO DEVIATION).

a. The Contractor must not use any funds obligated under this contract for the following:
    1. Any abortion,
    2. Cloning of human beings, or
    3. For the following:
       (i) The creation of a human embryo or embryos for research purposes; or
       (ii) Research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
b. The term "human embryo or embryos'' includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.

(End of clause).

Furthermore NIH will not fund any use of gene-editing technologies in human embryos.

ARTICLE H.22. 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.23. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.235-75 (Mar 2026) (RFO DEVIATION).

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

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

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

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

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

(End of clause)

ARTICLE H.24. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can

be accessed at: https://olaw.nih.gov/policies-laws/phs-policy.htm .

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

ARTICLE H.25. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

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

ARTICLE H.26. OMB CLEARANCE

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

ARTICLE H.27. 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.28. GUN CONTROL

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

ARTICLE H.29. 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 RFO Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item/RFO Clause 52.217-9, Option to Extend the Term of the Contract] set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST PLUS FIXED FEE Article in SECTION B of this contract.

ARTICLE H.30. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan**

1. In accordance with RFO 19.206-1 and RFO Clause 52.219-9, the submission of a subcontracting plan by other than small business offeror(s) is a requirement as a part of the proposal submission process and is to be submitted separately from the technical and cost proposals. An offeror's subcontracting plan must be determined to be acceptable, by the Contracting Officer, prior to the contract award.

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

b. **Subcontracting Plan Submission**

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

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

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

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

c. Subcontracting Reports

1. Individual Subcontract Reports (ISR)

The Contractor must submit the following Subcontracting reports electronically via the Subcontracting Plan Reporting (SPR) at SAM.gov.
Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

May 15th
November 14th
Expiration Date of Contract

2. Summary Subcontract Report (SSR)

Regardless of the effective date of this contract, the Summary Subcontract Report must be submitted annually on the following date for the entire life of this contract: November 14th

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

karen.telphia@nih.gov
Contracting Officer

ARTICLE H.31. INFORMATION AND INFORMATION SYSTEMS SECURITY, HHSAR 352.204-71 (FEB 2024) (DEVIATION).

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

Breach means the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where—

(1) A person other than an authorized user accesses or potentially accesses personally identifiable information, or

(2) An authorized user accesses personally identifiable information for an other than authorized purpose.

*Business associate (*see 45 CFR 160.103*),* except as provided in paragraph (2) of this definition, business associate means, with respect to a covered entity, a person who -

(1) On behalf of such covered entity or of an organized health care arrangement (as defined in this clause) in which the covered entity participates, but other than in the capacity of a member of the workforce of such covered entity or arrangement, creates, receives, maintains, or transmits protected health information for a function or activity regulated by this contract or agreement, including claims processing or administration, data analysis, processing or administration, utilization review, quality assurance, patient safety activities listed at 42 CFR 3.20, billing, benefit management, practice management, and repricing; or

(2) Provides, other than in the capacity of a member of the workforce of such covered entity, legal, actuarial, accounting, consulting, data aggregation (as defined in 45 CFR section 164.501), management, administrative, accreditation, or financial services to or for such covered entity, or to or for an organized health care arrangement in which the covered entity participates, where the provision of the service involves the disclosure of protected health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

(3) A covered entity may be a business associate of another covered entity.

(4) *Business associate* includes the following:

(i) A Health Information Organization, E-prescribing Gateway, or other person that provides data transmission services with respect to protected health information to a covered entity and that requires access on a routine basis to such protected health information.

(ii) A person that offers a personal health record to one or more individuals on behalf of a covered entity.

(iii) A subcontractor that creates, receives, maintains, or transmits protected health information on behalf of the business associate.

(5) *Business associate* does not include:

(i) A health care provider, with respect to disclosures by a covered entity to the health care provider concerning the treatment of the individual.

(ii) A plan sponsor, with respect to disclosures by a group health plan (or by a health insurance issuer or HMO with respect to a group health plan) to the plan sponsor, to the extent that the requirements of 45 CFR 164.504(f) apply and are met.

(iii) A government agency, with respect to determining eligibility for, or enrollment in, a government health plan that provides public benefits and is administered by another government agency, or collecting protected health information for such purposes, to the extent such activities are authorized by law.

(iv) A covered entity participating in an organized health care arrangement that performs a function or activity as described by paragraph (1)(i) of this definition for or on behalf of such organized health care arrangement, or that provides a service as described in paragraph (1)(ii) of this definition to or for such organized health care arrangement by virtue of such activities or services.

Business associate agreement means the agreement, or other arrangement, as dictated by the HIPAA Privacy Rule (45 CFR 160), between an HHS covered entity and a business associate, which must be entered into in addition to the underlying contract for services and before any disclosure (see 45 CFR 160.103) of PHI can be made to the business associate, in order for the business associate to perform certain functions or activities on behalf of an HHS entity.

Controlled unclassified information (CUI) means information that laws, regulations, or Government-wide policies require to have safeguarding or dissemination controls, excluding classified information.

Healthcare component means a component or combination of components of a hybrid entity designated by the hybrid entity in accordance with 45 CFR 164.105(a)(2)(iii)(D) (see 45

CFR 164.103). The Secretary of HHS has designated HHS as a covered entity (further designated as a "hybrid entity"), and has also designated four HHS divisions as healthcare components under HIPAA, including

(1) The Centers for Medicare and Medicaid Services (CMS), insofar as it operates the fee-for-service Medicare program;

(2) The Program Support Center (PSC), Division of Commissioned Personnel, insofar as it operates a health plan for Commissioned Corps officers;

(3) The World Trade Center (WTC) Health Program; and,

(4) The Indian Health Service (IHS), insofar as it operates a health plan and a program providing healthcare that uses electronic transactions.

HHS Information Technology General Rules of Behavior means a set of HHS rules that describes the responsibilities and expected behavior of users of HHS information or information systems.

HHS sensitive information means all HHS data, on any storage media or in any form or format, which requires confidentiality, integrity, and availability protection due to the risk of harm that could result to interests of HHS, other agencies or entities, or individuals from inadvertent or deliberate disclosure, alteration, or destruction of the information. The term includes—

(1) Information where the improper use or disclosure could adversely affect the ability of HHS to accomplish its mission, *i.e*., HHS proprietary information;

(2) Records about individuals requiring protection under laws and regulations such as the E-Government Act, Privacy Act and the HIPAA Privacy Rule, or based on a data use agreement or a promise or assurance of confidentiality; and

(3) Information that would be exempt from disclosure if requested under the Freedom of Information Act. Examples of HHS sensitive information include—

(i) Individually-identifiable medical, benefits, and personnel information;

(ii) Financial, budgetary, research, quality assurance, confidential commercial, critical infrastructure, security-sensitive, procurement-sensitive, investigatory, and law enforcement information;

(iii) Controlled unclassified information;

(iv) Information that would be confidential and privileged in litigation such as information protected by the deliberative process privilege, attorney work-product privilege, and the attorney-client privilege; and

(v) Other information which, if released, could result in a violation of law or agreement, could cause harm or unfairness to any individual or group, or could adversely affect the national interest or the conduct of Federal programs.

HIPAA Rules means the Privacy, Security, Breach Notification, and Enforcement Rules at 45 CFR Part 160 and part 164.

Incident means an occurrence that (A) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information systems; or (B) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable policies.

Information system means a discrete set of information resources organized for the collection, processing, maintenance, use, sharing, dissemination, or disposition of information.

Information system s*ecurity plan* means a formal document that provides an overview of the security requirements for an information system or an information security program and describes the security controls in place or planned for meeting those requirements.

Information technology (see FAR 2.101) also means Information and Communication Technology (ICT).

Information technology-related contracts means those contracts that include services (including support services), and related resources for information technology.

Organized health care arrangement (see 45 CFR 160.103) means:

(1) A clinically integrated care setting in which individuals typically receive health care from more than one health care provider;

(2) An organized system of health care in which more than one covered entity participates and in which the participating covered entities:

(i) Hold themselves out to the public as participating in a joint arrangement; and

(ii) Participate in joint activities that include at least one of the following:

(A) Utilization review, in which health care decisions by participating covered entities are reviewed by other participating covered entities or by a third party on their behalf;

(B) Quality assessment and improvement activities, in which treatment provided by participating covered entities is assessed by other participating covered entities or by a third party on their behalf; or

(C) Payment activities, if the financial risk for delivering health care is shared, in part or in whole, by participating covered entities through the joint arrangement and if protected health information created or received by a covered entity is reviewed by other participating covered entities or by a third party on their behalf for the purpose of administering the sharing of financial risk.

(3) A group health plan and a health insurance issuer or HMO with respect to such group health plan, but only with respect to protected health information created or received by such health insurance issuer or HMO that relates to individuals who are or who have been participants or beneficiaries in such group health plan;

(4) A group health plan and one or more other group health plans each of which are maintained by the same plan sponsor; or

(5) The group health plans described in paragraph (4) of this definition and health insurance issuers or HMOs with respect to such group health plans, but only with respect to protected health information created or received by such health insurance issuers or HMOs that relates to individuals who are or have been participants or beneficiaries in any of such group health plans.

Privacy officer means the HHS official(s) with responsibility for implementing and oversight of privacy related policies and practices that impact a given HHS acquisition.

(b) *General*. Contractors, subcontractors, their employees, third-parties, and business associates with access to HHS information, information systems, or information technology (IT) or providing and accessing IT-related goods and services, shall adhere to the HHS Cybersecurity Program and the directives and handbooks, complete HHS security training prior to accessing HHS information (including HHS sensitive information and information systems security and privacy) and on an annual basis thereafter, as well as those set forth in the contract specifications, statement of work, or performance work statement. These include, but are not limited to, HHS *Personnel Security and Suitability Program*, which establishes HHS procedures, responsibilities, and processes for complying with current Federal law, Executive Orders, policies, regulations, standards, and guidance for protecting HHS information, information systems (see 302.101, Definitions) security and privacy, and adhering to personnel security requirements when accessing HHS information or information systems.

(c) *Access to HHS information and HHS information systems*.

(1) Contractors are limited in their request for logical or physical access to HHS information or HHS information systems for their employees, subcontractors, third parties and business associates to the extent necessary to perform the services or provide the goods as specified in the contracts, agreements, task, delivery, or purchase orders.

(2) All Contractors, subcontractors, third parties, and business associates working with HHS information are subject to the same investigative requirements as those of HHS appointees or employees who have access to the same types of information. The level and process of background security investigations for Contractors to access HHS information and HHS information systems shall be in accordance with HHS *Personnel Security and Suitability Program*.

(3) Contractors, subcontractors, third parties, and business associates who require access to national security programs must have a valid security clearance.

(4) The Contractor (and/or any subcontractor) must comply with *Executive Order 13556, Controlled Unclassified Information, (implemented at 3 CFR,* part 2002*)* when handling CUI. 32 C.F.R. 2002.4(aa) As implemented the term "*handling*" refers to "…any use of CUI, including but not limited to marking, safeguarding, transporting, disseminating, re-using, and disposing of the information." 81 Fed. Reg. 63323. The requirements below apply only to nonfederal systems that process, store, or transmit CUI, or that provide security protection for such components. All sensitive information that has been identified as CUI by a regulation or statute, handled by this solicitation/contract, must be –

(i) Marked appropriately;

(ii) Disclosed to authorized personnel on a need-to-know basis;

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

(iv) Returned to HHS control, destroyed when no longer needed, or held until otherwise directed. Information and/or data must be disposed of in accordance with NIST SP 800-88*, Guidelines for Media Sanitization*.

(5) *HIPAA business associate agreements*. Under the HIPAA Privacy and Security Rules (see 45 CFR 164), pursuant to 45 CFR 164.502(e)(1), a covered entity may disclose protected health information to a business associate and may allow a business associate to create, receive, maintain, or transmit protected health information on its behalf, if the covered entity obtains satisfactory assurance that the business associate will appropriately safeguard the information. A covered entity is not required to obtain such satisfactory assurances from a business associate that is a subcontractor of a covered entity's business associate.

Additionally, a business associate may disclose protected health information to a business associate that is a subcontractor and may allow the subcontractor to create, receive, maintain, or transmit protected health information on its behalf, if the business associate obtains satisfactory assurances, in accordance with 45 CFR 164.504(e)(1)(i), that the subcontractor will appropriately safeguard the information. The satisfactory assurances required by 45 CFR 45 CFR 164.504(e)(1) of this section shall be documented through a written contract or other written agreement or arrangement with the business associate that meets the applicable requirements of 45 CFR 164.504(e). The contracts shall also include breach reporting policies and procedures for suspected or confirmed breaches of protected health information. The contract shall impose a duty to cooperate with the healthcare component and/or HHS breach investigation and response and must require all subcontractors to comply with the same HIPAA Rules requirements as a condition of receiving government data.

(i) *Contractors or entities required to execute business associate agreements for contracts and other agreements become HHS business associates.* Business associate agreements are issued by HHS or may be issued by other HHS programs in support of HHS. The HIPAA Privacy Rule requires HHS to execute compliant business associate agreements with persons or entities that create, receive, maintain, or transmit HHS PHI or that will store, generate, access, exchange, process, or utilize such PHI in order to perform certain activities, functions or services to, for, or on behalf of HHS. There may be other HHS components or staff offices which also provide certain services and support to HHS and must receive PHI in order to do so. If these components award contracts or enter into other agreements, purchase/delivery orders, modifications and issue governmentwide purchase card transactions to help in the delivery of these services to HHS, they will also fall within the requirement to obtain a satisfactory assurance from these contractors by executing a business associate agreements.

(ii) *Business associate agreement flow down to subcontractors.* A prime contractor required to execute a business associate agreement shall also obtain a satisfactory assurance, in the form of a business associate agreement, of its subcontractors who will also create, receive, maintain, or transmit PHI or that will store, generate, access, exchange, process, or utilize such PHI will comply with HIPAA Rules requirements to the same degree as the Contractor. A contractor employing a subcontractor who creates, receives, maintains, or transmits PHI or that will store, generate, access, exchange, process, or utilize such PHI under a contract or agreement is required to execute a business associate agreement with each of its subcontractors which also obligates the subcontractor (*i.e.*, also a business associate) to provide the same protections and safeguards and agree to the same disclosure restrictions to PHI that is required of the covered entity and the prime contractor.

(d) *Contractor operations required to be in United States*. Custom software development and outsourced operations must be located in the U.S. to the maximum extent practicable. If such services are proposed to be performed outside the continental United States, and are not otherwise disallowed by other Federal law, regulations or policy, or other HHS policy or other mandates as stated in the contract, specifications, statement of work or performance work statement (including applicable business associate agreements), the

Contractor/subcontractor must state in its proposal where all non-U.S. services are provided. At a minimum, the Contractor/subcontractor must include a detailed Information System Security Plan, for review and approval by the Contracting Officer, specifically to address mitigation of the resulting problems of communication, control, and data protection.

(e) *Roster of employees.* Contractors and subcontractors shall provide a roster containing the name, position, e-mail address, phone number, and responsibilities of each employee, including subcontractors, performing work under the contract to develop, have the ability to access, or host and/or maintain a government information system(s). The roster must be submitted to Contracting Officer within [_____] *[Contracting Officer to insert the number of days]* days stated number of days from the effective date of the contract. Revisions to the roster as a result of staffing changes must be submitted within the number of days of the change provided by the Contracting Officer. The Contracting Officer, or the Contracting Officer's Representative (COR), will notify the Contractor of the appropriate level of investigation required for each staff member based on the information provided on the roster. If an employee is filling a new position, the Contractor must provide a position description and the Government will determine the appropriate suitability level.

(f) *Contractor/subcontractor employee reassignment and termination notification*. Contractors and subcontractors shall provide written notification to the Contracting Officer and COR immediately, and not later than four (4) hours, when an employee working on an HHS information system or with access to HHS information is reassigned or leaves the Contractor or subcontractor's employment on the cognizant HHS contract. The Contracting Officer and COR must also be notified immediately by the Contractor or subcontractor prior to an unfriendly termination.

(g) *Non-disclosure agreement*. The Contractor and subcontractors shall submit completed non-disclosure agreements, as provided by the Contracting Officer, for each employee having access to non-public government information under this contract. The non-disclosure agreements shall be submitted to the Contracting Officer prior to the performance of work.

(h) *HHS information custodial requirements*. (1) *Release, publication, and use of data*. Information made available to a Contractor or subcontractor by HHS for the performance or administration of a contract or information developed by the Contractor/subcontractor in performance or administration of a contract shall be used only for the stated contract purpose and shall not be used in any other way without HHS prior written approval. This clause expressly limits the Contractor's/subcontractor's rights to use data as described in 52.227-14, Rights in Data—General, paragraph (d).

(2) *Media sanitization*. HHS information shall not be co-mingled with any other data on the Contractors/subcontractor's information systems or media storage systems in order to ensure federal and HHS requirements related to data protection, information segregation, classification requirements, and media sanitization can be met (see HHS Cybersecurity Program). HHS reserves the right to conduct scheduled or unscheduled on-site inspections, assessments, or audits of Contractor and subcontractor IT resources, information systems and assets to ensure data security and privacy controls, separation of data and job

duties, and destruction/media sanitization procedures are in compliance with Federal and HHS requirements. The Contractor and subcontractor will provide all necessary access and support to HHS and/or GAO staff during periodic control assessments or audits.

(3) *Data retention, destruction and contractor self-certification*. The Contactor and its subcontractors are responsible for collecting and destroying any HHS data provided, created, or stored under the terms of this contract, to a point where HHS data or materials are no longer readable or reconstructable to any degree, in accordance with NIST SP 800-88*, Guidelines for Media Sanitization*, or subsequent directive. Prior to termination or completion of this contract, the Contractor/subcontractor must provide its plan for destruction or return of all HHS data in its possession accordance with contract requirements or Contracting Officer instructions for disposition, including compliance with National Institute of Standards and Technology (NIST) SP 800-88, Guidelines for Media Sanitization, for the purposes of media sanitization on all IT equipment. The Contractor must certify in writing to the Contracting Officer within 30 days of termination of the contract that the data destruction requirements in this paragraph have been met.

(4) *Return of HHS data and information*. When information, data, documentary material, records and/or equipment is no longer required, it shall be returned to the HHS (as stipulated by the Contracting Officer or the COR) or the Contractor/subcontractor must hold it until otherwise directed. Items returned will be hand carried, securely mailed, emailed, or securely electronically transmitted to the Contracting Officer or to the address as provided in the contract or by the assigned COR, and/or accompanying business associate agreement. Depending on the method of return, Contractor/subcontractor must store, transport, or transmit HHS sensitive information, when permitted by the contract using HHS-approved encryption tools that are, at a minimum, validated under Federal Information Processing Standards (FIPS) 140-3 (or its successor). If mailed, Contractor/subcontractor must send via a trackable method (USPS, UPS, Federal Express, etc.) and immediately provide the Contracting Officer with the tracking information. No information, data, documentary material, records or equipment will be destroyed unless done in accordance with the terms of this contract and the HHS Agency Records Control Schedules (2019).

(5) *Use of HHS data and information*. The Contractor/subcontractor must receive, gather, store, back up, maintain, use, disclose and dispose of HHS information only in compliance with the terms of the contract and applicable Federal and HHS information confidentiality and security laws, regulations, and policies. If Federal or HHS information confidentiality and security laws, regulations, and policies become applicable to the HHS information or information systems after execution of the contract, or if the NIST issues or updates applicable FIPS or Special Publications (SP) after execution of this contract, the parties agree to negotiate in good faith to implement the information confidentiality and security laws, regulations and policies for this contract as a result of any updates, if required.

(6) *Copying HHS data or information*. The Contractor/subcontractor shall not make copies of HHS information except as authorized and necessary to perform the terms of the contract or to preserve electronic information stored on Contractor/subcontractor electronic storage media for restoration in case any electronic equipment or data used by the

Contractor/subcontractor needs to be restored to an operating state. If copies are made for restoration purposes, after the restoration is complete, the copies must be appropriately destroyed.

(7) *Violation of information custodial requirements*. If HHS determines that the Contractor has violated any of HHS information confidentiality, privacy, or security provisions, it shall be sufficient grounds for HHS to withhold payment to the Contractor or third-party or terminate the contract for default in accordance with FAR part 49 or terminate for cause in accordance with FAR 12.403.

(8) *Encryption*. The Contractor/subcontractor must store, transport, or transmit HHS sensitive information, when permitted by the contract, using cryptography, HHS encryption policies, and HHS-approved encryption tools that are, at a minimum, validated under FIPS 140-3 (or its successor).

(9) *Firewall and web services security controls*. The Contractor/subcontractor's firewall and Web services security controls, if applicable, shall meet or exceed HHS minimum requirements. HHS Configuration Standards Guidelines are available upon request.

(10) *Disclosure of HHS data and information*. Except for uses and disclosures of HHS information authorized in a cognizant contract for performance of the contract, the Contractor/subcontractor may use and disclose HHS information only in two other situations: (i) subject to paragraph 10 of this section, in response to a court order from a court of competent jurisdiction, or (ii) with HHS prior written approval. The Contractor/subcontractor must refer all requests for, demands for production of, or inquiries about, HHS information and information systems to the Contracting Officer for response. If the Contractor/subcontractor is in receipt of a court order or other request or believes it has a legal requirement to disclose HHS information, that Contractor/subcontractor shall immediately refer such court order or other request to the Contracting Officer for response. If the Contractor or subcontractor discloses information on behalf of HHS, the Contractor and/or subcontractor must maintain an accounting of disclosures. Accounting of Disclosures documentation maintained by the Contractor/subcontractor will include the name of the individual to whom the information pertains, the date of each disclosure, the nature or description of the information disclosed, a brief statement of the purpose of each disclosure or, in lieu of such statement, a copy of a written request for a disclosure, and the name and address of the person or agency to whom the disclosure was made. The Contractor/subcontractor will provide its Accounting of Disclosures upon request and within 15 calendar days to the assigned COR and Privacy Officer. Accounting of disclosures should be provided electronically via encrypted email to the COR and designated HHS facility Privacy Officer as provided in the contract, business associate agreement, or by the Contracting Officer. If providing the Accounting of disclosures electronically cannot be done securely, the Contractor/subcontractor will provide copies via trackable methods (UPS, USPS, Federal Express, etc.) immediately, providing the designated COR and Privacy Officer with the tracking information.

(11) *Compliance with privacy statutes and applicable regulations*. The Contractor/subcontractor shall not disclose HHS information protected by any of HHS privacy statutes or applicable regulations including, but not limited to, the Privacy Act of 1974 or the HIPAA Rules. If the Contractor/subcontractor is in receipt of a court order or other requests for HHS information or has questions if it can disclose information protected under the above-mentioned confidentiality statutes because it is required by law, that Contractor/subcontractor shall immediately refer such court order or other request to the Contracting Officer for response.

(i) *Compliance with identification policies*. Contractors shall comply with the Homeland Security Presidential Directive (HSPD)-12, Policy for a Common Identification Standard for Federal Employees and Contractors; OMB M-05-24; OMB M-19-17; FIPS 201, Personal Identity Verification (PIV) of Federal Employees and Contractors; HHS HSPD-12 policy; HHS Policy for Information Security and Privacy Protection (IS2P) Control Catalog, and Executive Order 13467, Part 1, section 1.2.

(j) *Report of known or suspected incident or breach*. The Contractor, subcontractor, third-party affiliate or business associate, and its employees shall notify HHS immediately via the Contracting Officer and the COR or within one (1) hour of a known or suspected incident or breach. The initial notification may first be made verbally but must be followed up in writing within one (1) hour. Report all actual or suspected incident and breach information to the Contracting Officer and the COR as identified in the contract or as directed in the contract, within one hour of discovery or suspicion.

(1) Such issues shall be remediated as quickly as is practical, but in no event longer than [____] days *[Fill in: Contracting Officer fills in the number of days]*. The Contractor shall notify the Contracting Officer in writing.

(2) When the security fixes involve installing third party patched (*e.g.*, Microsoft OS patches or Adobe Acrobat), the Contractor will provide written notice to HHS that the patch has been validated as not affecting the systems within 10 working days. When the Contractor is responsible for operations or maintenance of the systems, they shall apply the security fixes within [_____] *[Fill in: Contracting Officer fills in the number of days in consultation with requiring activity]*.

(3) All other vulnerabilities shall be remediated in a timely manner based on risk, in accordance with the timelines specified in the HHS Policy for Vulnerability Management, and the HHS Standard for Plan of Action and Milestones (POAM) Management and Reporting. Contractors shall notify the Contracting Officer, and COR within 2 business days after remediation of the identified vulnerability. Exceptions to this paragraph (e.g., for the convenience of HHS) must be requested by the Contractor through the COR and shall only be granted with approval of the Contracting Officer and the Office of the Chief Information Officer (OCIO). These exceptions will be tracked by the Contractor in concert with the Government in accordance with HHS Policy for IT Procurements–Security and Privacy Language.

(k) *Incident and breach investigation*. (1) The Contractor/ subcontractor shall immediately notify the Contracting Officer and COR for the contract of any known or suspected incident or breach (see definitions, paragraph (a)), or any other unauthorized disclosure of sensitive information, including that contained in system(s) to which the Contractor/subcontractor has access.

(2) To the extent known by the Contractor/subcontractor, the Contractor/ subcontractor's notice to HHS shall identify the information involved, an estimate of the number of potentially impacted individuals, the circumstances surrounding the incident (including to whom, how, when, and where the HHS information or assets were placed at risk or compromised), and any other information that the Contractor/subcontractor considers relevant.

(3) With respect to unsecured protected health information, the business associate is deemed to have discovered an incident as defined above when the business associate either knew, or by exercising reasonable diligence should have been known to an employee of the business associate. Upon discovery, the business associate must notify HHS of the incident immediately within one hour of discovery or suspicion as agreed to in the business associate agreement.

(4) In instances of theft or break-in or other criminal activity, the Contractor/subcontractor must concurrently report the incident to the appropriate law enforcement entity (or entities) of jurisdiction. The Contractor, its employees, and its subcontractors and their employees shall cooperate with HHS and any law enforcement authority responsible for the investigation and prosecution of any possible criminal law violation(s) associated with any incident. The Contractor/subcontractor shall cooperate with HHS in any civil litigation to recover HHS information, obtain monetary or other compensation from a third party for damages arising from any incident, or obtain injunctive relief against any third party arising from, or related to, the incident.

(l) *Incident and breach notification requirements*. (1) The Contractor/subcontractor shall provide notice to HHS of an incident as set forth in the incident and breach investigation section of this clause. The Contractor shall fully cooperate with HHS or third-party entity performing an independent risk analysis on behalf of HHS. Failure to cooperate may be deemed a material incident or breach and grounds for contract termination.

(2) The Contractor/subcontractor shall fully cooperate with the HHS Computer Security Incident Response Center (CSIRC), HHS Breach Response Team, Operating Divisions (OPDIVs), Staff Divisions (STAFFDIVs), other stakeholders or any Government agency conducting an analysis regarding any notice of an incident or breach, potential incident or breach, or incident which may require the Contractor to provide information to the Government or third-party performing a risk analysis for HHS, and shall address all relevant information concerning the incident or breach, including the following:

(i) Nature of the event (loss, theft, unauthorized access).

(ii) Description of the event, including:

(A) Date of occurrence.

(B) Date of incident or breach detection.

(C) Data elements involved, including any PII, such as full name, social security number, date of birth, home address, account number, disability code.

(D) Number of individuals affected or potentially affected.

(E) Names of individuals or groups affected or potentially affected.

(F) Ease of logical data access to the lost, stolen or improperly accessed data in light of the degree of protection for the data, e.g., unencrypted, plain text.

(G) Amount of time the data has been out of HHS control.

(H) The likelihood that the sensitive information will or has been compromised (made accessible to and usable by unauthorized persons).

(I) Known misuses of data containing sensitive information, if any.

(J) Assessment of the potential harm to the affected individuals.

(K) Incident or breach analysis as outlined in the HHS Breach Response Policy and Plan, as appropriate.

(L) Whether credit protection services may assist record subjects in avoiding or mitigating the results of identity theft based on the sensitive information that may have been compromised.

(M) Steps taken in response to mitigate or prevent a repetition of the incident.

(m) *Training*. (1) All Contractor employees and subcontractor employees requiring access to HHS information or HHS information systems shall complete the following before being granted access to HHS information and its systems:

(i) On an annual basis, successfully complete the HHS Privacy and Information Security Awareness and HHS Information Security Rules of Behavior training.

(ii) On an annual basis, sign and acknowledge (either manually or electronically) understanding of and responsibilities for compliance with the HHS Information Security Rules of Behavior, relating to access to HHS information and information systems.

(iii) Successfully complete any additional cyber security or privacy training, as required for HHS personnel with equivalent information system access.

(2) The Contractor shall provide to the Contracting Officer and/or the COR a copy of the training certificates and affirmation that HHS Information Security Rules of Behavior signed by each applicable employee have been completed and submitted within five (5) days of the initiation of the contract and annually thereafter, as required.

(3) Failure to complete the mandatory annual training and acknowledgement of the HHS Information Security Rules of Behavior, within the timeframe required, is grounds for suspension or termination of all physical or electronic access privileges and removal from work on the contract until such time as the training and documents are complete.

(n) *Subcontract flow down*. The Contractor shall include the substance of this clause, including this paragraph (k), in subcontracts, third-party agreements, and business associate agreements, of any amount and in which subcontractor employees, third-party servicers/employees, and business associates will perform functions where they will have access to HHS information (including HHS sensitive information), information systems, information technology (IT) or providing and accessing information technology-related contract services, support services, and related resources (see HHSAR 302.101 definition of information technology-related contracts.)

(End of clause).

SUPPLEMENT TO HHSAR 352.204-71 INFORMATION AND INFORMATION SYSTEMS SECURITY (FEB 2024) (DEVIATION).

CONFIDENTIALITY AND NONDISCLOSURE OF INFORMATION

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

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

i. 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records);
ii. 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information); and
iii. 44 U.S.C. Chapter 35, Subchapter I (Paperwork Reduction Act).

Each Contractor (and/or any subcontractor) employee who may have access to non-public information under this contract must sign the form, "Commitment to Protect Non-Public Information - Contractor Agreement" located at: https://ocio.nih.gov/sites/external/files/2024-01/Nondisclosure04082020.pdf. A copy of each signed and witnessed nondisclosure agreement shall be submitted to the Contracting Officer and/or COR prior to performing any work on the contract.

STANDARD FOR ENCRYPTION

The Contractor (and/or any subcontractor) must:

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

b. Encrypt all sensitive federal data and information (i.e., PII, protected health information [PHI], proprietary information, etc.) in transit (i.e., email, network connections, etc.) and at rest (i.e., servers, storage devices, mobile devices, backup media, etc.) with encryption solution that is validated with FIPS 140 (in accordance with HHSAR 352.204-71(h)(8)) validation certificate from the NIST CMVP.

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

d. Verify that the encryption solutions in use have been validated under the Cryptographic Module Validation Program to confirm compliance with current FIPS 140 (in accordance with HHSAR 352.204-71(h)(8)) validation certificate from the NIST CMVP. The Contractor must provide a written copy of the validation documentation to the COR **within 15 days** of the validation.

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

INCIDENT RESPONSE

a. The Contractor (and/or any subcontractor) must respond to all alerts/Indicators of Compromise (IOCs) provided by HHS Computer Security Incident Response Center (CSIRC)/NIH IRT teams (the NIH IRT is known as NIH Threat Mitigation and Incident Response (TMIR)) **within 24 hours,** whether the response is positive or negative. In accordance with FISMA and OMB M-17-12, *Preparing for and Responding to a Breach of Personally Identifiable Information (PII)*, an incident is "an occurrence that (1) actually or imminently jeopardizes, without lawful authority, the integrity, confidentiality, or availability of information or an information system; or (2) constitutes a violation or imminent threat of violation of law, security policies, security procedures, or acceptable use policies" and a privacy breach is "the loss of control, compromise, unauthorized disclosure, unauthorized acquisition, or any similar occurrence where (1) a person other than an authorized user accesses or potentially accesses personally identifiable information or (2) an authorized user accesses or potentially accesses personally

identifiable information for an other than authorized purpose." For additional information on the HHS breach response process, please see the *HHS Policy and Plan for Preparing for and Responding to a Breach of Personally Identifiable Information (PII)*."

Alert NIH CIO, CISO, TMIR and IC CIO, ISSO, System Owner, and incident response personnel when the following indications of compromise or potential compromise occur:

- Internal traffic that indicates the presence of malicious code within an information system or propagating among system components
- Attack signatures (a characteristic byte pattern used in malicious code or an indicator, or set of indicators, that allows the identification of malicious network activities)
- Signaling to an external information system
- Localized, targeted, and network-wide events

Note: The above list is a minimum set of compromises or potential compromises and may be expanded to include IC-specific items relevant to their missions.

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

i. Protect all sensitive information, including any PII created, stored, or transmitted in the performance of this contract, with encryption solution that is validated with current FIPS 140 (in accordance with HHSAR 352.204-71(h)(8)) validation certificate from the NIST CMVP.

ii. NOT notify affected individuals unless so instructed by the Contracting Officer or designated representative. If so instructed by the Contracting Officer or representative, the Contractor must send NIH approved notifications to affected individuals in accordance with https://wiki.ocio.nih.gov/wiki/index.php/US-CERT_Federal_Incident_Notification_Guidelines.

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

   - Cooperate and exchange any information, as determined by the Agency, necessary to effectively manage or mitigate a suspected or confirmed breach;
   - Not include any sensitive information in the subject or body of any reporting e-mail; and
   - Encrypt sensitive information in attachments to email, media, etc.

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

v. Provide full access and cooperate on all activities as determined by the Government to ensure an effective incident response, including providing all requested images, log files,

and event information to facilitate rapid resolution of sensitive information incidents. This may involve disconnecting the system processing, storing, or transmitting the sensitive information from the Internet or other networks or applying additional security controls. This may also involve physical access to contractor facilities during a breach/incident investigation within **one (1) hour** of discovery.

ROSTER

The roster must be submitted to Contracting Officer within fourteen (14) calendar days from the effective date of the contract. Any revisions to the roster as a result of staffing changes must be submitted within seven (7) calendar days of the change.

An electronic template, "Roster of Employees Requiring Suitability Investigations," is located at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Suitability%20Roster%202021%20Revised.xlsx. Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within thirty (30) days of the notification.

CONTRACT INITIATION AND EXPIRATION

a. **General Security Requirements.** The Contractor (and/or any subcontractor) must comply with information security and privacy requirements, Enterprise Performance Life Cycle (EPLC) processes, HHS Enterprise Architecture requirements to ensure information is appropriately protected from initiation to expiration of the contract. All information systems development or enhancement tasks supported by the Contractor must follow the HHS EPLC framework and methodology and in accordance with the HHS Contract Closeout Directive (2018) located at: https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/HHS-Closeout-Directive-2018.pdf.

b. **System Documentation.** Contractors (and/or any subcontractors) must follow and adhere to HHS System Development Life Cycle requirements, at a minimum, for system development and provide system documentation at designated intervals (specifically, at the expiration of the contract) within the EPLC that require artifact review and approval.

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

d. **Notification.** The Contractor (and/or any subcontractor) shall provide written notification to the Contracting Officer and COR immediately, and not later than four (4) hours, when an employee working on an HHS information system or with access to HHS information is reassigned or leaves the Contractor or subcontractor's employment on the cognizant HHS contract. The Contracting Officer and COR must also be notified immediately by the Contractor or subcontractor prior to an unfriendly termination.

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

f. The Contractor (and/or any subcontractor) must perform and document the actions identified in the NIH Contractor Employee Separation Checklist (https://ocio.nih.gov/sites/external/files/2024-01/Emp-sep-checklist.pdf) when an employee terminates work under this contract within two (2) days of the employee's exit from the contract. All documentation must be available to the CO and/or COR upon request.

(End of clause).

HOMELAND SECURITY PRESIDENTIAL DIRECTIVE (HSPD)-12

The Contractor (and/or any subcontractor) and its employees must comply with Homeland Security Presidential Directive (HSPD)-12, *Policy for a Common Identification Standard for Federal Employees and Contractors*; OMB M-05-24; OMB M-19-17; FIPS 201, *Personal Identity Verification (PIV) of Federal Employees and Contractors*; HHS HSPD-12 policy; and *Executive Order 13467, Part 1 §1.2*.

ARTICLE H.32. INFORMATION AND COMMUNICATION TECHNOLOGY ACCESSIBILITY NOTICE, HHSAR 352.239-78 (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.

(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).

ARTICLE H.33. INFORMATION AND COMMUNICATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-79 (FEB 2024) (DEVIATION).

(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 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).

ARTICLE H.35. STORAGE FACILITY REQUIREMENTS AND CERTIFICATION

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

The Contractor shall provide the Contracting Officer with the name(s) and location(s) of the commercial records storage facility used to store materials under this contract. In addition, the

Contractor shall provide a copy of the "Records Storage Certification Statement," found at: https://www.archives.gov/records-mgmt/storage-standards-toolkit/certification-statement.html self-certifying that the facility being used to store federal records meets established NARA standards. NARA Standards are available at: https://www.govinfo.gov/content/pkg/CFR-2013-title36-vol3/pdf/CFR-2013-title36-vol3-part1234.pdf . Ensuring compliance with the Federal Records Act of 1950; NARA regulations and/or guidance; OMB directives; and Government Accountability Office (GAO) audit requirements.

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

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

ARTICLE H.36. CONFIDENTIAL INFORMATION, HHSAR 352.224-71 (FEB 2024) (DEVIATION).

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

Confidential information means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.

(b) *Identification of information.* Specific confidential information or categories of information that the Government will furnish to the Contractor, or that the Contractor is expected to generate, is identified in this contract.

(c) *Disclosure.* The Contractor shall not disclose confidential information or records until written notice is provided to the Contracting Officer at least 45 days in advance of the Contractor's intent to release findings of studies or research, to which an agency response may be appropriate to protect the public interest or that of the agency. The Contractor shall not disseminate or publish such information without the written consent of the Contracting Officer.

(d) *Government furnished or provided information:* For information provided by or on behalf of the government—

(1) The publication or dissemination of the following types of information are restricted under this contract: [__TBD] *[Contracting Officer to insert restricted types of information, If none, so state.]*

(2) The reason(s) for restricting the types of information identified in subparagraph (d)(1) is/are: [_____] *[Contracting Officer to state why the public or Government interest requires the restriction of each type of information identified. Any basis for nondisclosure which would be valid under the Freedom of Information Act is sufficient under this clause.]*

(e) The Contractor shall consult with the Contracting Officer when there is uncertainty with regard to the confidentiality of, or a property interest in, information under this contract prior to the release, disclosure, dissemination, or publication of such information.

(End of clause).

ARTICLE H.37. RESPONSIBILITIES OF INSTITUTIONS REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: https://www.ecfr.gov/current/title-45/part-94.

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

a. Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this part, and make such policy available via a publicly accessible Web site. If the Institution does not have any current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request. If, however, the Institution acquires a presence on a publicly accessible Web site during the time of the NIH award, the requirement to post the information on that Web site will apply within 30 calendar days. If an Institution maintains a policy on financial conflicts of interest that includes standards that are more stringent than this part (e.g., that require a more extensive disclosure of financial interests), the Institution shall adhere to its policy and shall provide FCOI reports regarding identified financial conflicts of interest to the NIH Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by this part.

b. Inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any NIH-funded contract and at least every four years, and immediately when any of the following circumstances apply:

    1. The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;

    2. An Investigator is new to an Institution; or

    3. An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

c. If the Institution carries out the NIH-funded research through a subrecipient (e.g., subcontractors, or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this part by Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

    1. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this part. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;

    2. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the NIH as required by this part;

    3. Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this part.

    4. Providing FCOI reports to the NIH Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this part, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

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

e. Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than date of submission of the Institution's proposal for NIH-funded research

f. Require each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a NIH-funded project that was transferred from another Institution), and shall

include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

g. Require each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

h. Provide guidelines consistent with this part for the designated institutional official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to NIH-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: Could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the NIH-funded research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

i. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to § 94.5(a).

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

k. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest), and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date of final payment or, where applicable, for the time periods specified in 48 CFR part 4, subpart 4.7.

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

m. Certify, in each contract proposal to which this part applies, that the Institution:

    1. Has in effect at that Institution an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the NIH;

    2. Shall promote and enforce Investigator compliance with this part's requirements including those pertaining to disclosure of significant financial interests;

    3. Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the NIH Awarding Component consistent with this part;

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

5. Shall fully comply with the requirements of this part.

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

1. Management of financial conflicts of interest.

2. Prior to the Institution's expenditure of any funds under a NIH-funded research project, the designated official(s) of an Institution shall, consistent with § 94.4(f) : review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to NIH-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:

i. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);

ii. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;

iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, resulting from the financial conflict of interest;

iv. Modification of the research plan;

v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;

vi. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or

vii. Severance of relationships that create financial conflicts.

o. Whenever, in the course of an ongoing NIH-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the designated official(s) of the Institution shall, within sixty days: review the disclosure of the significant financial interest; determine whether it is related to NIH-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-

funded research project between the date of disclosure and the completion of the Institution's review.

p. Whenever an Institution identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to NIH-funded research; determine whether a financial conflict of interest exists; and, if so:

    1. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;

    2. (A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

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

            1. Project number;

            2. Project title;

            3. PD/PI or contact PD/PI if a multiple PD/PI model is used;

            4. Name of the Investigator with the FCOI;

            5. Name of the entity with which the Investigator has a financial conflict of interest;

            6. Reason(s) for the retrospective review;

            7. Detailed methodology used for the retrospective review (e.g., methodology of the review process, composition of the review panel, documents reviewed);

            8. Findings of the review; and

            9. Conclusions of the review.

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

r. Whenever an Institution implements a management plan pursuant to this part, the Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the NIH-funded research project.

s. Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:

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

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

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

t. The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: The Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

u. If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution's receipt or identification of

information concerning any additional significant financial interest of the senior/key personnel for the NIH-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the NIH-funded research project, if the Institution determines that the significant financial interest is related to the NIH-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

v. Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

w. In addition to the types of financial conflicts of interest as defined in this part that must be managed pursuant to this section, an Institution may require the management of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

2. Reporting of financial conflicts of interest.

a. Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution shall provide to the NIH Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this part. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of NIH-awarded funds, the Institution shall not submit an FCOI report to the NIH Awarding Component.

b. For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing NIH-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the NIH Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this part. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also is required to complete a retrospective review to determine whether any NIH-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is

found, the Institution is required to notify the NIH Awarding Component promptly and submit a mitigation report to the NIH Awarding Component.

c. Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section shall include sufficient information to enable the NIH Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:
    i. Project/Contract number;
    ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
    iii. Name of the Investigator with the financial conflict of interest;
    iv. Name of the entity with which the Investigator has a financial conflict of interest;
    v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
    vi. Value of the financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
    vii. A description of how the financial interest relates to the NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
    viii. A description of the key elements of the Institution's management plan, including:
        A. Role and principal duties of the conflicted Investigator in the research project;
        B. Conditions of the management plan;
        C. How the management plan is designed to safeguard objectivity in the research project;
        D. Confirmation of the Investigator's agreement to the management plan;
        E. How the management plan will be monitored to ensure Investigator compliance; and
        F. Other information as needed.

d. For any financial conflict of interest previously reported by the Institution with regard to an ongoing NIH-funded research project, the Institution shall provide to the NIH Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the NIH-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Institution shall provide annual FCOI reports to the NIH Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the NIH Awarding Component.

e. In addition to the types of financial conflicts of interest as defined in this part that must be reported pursuant to this section, an Institution may require the reporting of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

ARTICLE H. 38. 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 Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. "**To be specified at time of award**."

ARTICLE H.39. ADVANCED COPIES OF PRESS RELEASES

f. **Advanced Copies of Press Releases**

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the Contracting Officer Representative (COR) has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

ARTICLE H.40. TASK ORDER/DELIVERY ORDER CONTRACT OMBUDSMAN

In accordance with RFO 16.507-2(b) , the following individual has been designated as the NIH Ombudsman for task order and delivery order contracts.

The appropriate individual will be included in the resultant contract as follows:

For R&D Contracts:
Dr. Anna Taylor
NIH Advocate for Competition
1 Center Drive, Room 150
Bethesda, MD 20892-0140
Email: Anna.Taylor@nih.gov

ARTICLE H.41. 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.42. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

ARTICLE H.43. SHARING RESEARCH DATA

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 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.44. 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.

ARTICLE H.45. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

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

ARTICLE H.46. CONSTITUTION DAY

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

ARTICLE H.47. 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.

ARTICLE H.48. RECORDS MANAGEMENT, HHSAR 352.204-72 (FEB 2024) (DEVIATION).

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

(b) Definition. As used in this clause—

Federal record means all recorded information, regardless of form or characteristics, made or received by a Federal agency under Federal law or in connection with the transaction of public business and preserved or appropriate for preservation by that agency or its legitimate successor as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of the United States Government or because of the informational value of data in them. See 44 U.S.C. 3301.
(1) The term Federal record—
(i) Includes HHS records;
(ii) Does not include personal materials;
(iii) Applies to records created, received, or maintained by Contractors pursuant to their contract; and
(iv) May include deliverables and documentation associated with deliverables.

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

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

(c) Requirements.

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

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

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

records and associated metadata must be accompanied by sufficient technical documentation to permit understanding and use of the records and data.

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

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

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

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

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

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

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

(End of clause).

ARTICLE H.49. RESPONSIBILITIES OF INSTITUTIONS REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: https://www.ecfr.gov/current/title-45/part-94.

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

a. Maintain an up-to-date, written, enforced policy on financial conflicts of interest that complies with this part, and make such policy available via a publicly accessible Web site. If the Institution does not have any current presence on a publicly accessible Web site (and only in those cases), the Institution shall make its written policy available to any requestor within five business days of a request. If, however, the Institution acquires a presence on a publicly accessible Web site during the time of the NIH award, the requirement to post the information on that Web site will apply within 30 calendar days. If an Institution maintains a policy on financial conflicts of interest that includes standards that are more stringent than this part (e.g., that require a more extensive disclosure of financial interests), the Institution shall adhere to its policy and shall provide FCOI reports regarding identified financial conflicts of interest to the NIH Awarding Component in accordance with the Institution's own standards and within the timeframe prescribed by this part.

b. Inform each Investigator of the Institution's policy on financial conflicts of interest, the Investigator's responsibilities regarding disclosure of significant financial interests, and of these regulations, and require each Investigator to complete training regarding the same prior to engaging in research related to any NIH-funded contract and at least every four years, and immediately when any of the following circumstances apply:

1. The Institution revises its financial conflict of interest policies or procedures in any manner that affects the requirements of Investigators;
2. An Investigator is new to an Institution; or
3. An Institution finds that an Investigator is not in compliance with the Institution's financial conflict of interest policy or management plan.

c. If the Institution carries out the NIH-funded research through a subrecipient (e.g., subcontractors, or consortium members), the Institution (awardee Institution) must take reasonable steps to ensure that any subrecipient Investigator complies with this part by Incorporating as part of a written agreement with the subrecipient terms that establish whether the financial conflicts of interest policy of the awardee Institution or that of the subrecipient will apply to the subrecipient's Investigators.

1. If the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the subrecipient shall certify as part of the agreement referenced above that its policy complies with this part. If the subrecipient cannot provide such certification, the agreement shall state that subrecipient Investigators are subject to the financial conflicts of interest policy of the awardee

Institution for disclosing significant financial interests that are directly related to the subrecipient's work for the awardee Institution;

2. Additionally, if the subrecipient's Investigators must comply with the subrecipient's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to report all identified financial conflicts of interest to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to provide timely FCOI reports, as necessary, to the NIH as required by this part;

3. Alternatively, if the subrecipient's Investigators must comply with the awardee Institution's financial conflicts of interest policy, the agreement referenced above shall specify time period(s) for the subrecipient to submit all Investigator disclosures of significant financial interests to the awardee Institution. Such time period(s) shall be sufficient to enable the awardee Institution to comply timely with its review, management, and reporting obligations under this part.

4. Providing FCOI reports to the NIH Awarding Component regarding all financial conflicts of interest of all subrecipient Investigators consistent with this part, i.e., prior to the expenditure of funds and within 60 days of any subsequently identified FCOI.

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

e. Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interests (and those of the Investigator's spouse and dependent children) no later than date of submission of the Institution's proposal for NIH-funded research

f. Require each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution, during the period of the award. Such disclosure shall include any information that was not disclosed initially to the Institution pursuant to paragraph (e)(1) of this section, or in a subsequent disclosure of significant financial interests (e.g., any financial conflict of interest identified on a NIH-funded project that was transferred from another Institution), and shall include updated information regarding any previously disclosed significant financial interest (e.g., the updated value of a previously disclosed equity interest).

g. Require each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests within thirty days of discovering or acquiring (e.g., through purchase, marriage, or inheritance) a new significant financial interest.

h. Provide guidelines consistent with this part for the designated institutional official(s) to determine whether an Investigator's significant financial interest is related to NIH-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to NIH-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: Could be affected by the NIH-funded research; or is in an entity whose financial interest could be affected by the research. The Institution may involve the Investigator in the designated official(s)'s determination of whether a significant financial interest is related to the NIH-funded research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.

i. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subrecipient Investigator pursuant to paragraph (c) of this section. Management of an

identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to § 94.5(a).
j. Provide initial and ongoing FCOI reports to the NIH as required pursuant to § 94.5(b) .
k. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures (whether or not a disclosure resulted in the Institution's determination of a financial conflict of interest), and all actions under the Institution's policy or retrospective review, if applicable, for at least three years from the date of final payment or, where applicable, for the time periods specified in 48 CFR part 4, subpart 4.7.
l. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
m. Certify, in each contract proposal to which this part applies, that the Institution:
1. Has in effect at that Institution an up-to-date, written, and enforced administrative process to identify and manage financial conflicts of interest with respect to all research projects for which funding is sought or received from the NIH;
2. Shall promote and enforce Investigator compliance with this part's requirements including those pertaining to disclosure of significant financial interests;
3. Shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to the NIH Awarding Component consistent with this part;
4. Agrees to make information available, promptly upon request, to the HHS relating to any Investigator disclosure of financial interests and the Institution's review of, and response to, such disclosure, whether or not the disclosure resulted in the Institution's determination of a financial conflict of interest; and
5. Shall fully comply with the requirements of this part.
n. As required by 45 CFR Part 94.5, Management and reporting of financial conflicts of interest:
1. Management of financial conflicts of interest.
2. Prior to the Institution's expenditure of any funds under a NIH-funded research project, the designated official(s) of an Institution shall, consistent with § 94.4(f) : review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to NIH-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
i. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
ii. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, resulting from the financial conflict of interest;
iv. Modification of the research plan;
v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
vi. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
vii. Severance of relationships that create financial conflicts.
o. Whenever, in the course of an ongoing NIH-funded research project, an Investigator who is new to participating in the research project discloses a significant financial interest or an existing Investigator discloses a new significant financial interest to the Institution, the designated official(s) of the Institution shall, within sixty days: review the disclosure of the significant financial interest; determine

whether it is related to NIH-funded research; determine whether a financial conflict of interest exists; and, if so, implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest. Depending on the nature of the significant financial interest, an Institution may determine that additional interim measures are necessary with regard to the Investigator's participation in the NIH-funded research project between the date of disclosure and the completion of the Institution's review.

p. Whenever an Institution identifies a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed by the Institution during an ongoing NIH-funded research project (e.g., was not timely reviewed or reported by a subrecipient), the designated official(s) shall, within sixty days: review the significant financial interest; determine whether it is related to NIH-funded research; determine whether a financial conflict of interest exists; and, if so:

1. Implement, on at least an interim basis, a management plan that shall specify the actions that have been, and will be, taken to manage such financial conflict of interest going forward;
2. (A) In addition, whenever a financial conflict of interest is not identified or managed in a timely manner including failure by the Investigator to disclose a significant financial interest that is determined by the Institution to constitute a financial conflict of interest; failure by the Institution to review or manage such a financial conflict of interest; or failure by the Investigator to comply with a financial conflict of interest management plan, the Institution shall, within 120 days of the Institution's determination of noncompliance, complete a retrospective review of the Investigator's activities and the NIH-funded research project to determine whether any NIH-funded research, or portion thereof, conducted during the time period of the noncompliance, was biased in the design, conduct, or reporting of such research.

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

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

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

regard to the Investigator's participation in the NIH-funded research project between the date that the financial conflict of interest or the Investigator's noncompliance is determined and the completion of the Institution's retrospective review.

r. Whenever an Institution implements a management plan pursuant to this part, the Institution shall monitor Investigator compliance with the management plan on an ongoing basis until the completion of the NIH-funded research project.

s. Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution shall ensure public accessibility, via a publicly accessible Web site or written response to any requestor within five business days of a request, of information concerning any significant financial interest disclosed to the Institution that meets the following three criteria:

1. The significant financial interest was disclosed and is still held by key personnel as defined in this part;
2. The Institution determines that the significant financial interest is related to the NIH-funded research; and
3. The Institution determines that the significant financial interest is a financial conflict of interest.

t. The information that the Institution makes available via a publicly accessible Web site or written response to any requestor within five business days of a request, shall include, at a minimum, the following: The Investigator's name; the Investigator's title and role with respect to the research project; the name of the entity in which the significant financial interest is held; the nature of the significant financial interest; and the approximate dollar value of the significant financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value.

u. If the Institution uses a publicly accessible Web site for the purposes of this subsection, the information that the Institution posts shall be updated at least annually. In addition, the Institution shall update the Web site within sixty days of the Institution's receipt or identification of information concerning any additional significant financial interest of the senior/key personnel for the NIH-funded research project that was not previously disclosed, or upon the disclosure of a significant financial interest of senior/key personnel new to the NIH-funded research project, if the Institution determines that the significant financial interest is related to the NIH-funded research and is a financial conflict of interest. The Web site shall note that the information provided is current as of the date listed and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest. If the Institution responds to written requests for the purposes of this subsection, the Institution will note in its written response that the information provided is current as of the date of the correspondence and is subject to updates, on at least an annual basis and within 60 days of the Institution's identification of a new financial conflict of interest, which should be requested subsequently by the requestor.

v. Information concerning the significant financial interests of an individual subject to paragraph (a)(5) of this section shall remain available, for responses to written requests or for posting via the Institution's publicly accessible Web site for at least three years from the date that the information was most recently updated.

w. In addition to the types of financial conflicts of interest as defined in this part that must be managed pursuant to this section, an Institution may require the management of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

2. Reporting of financial conflicts of interest.

a. Prior to the Institution's expenditure of any funds under a NIH-funded research project, the Institution shall provide to the NIH Awarding Component an FCOI report regarding any Investigator's significant financial interest found by the Institution to be conflicting and ensure that the Institution has implemented a management plan in accordance with this part. In cases in which the Institution identifies a financial conflict of interest and eliminates it prior to the expenditure of NIH-awarded funds, the Institution shall not submit an FCOI report to the NIH Awarding Component.

b. For any significant financial interest that the Institution identifies as conflicting subsequent to the Institution's initial FCOI report during an ongoing NIH-funded research project (e.g., upon the participation of an Investigator who is new to the research project), the Institution shall provide to the NIH Awarding Component, within sixty days, an FCOI report regarding the financial conflict of interest and ensure that the Institution has implemented a management plan in accordance with this part. Pursuant to paragraph (a)(3)(ii) of this section, where such FCOI report involves a significant financial interest that was not disclosed timely by an Investigator or, for whatever reason, was not previously reviewed or managed by the Institution (e.g., was not timely reviewed or reported by a subrecipient), the Institution also is required to complete a retrospective review to determine whether any NIH-funded research, or portion thereof, conducted prior to the identification and management of the financial conflict of interest was biased in the design, conduct, or reporting of such research. Additionally, pursuant to paragraph (a)(3)(iii) of this section, if bias is found, the Institution is required to notify the NIH Awarding Component promptly and submit a mitigation report to the NIH Awarding Component.

c. Any FCOI report required under paragraphs (b)(1) or (b)(2) of this section shall include sufficient information to enable the NIH Awarding Component to understand the nature and extent of the financial conflict, and to assess the appropriateness of the Institution's management plan. Elements of the FCOI report shall include, but are not necessarily limited to the following:

i. Project/Contract number;
ii. PD/PI or Contact PD/PI if a multiple PD/PI model is used;
iii. Name of the Investigator with the financial conflict of interest;
iv. Name of the entity with which the Investigator has a financial conflict of interest;
v. Nature of the financial interest (e.g., equity, consulting fee, travel reimbursement, honorarium);
vi. Value of the financial interest (dollar ranges are permissible: $0-$4,999; $5,000-$9,999; $10,000-$19,999; amounts between $20,000-$100,000 by increments of $20,000; amounts above $100,000 by increments of $50,000), or a statement that the interest is one whose value cannot be readily determined through reference to public prices or other reasonable measures of fair market value;
vii. A description of how the financial interest relates to the NIH-funded research and the basis for the Institution's determination that the financial interest conflicts with such research; and
viii. A description of the key elements of the Institution's management plan, including:

A. Role and principal duties of the conflicted Investigator in the research project;
B. Conditions of the management plan;
C. How the management plan is designed to safeguard objectivity in the research project;
D. Confirmation of the Investigator's agreement to the management plan;
E. How the management plan will be monitored to ensure Investigator compliance; and
F. Other information as needed.

d. For any financial conflict of interest previously reported by the Institution with regard to an ongoing NIH-funded research project, the Institution shall provide to the NIH Awarding Component an annual FCOI report that addresses the status of the financial conflict of interest and any changes to the management plan for the duration of the NIH-funded research project. The annual FCOI report shall specify whether the financial conflict is still being managed or explain why the financial conflict of interest no longer exists. The Institution shall provide annual FCOI reports to the NIH Awarding Component for the duration of the project period (including extensions with or without funds) in the time and manner specified by the NIH Awarding Component.

e. In addition to the types of financial conflicts of interest as defined in this part that must be reported pursuant to this section, an Institution may require the reporting of other financial conflicts of interest in its policy on financial conflicts of interest, as the Institution deems appropriate.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

1. **RFO Clause 52.215-23, Limitations on Pass-Through Charges** (DEVIATION) (Nov 2025), is added.

2. **Alternate IV** (Oct 2010) of **RFO Clause 52.215-21, Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data--Modifications** (DEVIATION) (Nov 2025) is added.

3. **RFO Clauses 52.219-9, Small Business Subcontracting Plan** (DEVIATION) (Nov 2025), and **52.219-16, Liquidated Damages--Subcontracting Plan** (DEVIATION) (Nov 2025) are deleted in their entirety.

4. **Alternate II** (DEVIATION) (Nov 2025) of **RFO Clause 52.219-9, Small Business Subcontracting Plan** (DEVIATION) (Nov 2025) is added.

5. **Alternate I** (Feb 2002), of **RFO Clause 52.232-25, Prompt Payment** (Jan 2017).

6. **Alternate II,** (Sep 1996), of **RFO Clause 52.249-6, Termination (Cost-Reimbursement)** (May 2004) is added.

7. **RFO Clause 52.216-11, Cost Contract--No Fee** (Apr 1984) is deleted in its entirety and RFO Clause **52.216-8 Fixed Fee** (Jun 2011) is substituted therefor.

8. **RFO Clause 52.232-17, Interest** (DEVIATION) (Nov 2025) is added.

9. **RFO Clause 52.249-5, Termination for Convenience of the Government (Educational and Other Non-Profit Institutions)** (Aug 2016) is deleted in its entirety and **RFO Clause 52.249-6, Termination (Cost-Reimbursement)** (May 2004) is substituted therefor.

ARTICLE I.3. ADDITIONAL RFO 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:

REVOLUTIONARY FAR OVERHAUL CLAUSES

1. **RFO Clause 52.203-13, Contractor Code of Business Ethics and Conduct** (Nov 2021).

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

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

Poster(s)	Obtain From:
HHS Contractor Code of Ethics and Business Conduct Poster	https://core-docs.s3.amazonaws.com/documents/asset/uploaded_file/576385/OIG_Hotline_Poster__1_.pdf

3. **RFO Clause 52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts** (DEVIATION) (Nov 2025).

4. **RFO Clause 52.240-93, Basic Safeguarding of Covered Contractor Information Systems** (DEVIATION) (Nov 2025).

5. **RFO Clause 52.209-10, Prohibition on Contracting with Inverted Domestic Corporations** (DEVIATION) (Nov 2025).

6. **RFO Clause 52.210-1, Market Research** (DEVIATION) (July 2025).

7. **RFO Clause 52.217-7, Option for Increased Quantity - Separately Priced Line Item** (Mar 1989).

"....The Contracting Officer may exercise the option by written notice to the Contractor within 60 days_...."

a) **RFO Clause 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 60 days ; provided that the Government gives the Contractor

a preliminary written notice of its intent to extend at least ___60_____ days before the contract expires. The preliminary notice does not commit the Government to an extension.

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

c. The total duration of this contract, including the exercise of any options under this clause, shall not exceed 7 years.

(End of clause).

8. **RFO Clause 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (DEVIATION) (Nov 2025).

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

9. **RFO Clause 52.219-9, Small Business Subcontracting Plan** (DEVIATION) (RFO FEB 2026)
10.
11. **RFO Clause 52.219-28, Post-Award Small Business Program Rerepresentation** (DEVIATION) (Nov 2025).

12. **RFO Clause 52.224-1, Privacy Act Notification** (Apr 1984).

13. **RFO Clause 52.224-2, Privacy Act** (Apr 1984).

14. **Alternate IV** (Dec 2007), **RFO Clause 52.227-14, Rights in Data - General** (May 2014).

15. **RFO Clause 52.227-16, Additional Data Requirements** (Jun 1987).

16. **RFO Clause 52.230-2, Cost Accounting Standards** (DEVIATION) (Nov 2025).

17. **RFO Clause 52.230-6, Administration of Cost Accounting Standards** (DEVIATION) (Nov 2025).

18. **RFO Clause 52.237-3, Continuity of Services** (Jan 1991).

19. **RFO Clause 52.219-28, Post-Award Small Business Program Representation** (DEVIATION) (Nov 2025).

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

2. **HHSAR Clause 352.211-3, Paperwork Reduction Act** (Nov 2025)(RFO DEVIATION).

3. **HHSAR Clause 352.223-70, Safety and Health** (Dec 2015).

4. HHSAR Clause **352.231-70, Salary Rate Limitation** (Feb 2026)(RFO DEVIATION).

   (a) The Contractor shall[must] 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 pay an individual working under a Department of Health and Human Services [(HHS)] 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 website for Federal Executive Schedule (EX) salary levels at www.opm.gov.

   (f) The Contractor must insert the substance of this clause, including this paragraph (f), in all subcontracts.

(End of clause)

5. **HHSAR 352.232-71 Electronic Submission of Payment Requests (FEB 2026)(RFO DEVIATION).**

(a) Definitions. As used in this clause-

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

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

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

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

(End of clause).

6. **HHSAR Clause 352.208-70, Printing and Duplication** (Feb 2026)(RFO DEVIATION).

a. NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:
The following clauses are attached and made a part of this contract:

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

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

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

This contract incorporates the following clauses in full text.

RFO FAR Clause 52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Oct 2018) (Deviation NOV 2025)

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

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

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

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

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

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

(i) Past performance reviews required by subpart 42.15;

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

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

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

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

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

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

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

(End of clause)

RFO Clause 52.216-18, Ordering (Aug 2020).

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

(End of clause).

RFO Clause 52.216-19, Order Limitations (Oct 1995).

a. Minimum Order. When the Government requires supplies or services covered by this contract in an amount of less than $2,500, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.
b. Maximum Order. The Contractor is not obligated to honor--
   1. Any order for a single item in excess of $100 Million.
   2. Any order for a combination of items in excess of$100 million; or
   3. A series of orders from the same ordering office within 30 days that together call for quantities exceeding the limitation in subparagraph (1) or (2) above.

c. If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Revolutionary FAR Overhaul (RFO)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) above.
d. Notwithstanding paragraphs (b) and (c) above, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the

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

(End of clause).

RFO 52.209-9 Updates of Publicly Available Information Regarding Responsibility Matters. (NOV 2025)

C. RFO **52.222-90 Addressing DEI Discrimination by Federal Contractors.**

Addressing DEI Discrimination by Federal Contractors (April 2026)

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

Program participation means membership or participation in, or access or admission to: training, mentoring, or leadership development programs; educational opportunities; clubs; associations; or similar opportunities that are sponsored or established by the contractor or subcontractor.

Racially discriminatory diversity, equity, and inclusion (DEI) activities means disparate treatment based on race or ethnicity in the recruitment, employment (e.g., hiring, promotions), contracting (*e.g.*, vendor agreements), program participation, or allocation or deployment of an entity's resources.

(b) In connection with the performance of work under this contract, the Contractor agrees as follows:

(1) The Contractor will not engage in any racially discriminatory DEI activities;

(2) The Contractor will furnish all information and reports, including providing access to books, records, and accounts, as required by the Contracting Officer, for purposes of ascertaining compliance with this clause;

(3) In the event of the Contractor's or a subcontractor's noncompliance with this clause, this contract may be canceled, terminated, or suspended in whole or in part, and the Contractor or subcontractor may be declared ineligible for further Government contracts;

(4) The Contractor will report any subcontractor's known or reasonably knowable conduct that may violate this clause to the Contracting Officer and take any appropriate remedial actions directed by the Contracting Officer; and

(5) The Contractor will inform the Contracting Officer if a subcontractor sues the Contractor and the suit puts at issue, in any way, the validity of this clause.

(6) The Contractor recognizes that compliance with the requirements of this clause are material to the Government's payment decisions for purposes of 31 U.S.C. 3729(b)(4).

(c) The Contractor must include the substance of this clause, including this paragraph (c), in subcontracts at any tier, including those for commercial products and commercial services, except those where the place of delivery or performance is outside the United States.

(End of clause)

10. HHSAR 352.227-11, Patent Rights--Exceptional Circumstances (Sept 2014).

This clause applies to all Contractor and subcontractor (at all tiers) Subject Inventions.

(a) Definitions. As used in this clause-

Agency means the Agency of the U.S. Department of Health and Human Services that is entering into this contract.

Class 1 Subject Invention means a Subject Invention described and defined in the DEC that will be assigned to a third party assignee, or assigned as directed by the Agency.

Class 2 Subject Invention means a Subject Invention described and defined in the DEC.

Class 3 Subject Invention means a Subject Invention that does not fall into Class 1 or Class 2 as defined in this clause.

DEC means the Determination of Exceptional Circumstances signed by Francis Collins, M.D., Ph.D., on 3/22/2019 and titled "Director, National Institute of Health.

Invention means any invention or discovery, which is or may be patentable or otherwise protectable under Title 35 of United States Code, or any novel variety of plant that is or may be protectable under the Plant Variety Protection Act (7 U.S.C. 2321, et. seq.)

Made means: When used in relation to any invention other than a plant variety, the conception or first actual reduction to practice of such invention; or when used in relation to a plant variety, that the Contractor has at least tentatively determined that the variety has been reproduced with recognized characteristics.

Material means any proprietary material, method, product, composition, compound, or device, whether patented or unpatented, which is provided to the Contractor under this contract.

Nonprofit organization means a university or other institution of higher education or an organization of the type described in section 501(c)(3) of the Internal Revenue Code of 1954 (26 U.S.C. 501(c)) and exempt from taxation under section 501(a) of the Internal Revenue Code (26 U.S.C. 501(a)) or any nonprofit scientific or educational organization qualified under a state nonprofit organization statute.

Practical application means to manufacture, in the case of a composition or product; to practice, in the case of a process or method, or to operate, in the case of a machine or system; and, in each case, under such conditions as to establish that the invention is being utilized and that its benefits are, to the extent permitted by law or Government regulations, available to the public on reasonable terms.

Small business firm means a small business concern as defined at section 2 of Public Law 85-536 (15 U.S.C. 632) and implementing regulations of the Administrator of the Small Business Administration. For the purpose of this clause, the size standards for small business concerns involved in Government procurement and subcontracting at 13 CFR 121.3-8 and 13 CFR 121.3-12, respectively, will be used.

Subject Invention means any invention of the Contractor made in the performance of work under this contract.

Third party assignee means any entity or organization that may, as described in the DEC, be assigned Class 1 inventions.

(b) Allocation of principal rights. (1) Retention of pre-existing rights. Third party assignees shall retain all preexisting rights to Material in which the Third party assignee has a proprietary interest.

(2) Allocation of Subject Invention rights.

(i) Disposition of Class 1 Subject Inventions.

(A) Assignment to the Third party assignee or as directed by the Agency. The Contractor shall assign to the Third party assignee designated by the Agency the entire right, title, and interest throughout the world to each Subject Invention, or otherwise dispose of or transfer those rights as directed by the Agency, except to the extent that rights are retained by the Contractor under paragraph (b)(3) of this clause. Any such assignment or other disposition or transfer of rights will be subject to a nonexclusive, nontransferable, irrevocable, paid-up license to the U.S. Government to practice or have practiced the Subject Invention for or on behalf of the U.S. throughout the world. Any assignment shall additionally be subject to the "March-in rights" of 35 U.S.C. 203. If the Contractor is a U.S. nonprofit organization it may retain a royalty free, nonexclusive, nontransferable license to practice the invention for all nonprofit research including for educational purposes, and to permit other U.S. nonprofit organizations to do so.

(B) [Reserved]

(ii) Disposition of Class 2 and 3 Subject Inventions. Class 2 Subject Inventions shall be governed by FAR clause 52.227-11, Patent Rights-Ownership (December 2007) (incorporated herein by reference). However, the Contractor shall grant a license in the Class 2 Subject Inventions to the provider of the Material or other party designated by the Agency as set forth in Alternate I.

(iii) Class 3 Subject Inventions shall be governed by FAR clause 52.227-11, Patent Rights-Ownership by the Contractor (December 2007) (previously incorporated herein by reference).

(3) Greater Rights Determinations.

The Contractor, or an employee-inventor after consultation by the Agency with the Contractor, may request greater rights than are provided in paragraph (b)(1) of this clause in accordance with the procedures of FAR paragraph 27.304-1(c). In addition to the considerations set forth in paragraph 27.304-1(c), the Agency may consider whether granting the requested greater rights will interfere with rights of the Government or any Third party assignee or otherwise impede the ability of the Government or the Third party assignee to, for example, develop and commercialize new compounds, dosage forms, therapies, preventative measures, technologies, or other approaches with potential for the diagnosis, prognosis, prevention, and treatment of human diseases.

A request for a determination of whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the Agency Contracting Officer at the time of the first disclosure of the invention pursuant to paragraph (c)(1) of this clause, or not later than 8 months thereafter, unless a longer period is authorized in writing by the Contracting Officer for good cause shown in writing by the Contractor. Each determination of greater rights under this contract shall be subject to paragraph (c) of the FAR clause at 52.227-13 (incorporated herein by reference), and to any reservations and conditions deemed to be appropriate by the Agency such as the requirement to assign or exclusively license the rights to Subject Inventions to the Third party assignee.

A determination by the Agency denying a request by the Contractor for greater rights in a Subject Invention may be appealed within 30 days of the date the Contractor is notified of the determination to an Agency official at a level above the individual who made the determination. If greater rights are granted, the Contractor must file a patent application on the invention. Upon request, the Contractor shall provide the filing date, serial number and title, a copy of the patent application (including an English-language version if filed in a language other than English), and patent number and issue date for any Subject Invention in any country for which the Contractor has retained title. Upon request, the Contractor shall furnish the Government an irrevocable power to inspect and make copies of the patent application file.

(c) Invention disclosure by Contractor. The Contractor shall disclose in writing each Subject Invention to the Agency Contracting Officer and to the Director, Division of Extramural Inventions and Technology Resources (DEITR), if directed by the Contracting Officer, as provided in paragraph (j) of this clause within 2 months after the inventor discloses it in writing to Contractor personnel responsible for patent matters. The disclosure to the Agency Contracting Officer shall be in the form of a written report and shall identify the contract under which the invention was Made and all inventors. It shall be sufficiently complete in technical detail to convey a clear understanding to the

extent known at the time of the disclosure, of the nature, purpose, operation, and the physical, chemical, biological, or electrical characteristics of the invention. The disclosure shall also identify any publication, on sale (offer for sale), or public use of the invention and whether a manuscript describing the invention has been submitted for publication, and if so, whether it has been accepted for publication at the time of disclosure.

In addition, after disclosure to the Agency, the Contractor will promptly notify the Contracting Officer and DEITR of the acceptance of any manuscript describing the invention for publication or of any on sale or public use planned by the Contractor. If the Contractor assigns a Subject Invention to the Third party assignee, then the Contractor and its employee inventors shall assist the Third party assignee in securing patent protection. All costs of securing the patent, including the cost of the Contractor's assistance, are at the Third party's expense. Any assistance provided by the Contractor and its employee inventors to the Third party assignee or other costs incurred in securing patent protection shall be solely at the Third party's expense and not billable to the contract.

(d) Contractor action to protect the Third party assignee's and the Government's interest.

(1) The Contractor agrees to execute or to have executed and promptly deliver to the Agency all instruments necessary to: Establish or confirm the rights the Government has throughout the world in Subject Inventions pursuant to paragraph (b) of this clause; convey title to a Third party assignee in accordance with paragraph (b) of this clause; and enable the Third party assignee to obtain patent protection throughout the world in that Subject Invention.

(2) The Contractor agrees to require, by written agreement, its employees, other than clerical and nontechnical employees, to disclose promptly in writing to personnel identified as responsible for the administration of patent matters and in a format suggested by the Contractor, each Subject Invention "Made" under contract in order that the Contractor can comply with the disclosure provisions of paragraph (c) of this clause, and to execute all papers necessary to file patent applications on Subject Inventions and to establish the Government's rights or a Third party assignee's rights in the Subject Inventions. This disclosure format should require, as a minimum, the information required by subparagraph (c)(1) of this clause. The Contractor shall instruct such employees, through employee agreements or other suitable educational programs, on the importance of reporting inventions in sufficient time to permit the filing of patent applications prior to U.S. or foreign statutory bars.

(3) If the Contractor is granted greater rights, the Contractor agrees to include, within the specification of any United States non-provisional patent application it files, and any patent issuing thereon, covering a Subject Invention the following statement: "This invention was made with Government support under (identify the Contract) awarded by (identify the specific Agency). The Government has certain rights in the invention."

(4) The Contractor agrees to provide a final invention statement and certification prior to the closeout of the contract listing all Subject Inventions or stating that there were none.

(e) Subcontracts.

(1) The Contractor will include this clause in all subcontracts, regardless of tier, for experimental, developmental, or research work. At all tiers, the clause must be modified to identify the parties as follows: References to the Government are not changed, and the subcontractor has all rights and obligations of the Contractor in the clause. The Contractor will not, as part of the consideration for awarding the contract, obtain rights in the subcontractor's Subject Inventions.

(2) In subcontracts, at any tier, the Agency, the subcontractor, and the Contractor agree that the mutual obligations of the parties created by this clause constitute a contract between the subcontractor and the Agency with respect to the matters covered by the clause; provided, however, that nothing in this paragraph is intended to confer any jurisdiction under the Contract Disputes Act in connection with proceedings under paragraph (c)(1)(ii) of FAR clause 52.227-13.

(f) Reporting on utilization of Subject Inventions in the event greater rights are granted to the Contractor.

The Contractor agrees to submit, on request, periodic reports no more frequently than annually on the utilization of a Subject Invention or on efforts at obtaining such utilization that are being made by the Contractor or its licensees or assignees when a request under subparagraph b.3. has been granted by the Agency. Such reports shall include information regarding the status of development, date of first commercial sale or use, gross royalties received by the Contractor, and such other data and information as the Agency may reasonably specify. The Contractor also agrees to provide additional reports as may be requested by the Agency in connection with any march-in proceeding undertaken by the Agency in accordance with paragraph (h) of this clause. As required by 35 U.S.C. 202(c)(5), the Agency agrees it will not disclose such information to persons outside the Government without permission of the Contractor.

(g) Preference for United States industry in the event greater rights are granted to the Contractor.

Notwithstanding any other provision of this clause, the Contractor agrees that neither it nor any assignee will grant to any person the exclusive right to use or sell any Subject Invention in the United States unless such person agrees that any product embodying the Subject Invention or produced through the use of the Subject Invention will be manufactured substantially in the United States. However, in individual cases, the requirement for such an agreement may be waived by the Agency upon a showing by the Contractor or its assignee that reasonable but unsuccessful efforts have been made to grant licenses on similar terms to potential licensees that would be likely to manufacture substantially in the United States or that under the circumstances domestic manufacture is not commercially feasible.

(h) March-in rights in the event greater rights are granted to the Contractor.

The Contractor acknowledges that, with respect to any Subject Invention in which it has acquired ownership through the exercise of the rights specified in paragraph (b)(3) of this clause, the Agency has the right to require licensing pursuant to 35 U.S.C. 203 and 210(c), and in accordance with the procedures in 37 CFR 401.6 and any supplemental regulations of Agency in effect on the date of contract award.

(i) Special provisions for contracts with nonprofit organizations in the event greater rights are granted to the Contractor. If the Contractor is a nonprofit organization, it shall:

(1) Not assign rights to a Subject Invention in the United States without the written approval of the Agency, except where an assignment is made to an organization that has as one of its primary functions the management of inventions, provided that the assignee shall be subject to the same provisions as the Contractor;

(2) Share royalties collected on a Subject Invention with the inventor, including Federal employee co-inventors (but through their Agency if the Agency deems it appropriate) when the Subject Invention is assigned in accordance with 35 U.S.C. 202(e) and 37 CFR 401.10;

(3) Use the balance of any royalties or income earned by the Contractor with respect to Subject Inventions, after payment of expenses (including payments to inventors) incidental to the administration of Subject Inventions for the support of scientific research or education;

(4) Make efforts that are reasonable under the circumstances to attract licensees of Subject Inventions that are small business concerns, and give a preference to a small business concern when licensing a Subject Invention if the Contractor determines that the small business concern has a plan or proposal for marketing the invention which, if executed, is equally as likely to bring the invention to practical application as any plans or proposals from applicants that are not small business concerns; provided, that the Contractor is also satisfied that the small business concern has the capability and resources to carry out its plan or proposal. The decision whether to give a preference in any specific case will be at the discretion of the Contractor; and

(5) Allow the Secretary of Commerce to review the Contractor's licensing program and decisions regarding small business applicants, and negotiate changes to its licensing policies, procedures, or practices with the Secretary of Commerce when the Secretary's review discloses that the Contractor could take reasonable steps to more effectively implement the requirements of paragraph (i)(4) of this clause.

(j) Communications.

All invention disclosures and requests for greater rights shall be sent to the Agency Contracting Officer, as directed by the Contracting Officer. Additionally, a copy of all disclosures, confirmatory licenses to the Government, face page of the patent applications, waivers and other routine communications under this funding agreement at all tiers must be sent to:

[Insert Agency Address]

Agency Invention Reporting Web site: http://www.iEdison.gov.

Alternate I (Sept 2014). As prescribed in 327.303, the license to Class 2 inventions recited in 352.227-11(b)(2)(a) is as follows:

[Insert description of license to Class 2 inventions]

(End of clause).

11. **HHSAR 352.227-14 Rights in Data-Exceptional Circumstances** (Sept 2014).

(a) *Definitions.* As used in this clause-[Definitions may be added or modified in paragraph (a) as applicable.]

Computer database or *database* means a collection of recorded information in a form capable of, and for the purpose of, being stored in, processed, and operated on by a computer. The term does not include computer software.

Computer software -(i) Means (A) Computer programs that comprise a series of instructions, rules, routines, or statements, regardless of the media in which recorded, that allow or cause a computer to perform a specific operation or series of operations; and

(B) Recorded information comprising source code listings, design details, algorithms, processes, flow charts, formulas, and related material that would enable the computer program to be produced, created, or compiled.

(ii) Does not include computer databases or computer software documentation.

Computer software documentation means owner's manuals, user's manuals, installation instructions, operating instructions, and other similar items, regardless of storage medium, that explain the capabilities of the computer software or provide instructions for using the software.

Data means recorded information, regardless of form or the media on which it may be recorded. The term includes technical data and computer software. The term does not include information incidental to contract administration, such as financial, administrative, cost or pricing, or management information.

Form, fit, and function data means data relating to items, components, or processes that are sufficient to enable physical and functional interchangeability, and data identifying source, size, configuration, mating and attachment characteristics, functional characteristics, and performance requirements. For computer software it means data identifying source, functional characteristics, and performance requirements but specifically excludes the source code, algorithms, processes, formulas, and flow charts of the software.

Limited rights means the rights of the Government in limited rights data as set forth in the Limited Rights Notice in Alternate II paragraph (g)(3) if included in this clause. "Limited rights data" means data, other than computer software, that embody trade secrets or are commercial or financial and confidential or privileged, to the extent that such data pertain to items, components, or processes developed at private expense, including minor modifications.

Restricted computer software means computer software developed at private expense and that is a trade secret, is commercial or financial and confidential or privileged, or is copyrighted computer software, including minor modifications of the computer software.

Restricted rights, as used in this clause, means the rights of the Government in restricted computer software, as set forth in a Restricted Rights Notice of Alternate III paragraph (g)(4) if included in this clause, or as otherwise may be provided in a collateral agreement incorporated in and made part of this contract, including minor modifications of such computer software.

Technical data means recorded information (regardless of the form or method of the recording) of a scientific or technical nature (including computer databases and computer software documentation). This term does not include computer software or financial, administrative, cost or pricing, or management data or other information incidental to contract administration. The term includes recorded information of a scientific or technical nature that is included in computer databases (See 41 U.S.C. 403(8)).

Unlimited rights means the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so.

(b) *Allocation of rights.*

(1) Except as provided in paragraph (c) of this clause, the Government shall have unlimited rights in-

(i) Data first produced in the performance of this contract;

(ii) Form, fit, and function data delivered under this contract;

(iii) Data delivered under this contract (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items,

components, or processes delivered or furnished for use under this contract; and

(iv) All other data delivered under this contract unless provided otherwise for limited rights data or restricted computer software in accordance with paragraph (g) of this clause.

(2) The Contractor shall have the right to-

(i) Assert copyright in data first produced in the performance of this contract to the extent provided in paragraph (c)(1) of this clause;

(ii) Use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, unless provided otherwise in paragraph (d) of this clause;

(iii) Substantiate the use of, add, or correct limited rights, restricted rights, or copyright notices and to take other appropriate action, in accordance with paragraphs (e) and (f) of this clause; and

(iv) Protect from unauthorized disclosure and use those data that are limited rights data or restricted computer software to the extent provided in paragraph (g) of this clause.

(c) *Copyright.*

(1) *Data first produced in the performance of this contract.*

(i) Unless provided otherwise in paragraph (d) of this clause, the Contractor may, without prior approval of the Contracting Officer, assert copyright in scientific and technical articles based on or containing data first produced in the performance of this contract and published in academic, technical or professional journals, symposia proceedings, or similar works. The prior, express written permission of the Contracting Officer is required to assert copyright in all other data first produced in the performance of this contract.

(ii) When authorized to assert copyright to the data, the Contractor shall affix the applicable copyright notices of 17 U.S.C. 401 or 402, and an acknowledgment of Government sponsorship (including contract number).

(iii) For data other than computer software, the Contractor grants to the Government and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly by or on behalf of the Government. For

computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license in such copyrighted computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public) by or on behalf of the Government.

(2) Data not first produced in the performance of this contract. The Contractor shall not, without the prior written permission of the Contracting Officer, incorporate in data delivered under this contract any data not first produced in the performance of this contract unless the Contractor-

(i) Identifies the data; and

(ii) Grants to the Government, or acquires on its behalf, a license of the same scope as set forth in paragraph (c)(1) of this clause or, if such data are restricted computer software, the Government shall acquire a copyright license as set forth in paragraph (g)(4) of this clause (if included in this contract) or as otherwise provided in a collateral agreement incorporated in or made part of this contract.

(3) *Removal of copyright notices.* The Government will not remove any authorized copyright notices placed on data pursuant to this paragraph (c), and will include such notices on all reproductions of the data.

(d) Release, publication, and use of data. The Contractor shall have the right to use, release to others, reproduce, distribute, or publish any data first produced or specifically used by the Contractor in the performance of this contract, except-

(1) As prohibited by Federal law or regulation (*e.g.,* export control or national security laws or regulations);

(2) As expressly set forth in this contract; or

(3) If the Contractor receives or is given access to data necessary for the performance of this contract that contain restrictive markings, the Contractor shall treat the data in accordance with such markings unless specifically authorized otherwise in writing by the Contracting Officer or in the following paragraphs.

(4) In addition to any other provisions, set forth in this contract, the Contractor shall ensure that information concerning possible inventions made under this contract is not prematurely published thereby adversely affecting the ability to obtain patent protection on such inventions. Accordingly, the Contractor will provide the Contracting Officer a copy of any

publication or other public disclosure relating to the work performed under this contract at least 30 days in advance of the disclosure. Upon the Contracting Officer's request the Contractor agrees to delay the public disclosure of such data or publication of a specified paper for a reasonable time specified by the Contracting Officer, not to exceed 6 months, to allow for the filing of domestic and international patent applications in accordance with Clause 352.227-11, Patent Rights-Exceptional Circumstances (abbreviated month and year of Final Rule publication).

(5) *Data on Material(s).* The Contractor agrees that in accordance with paragraph (d)(2), proprietary data on Material(s) provided to the Contractor under or through this contract shall be used only for the purpose for which they were provided, including screening, evaluation or optimization and for no other purpose.

(6) *Confidentiality.*

(i) The Contractor shall take all reasonable precautions to maintain Confidential Information as confidential, but no less than the steps Contractor takes to secure its own confidential information.

(ii) Contractor shall maintain Confidential Information as confidential unless specifically authorized otherwise in writing by the Contracting Officer. Confidential Information includes/does not include [Government may define confidential information here.]

(e) *Unauthorized marking of data.*

(1) Notwithstanding any other provisions of this contract concerning inspection or acceptance, if any data delivered under this contract are marked with the notices specified in paragraph (g)(3) or (4) of this clause (if those alternate paragraphs are included in this clause), and use of the notices is not authorized by this clause, or if the data bears any other restrictive or limiting markings not authorized by this contract, the Contracting Officer may cancel or ignore the markings. However, pursuant to 41 U.S.C. 253 d, the following procedures shall apply prior to canceling or ignoring the markings.

(i) The Contracting Officer will make written inquiry to the Contractor affording the Contractor 60 days from receipt of the inquiry to provide written justification to substantiate the propriety of the markings;

(ii) If the Contractor fails to respond or fails to provide written justification to substantiate the propriety of the markings within the 60-day period (or a longer time approved in writing by the Contracting Officer for good cause shown), the Government shall have the right to cancel or ignore the markings

at any time after said period and the data will no longer be made subject to any disclosure prohibitions.

(iii) If the Contractor provides written justification to substantiate the propriety of the markings within the period set in paragraph (e)(1)(i) of this clause, the Contracting Officer will consider such written justification and determine whether or not the markings are to be cancelled or ignored. If the Contracting Officer determines that the markings are authorized, the Contractor will be so notified in writing. If the Contracting Officer determines, with concurrence of the head of the contracting activity, that the markings are not authorized, the Contracting Officer will furnish the Contractor a written determination, which determination will become the final Agency decision regarding the appropriateness of the markings unless the Contractor files suit in a court of competent jurisdiction within 90 days of receipt of the Contracting Officer's decision. The Government will continue to abide by the markings under this paragraph(e)(1)(iii) until final resolution of the matter either by the Contracting Officer's determination becoming final (in which instance the Government will thereafter have the right to cancel or ignore the markings at any time and the data will no longer be made subject to any disclosure prohibitions), or by final disposition of the matter by court decision if suit is filed.

(2) The time limits in the procedures set forth in paragraph (e)(1) of this clause may be modified in accordance with Agency regulations implementing the Freedom of Information Act (5 U.S.C. 552) if necessary to respond to a request there under.

(3) Except to the extent the Government's action occurs as the result of final disposition of the matter by a court of competent jurisdiction, the Contractor is not precluded by this paragraph (e) from bringing a claim, in accordance with the Disputes clause of this contract, that may arise as the result of the Government removing or ignoring authorized markings on data delivered under this contract.

(f) *Omitted or incorrect markings.*

(1) Data delivered to the Government without any restrictive markings shall be deemed to have been furnished with unlimited rights. The Government is not liable for the disclosure, use, or reproduction of such data.

(2) If the unmarked data has not been disclosed without restriction outside the Government, the Contractor may request, within 6 months (or a longer time approved by the Contracting Officer in writing for good cause shown) after delivery of the data, permission to have authorized notices placed on

the data at the Contractor's expense. The Contracting Officer may agree to do so if the Contractor-

(i) Identifies the data to which the omitted notice is to be applied;

(ii) Demonstrates that the omission of the notice was inadvertent;

(iii) Establishes that the proposed notice is authorized; and

(iv) Acknowledges that the Government has no liability for the disclosure, use, or reproduction of any data made prior to the addition of the notice or resulting from the omission of the notice.

(3) If data has been marked with an incorrect notice, the Contracting Officer may-

(i) Permit correction of the notice at the Contractor's expense if the Contractor identifies the data and demonstrates that the correct notice is authorized; or

(ii) Correct any incorrect notices.

(g) *Protection of limited rights data and restricted computer software.*

(1) The Contractor may withhold from delivery qualifying limited rights data or restricted computer software that are not data identified in paragraphs (b)(1)(i) through (iii) of this clause. As a condition to this withholding, the Contractor shall-

(i) Identify the data being withheld; and

(ii) Furnish form, fit, and function data instead.

(2) Limited rights data that are formatted as a computer database for delivery to the Government shall be treated as limited rights data and not restricted computer software.

(3) [Reserved]

(h) *Subcontracting.*

The Contractor shall obtain from its subcontractors all data and rights therein necessary to fulfill the Contractor's obligations to the Government under this contract. If a subcontractor refuses to accept terms affording the Government those rights, the Contractor shall promptly notify the

Contracting Officer of the refusal and shall not proceed with the subcontract award without authorization in writing from the Contracting Officer.

(i) *Relationship to patents or other rights.* Nothing contained in this clause shall imply a license to the Government under any patent or be construed as affecting the scope of any license or other right otherwise granted to the Government.

(End of clause).

Limited Rights Notice (SEPT 2014)

(a) These data are submitted with limited rights under Government Contract No. ____ (and subcontract ____, if appropriate). These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure: [Agencies may list additional purposes or if none, so state.]

(b) This notice shall be marked on any reproduction of these data, in whole or in part.

(End of notice).

Restricted Rights Notice (SEPT 2014)

(a) This computer software is submitted with restricted rights under Government Contract No. __TBD__ (and subcontract __TBD__, if appropriate). It may not be used, reproduced, or disclosed by the Government except as provided in paragraph (b) of this notice or as otherwise expressly stated in the contract.

(b) This computer software may be-

(1) Used or copied for use with the computer(s) for which it was acquired, including use at any Government installation to which the computer(s) may be transferred;

(2) Used or copied for use with a backup computer if any computer for which it was acquired is inoperative;

(3) Reproduced for safekeeping (archives) or backup purposes;

(4) Modified, adapted, or combined with other computer software, provided that the modified, adapted, or combined portions of the derivative software incorporating any of the delivered, restricted computer software shall be subject to the same restricted rights;

(5) Disclosed to and reproduced for use by support service Contractors or their subcontractors in accordance with paragraphs (b)(1) through (4) of this notice; and

(6) Used or copied for use with a replacement computer.

(c) Notwithstanding the foregoing, if this computer software is copyrighted computer software, it is licensed to the Government with the minimum rights set forth in paragraph (b) of this notice.

(d) Any other rights or limitations regarding the use, duplication, or disclosure of this computer software are to be expressly stated in, or incorporated in, the contract.

(e) This notice shall be marked on any reproduction of this computer software, in whole or in part.

(End of notice).

Restricted Rights Notice Short Form (SEPT 2014)

Use, reproduction, or disclosure is subject to restrictions set forth in Contract No. TBD with TBD.

(End of notice).

ARTICLE I.5. SERVICE CONTRACT LABOR STANDARDS

This contract is subject to the Service Contract Labor Standards. The following clauses are hereby incorporated and made a part of this contract. All clauses incorporated by reference have the same force and effect as if they were given full text. Upon request, the Contracting Officer will make their full text available.

a. RFO Clause 52.222-41, Service Contract Labor Standards (Aug 2018).

b. RFO Clause 52.222-42, Statement of Equivalent Rates for Federal Hires (May 2014). In compliance with the Contract Labor Standards statute and the regulations of the Secretary of Labor (29 CFR Part 4), this clause identifies the classes of service employees

expected to be employed under the contract and states the wages and fringe benefits payable to each if they were employed by the contracting agency subject to the provisions of 5 U.S.C. 5341 or 5332.

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

Employee Class Monetary Wage-Fringe Benefit

See Attachment 21 Wage Determination No.: 2015-5637

c. RFO Clause 52.222-55, Minimum Wages Under Executive Order 14026 (DEVIATION)(Apr 2024).

d. RFO Clause 52.222-62, Paid Sick Leave Under Executive Order 13706 (Jan 2022).

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (R&D)	See Attachment Section at the end of this RFP.
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at the end of this RFP.
Attachment 3:	Statement of Work	See Attachment Section at the end of this RFP.
Attachment 4:	Statement of Work & Reporting Requirements for Task Order A-1: Administrative and Technical Support	See Attachment Section at the end of this RFP.
Attachment 5:	Statement of Work & Reporting Requirements for Task Order B-1: Animal Model Development and Efficacy Testing of Candidate MCMs	See Attachment Section at the end of this RFP.
Attachment 6:	Statement of Work & Reporting Requirements for Sample Task Order B-2: Pivotal Efficacy Studies for Gastrointestinal Medical Countermeasure in Mouse and Non-Human Primate	See Attachment Section at the end of this RFP.
Attachment 7:	Statement of Work & Reporting Requirements for Sample Task Order	See Attachment Section at the end of this RFP.

	C-1 Non-Clinical Studies in Support of IND/NDA/ BLA Submissions	
Attachment 8:	Statement of Work & Reporting Requirements for Sample Task Order D-1: Chemistry, Manufacturing, and Control (CMC) Support	See Attachment Section at the end of this RFP.
Attachment 9:	Statement of Work & Reporting Requirements for Sample Task Order E-1: Phase I Clinical Safety Studies and Support Services	See Attachment Section at the end of this RFP.
Attachment 10:	Additional Technical Proposal Instructions, Format for Technical Proposal, and Table of Content	See Attachment Section at the end of this RFP.
Attachment 11:	Additional Business Proposal Instructions and Uniform Cost Assumption	See Attachment Section at the end of this RFP.

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 12:	Planned Enrollment Report, PHS 398/2590 (Rev. 08/12)	http://grants.nih.gov/grants/funding/phs398/PlannedEnrollmentReport.pdf
Attachment 13:	Technical Proposal Cost Summary	http://oamp.od.nih.gov/sites/default/files/ DGS/contracting-forms/summary-related-activities.pdf
Attachment 14:	Summary of Related Activities	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf
Attachment 15:	Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310)	http://www.hhs.gov/ohrp/sites/default/files/ohrp/assurances/forms/optional310form.rtf
Attachment 16:	Contract Proposal Vertebrate Animal Section (VAS) Worksheet	https://grants.nih.gov/grants/olaw/vascontracts.pdf

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location

Attachment 17:	Proposal Summary and Data Record, NIH-2043	https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf
Attachment 18:	Small Business Subcontracting Plan	https://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files
Attachment 19:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	https://oamp.od.nih.gov/content/breakdown- proposed-estimated-cost-plus-fee-and-labor-hours
Attachment 20:	Offeror's Points of Contact	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/cert-current-cost.pdf
Attachment 21:	Wage Rate Determination	See Attachment Section at the end of this RFP.
Attachment 22:	Disclosure of Lobbying Activities, OMB Form SF-LLL	https://www.gsa.gov/reference/forms/disclosure-of-lobbying-activities

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 23:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://oamp.od.nih.gov/sites/default/files/ DGS/contracting-forms/rc4_508.pdf
Attachment 24:	Privacy Act System of Records	https://www.hhs.gov/foia/privacy/sorns/nih-sorns.html
Attachment 25:	Safety and Health, HHSAR Clause 352.223-70	https://oamp.od.nih.gov/sites/default/files/DGS/FORMS/hhsar_352.223-70_safety_and_health_508.pdf
Attachment 26:	Electronic Invoicing Instructions for NIH Contractors/Vendors	
	Electronic Invoicing Instructions Notification to NIH Contractors/Vendors, located at:	https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j
	Electronic Invoicing Step by Step Instructions for NIH Contractors/Vendors	https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j
Attachment 27:	Research Patient Care Costs, NIH(RC)-11	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc11.pdf
Attachment 28:	PHS HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM	https://oamp.od.nih.gov/ DGS/DGS- workform-information/attachment-files
Attachment 29:	eRDS Electronic Report Deliverable Submission	eRDS Electronic Report Deliverable Submission User Guide, 9 pages.

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

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

2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL: SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS** which is included as an Attachment in Section J-LIST OF ATTACHMENTS, SOLICITATION ATTACHMENTS of this solicitation. If you are unable to access this SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

3. **RFO Clause 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).

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST:

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

2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**

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

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

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

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

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

(End of clause).

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

*Note to Offerors : When using RFO provisions or clauses, NIH contracting staff must include the following System for Award Management (SAM) language in the solicitation or contract:

"System updates may lag policy updates. The System for Award Management (SAM) may continue to require entities to complete representations based on provisions that are not included in this solicitation. Contracting officers will rely on representations from offerors based on provisions in the solicitation. Entities are not required to, nor are they able to, update their entity registration to remove these representations in SAM."

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION RFO 52.215-1 (DEVIATION) (Nov 2025).

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

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 request for proposal 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 material elements of a proposal made after the request for proposal 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 requests for proposals*. If this request for proposal (RFP) is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this RFP by the date and time specified in the amendment(s).

(c) Submission, modification, revision, and withdrawal of proposals. (1)

(i) Proposals and modifications to proposals shall be—

(A) Submitted using the method and the format specified in the RFP;

(B) Addressed to the office specified in the RFP; and

(C) Showing the time and date specified for receipt, the RFP number, and the name and address of the offeror.

(ii) Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i)(B) and (C) of this provision.

(2) The first page of the proposal must show—

(i) The RFP number;

(ii) The name, address, and telephone number 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 RFP 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 number (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this RFP; and

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

(3)

(i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the RFP by the time specified in the RFP. If no time is specified in the RFP, 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 RFP 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 RFP, 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 RFP, and urgent Government requirements preclude amendment of the RFP, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the RFP 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 RFPs may be withdrawn orally. 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 RFP, the offeror may propose to provide any item or combination of items.

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

(6) Offerors may submit modifications to their proposals at any time before the RFP 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 RFP will be valid for the number of days specified on the RFP 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:

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 RFP to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the RFP.

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

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

(4) The Government intends to evaluate proposals and award a contract without negotiations with offerors (except clarifications as described in FAR 15.202(b)). 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 negotiations 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 evaluated 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) 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.

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

(9) 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.

(10) 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 weaknesses or deficiencies in the debriefed offeror's offer.

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

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

(iv) A summary of the rationale for award.

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

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

(vii) For DoD contracts in excess of $10 million but not in excess of $100 million with a small business or nontraditional defense contractor (10 U.S.C. 3014), an option for the contractor to request disclosure of the agency's written source selection decision document, redacted to protect the confidential and proprietary information of other offerors for the contract award.

(viii) For award of a DoD contract in excess of $100 million, disclosure of the agency's written source selection decision document, redacted to protect the confidential and proprietary information of other offerors for the contract award.

(End of provision)

Alternate I–*DEVIATION* (Nov 2025). As prescribed in 15.110(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the provision:

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

f. **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, RFO Clause 52.219-1.

1. The North American Industry Classification System (NAICS) code for this acquisition is 541715.
2. The small business size standard is 500.

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

g. **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 7/01/2027.
2. It is anticipated that the award from this solicitation will be a multiple-year Indefinite Delivery/Indefinite Quantity type contract with a seven year ordering period. Task Orders issued against the contract will be cost reimbursement, term/completion type orders.
3. RFO 16.301-3 limits use of any contract type, other than firm-fixed price, to a Contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

l. **LEVEL OF EFFORT**

The Government's requirement for the work set forth in the Statement of Work for Task Order #001

of this solicitation is included in Attachment **11**, Additional Business Proposal Instructions and Uniform Cost Assumptions.

n. **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.

o. **PROMOTING EFFICIENT SPENDING**

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

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

Any contract awarded as a result of this solicitation will:

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

p. **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.

q. **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.

t. **PREPARATION COSTS**

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

u. **SERVICE OF PROTEST** RFO 52.233-2 (DEVIATION)(NOV 2025).

(a) Protests, as defined in section 33.102 of the RFO, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Contracting Officer
Office of R&D and Professional Services Contracts, Division A
Office of Acquisitions & Logistic Management
6701 Rockledge Drive
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).

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

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

2. **INSTRUCTIONS TO OFFERORS**

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

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

1. **Contract Type and General Clauses**

It is contemplated that a single award, Indefinite Delivery/Indefinite Quantity (IDIQ) type

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

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

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

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

BUSINESS PROPOSAL

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

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

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

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

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business

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

5. Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the terms and conditions of the solicitation, as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the solicitation to allow all offerors an opportunity to submit revised proposals based on the revised requirements.

6. **Evaluation of Proposals**

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

7. **Potential Award Without Discussions**

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

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

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

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

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

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

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

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

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR).

DHHS provides information about health information privacy here: https://www.hhs.gov/hipaa/for-professionals/index.html. Discussion of the definition of "covered entities" and "business associates" can be found here: https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html. Decisions about the applicability and implementation of the Privacy Rule reside with the Contractor and his/her institution. Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html .

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

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

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

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

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

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

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

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

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

11. **Selection of Offerors**

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 NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID 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 RFO 15.103 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 NIAID 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 NIAID requirements. Synopses of awards exceeding $25,000 will be published in Contract Opportunities at: https://sam.gov/content/home

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

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any Investigator financial conflicts of interest. The Institution shall comply with all requirements of 45 CFR Part 94 at:
https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94

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

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

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

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

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

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

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

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

(3) Has not [ ] , more than 90 days prior to certification, been notified of any unpaid Federal tax assessment for which the liability remains unsatisfied, unless the assessment is the subject of an installment agreement or offer in compromise that has been approved by the Internal Revenue Service and is not in default, or the assessment is the subject of a non- frivolous administrative or judicial proceeding.

(End of provision).

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

a. *Definition.* As used in this provision-
Internal confidentiality agreement or statement, subcontract, and subcontractor, are defined in the clause at 52.203-19 , Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements.

b. In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use funds appropriated (or otherwise made available) for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

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

d. Representation. By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(End of provision).

16. **Past Performance Information**

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

A list of the last 5 contracts completed during the past Three years and CONTRACTS AWARDED and currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel

who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as $900,000.

Include the following information for each contract or subcontract listed:

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

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

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

17. Information and Communication Technology Accessibility Notice, HHSAR 352.239-78 (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.

(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).

18. **Information and Communication Technology Accessibility,** HHSAR 352.239-79 (Feb 2024) (Deviation).

(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 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).

18. **Solicitation Provisions Incorporated by Reference,** RFO 52.252-1 (Feb 1998).

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. System for Award Management, RFO Provision 52.204-7 (DEVIATION) (Nov 2025).

Alternate I (Oct 2018) is applicable to this solicitation.

c. Submission of Offers in the English Language, FAR Clause 52.214-34, (Apr 1991).

d. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (Apr 1991).

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

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

h. Limitations on Pass-Through Charges--Identification of Subcontract Effort, RFO Provision 52.215-22, (DEVIATION)(Nov 2025).

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

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

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

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

1. **Technical Discussions**

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

a. **Statement of Work**

1. Objectives

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

2. Approach

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

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

3. Methods

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

unusual expenses you anticipate.

4. Schedule

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

b. **Personnel**

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

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

1. Single Principal Investigator/Project Director

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

3. Other Investigators

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

4. Additional Personnel

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

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

5. Resumes

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

2. **Other Considerations**

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

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

3. **Technical Evaluation**

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

4. **Human Subjects**

IMPORTANT NOTE TO OFFERORS: The following subparagraphs shall be addressed, as applicable, in a SEPARATE FILE of the Technical Proposal entitled, "HUMAN SUBJECTS."

a. **Notice to Offerors, Protection of Human Subjects, HHSAR 352.235-70)** (Mar 2026) (RFO DEVIATION).

(a) The Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR part 46, are available on the Office for Human Research Protections (OHRP) website at: http://www.hhs.gov/ohrp/index.html.

(1) These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of human subjects participating in research activities supported or conducted by HHS.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable public information through intervention or interaction with the individual, or identifiable private information. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. 45 CFR part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.

(c) Activities which involve human subjects in one or more of the categories set forth in 45 CFR 46.104(d)(1)-(8) are exempt from complying with 45 CFR part 46. See http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal.

(e) In accordance with 45 CFR part 46, Offerors considered for award must file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board must ensure that: The risks

to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; see http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111 for additional requirements regarding initial and continuing review. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP Web site (at http://www.hhs.gov/ohrp/assurances/index.html).

(f) Offerors may consult with OHRP only for general advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. ONLY the contracting officer may offer information concerning a solicitation.

(g) The Offeror must document in its proposal the approved or active FWA from OHRP, related to the designated Institutional Review Board (IRB) reviewing and overseeing the research.

(1) If the Offeror does not have an approved FWA from OHRP, the Offeror must obtain an FWA before the deadline for proposal submission.

(h) When possible, the Offeror must also certify the IRB's review and approval of the research. If the Offeror cannot obtain this certification by the time of proposal submission, they must include an explanation in their proposal.

(i) Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.

(End of provision)

Alternate I (March 2026) (RFO DEVIATION).

(1) If the Offeror does not have an active FWA from OHRP, the Offeror must take all necessary steps to obtain an FWA prior to the proposal submission deadline. If the Offeror cannot obtain an FWA before the proposal submission deadline, the proposal must indicate the steps/actions the Offeror will take to obtain OHRP approval within (Contracting Officer insert a time period in which the FWA must be obtained). Upon obtaining FWA approval, submit the approval notice to the Contracting Officer.

b. **Instructions to Offerors Regarding Protection of Human Subjects**

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

a. Risks to the subjects
    1. Human Subjects Involvement, Characteristics, and Design :
        i. Briefly describe the overall study design in response to the solicitation.
        ii. Describe the subject population(s) to be included in the study; the procedures for assignment to a study group, if relevant; and the anticipated numbers of subjects for each study group.
        iii. List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research.
    2. Study Procedures, Materials, and Potential Risks
        i. Describe all planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data, and/or records, will be obtained; and whether any private identifiable information will be collected in the proposed research project.
        ii. For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials.
        iii. Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects.
        iv. Where appropriate, describe alternative treatments and procedures, including their risks and potential benefits. When alternative treatments or procedures are possible, make the rationale for the proposed approach clear.
b. Adequacy of Protection Against Risks
    1. Recruitment and Informed Consent:
        i. Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the

method of documenting consent. When appropriate, describe how potential adult subjects' capacity to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent. The informed consent document for the Contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the Contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

   i. For research involving children: If the proposed studies will include children, describe the process for meeting HHS regulatory requirements for parental permission and child assent (45 CFR 46.408). See the HHS page on Research with Children FAQs and the NIH page on Requirements for Child Assent and Parent/Guardian Permission.
   ii. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver.

2. Protection Against Risk:
   i. Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
   ii. Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
   iii. In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.
3. **Vulnerable Subjects, if relevant to your study** - Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. 'Prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers).
   i. <u>Pregnant Women, Fetuses, and Neonates or Children</u> - If the study involves vulnerable subjects subject to additional protections under Subparts B and D (pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements.
      1. HHS' Subpart B - Additional Protections for Pregnant Women, Fetuses, and Neonates

2. HHS' Subpart D - Additional Protections for Children
3. OHRP Guidance on Subpart D Special Protections for Children as Research Subjects and the HHS 407 Review Process

c. Potential Benefits of the Proposed Research to the Subjects and Others
   1. Discuss the potential benefits of the research to the subjects and others.
   2. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
   3. Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

Note: Financial compensation of subjects should not be presented as a benefit of participation in research.

d. Importance of the Knowledge to be Gained
   1. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
   2. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note : If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

c. **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 and amended September 24, 2010, at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html . Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH Office of Extramural Research (OER) on-line tutorial, entitled "Protecting Human Research Participants" at: https://phrptraining.com/ . This course is also available in Spanish under the title "Protección de los participantes humanos de la investigación" at: https://phrptraining.com/ . You may take the tutorials on-line or download the information in PDF form at no cost. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement.

If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

d. **Inclusion of Women and Minorities in Research Involving Human Subjects**

NIH-conducted and supported clinical research must conform to the NIH Policy and Guidelines on the Inclusion of Women and Members of Racial and/or Ethnic Minority Groups as Subjects in Clinical Research in accord with Public Health Service Act sec. 4928 U.S.C. sec 289a-2. The policy requires that women and members of racial and/or ethnic minority groups and their subpopulations must be included in all NIH-conducted or supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant NIH Institute/Center (IC) Director that inclusion is inappropriate with respect to the health of

the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an IC Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Members of Racial and/or Ethnic Minority Groups as Subjects in Clinical Research, effective August 16, 2025," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:
https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-131.html

Effective August 16, 2025, these guidelines contain a definition of **clinical research**, as: " Research with human participants that is:
(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies; or
(2) Epidemiological and behavioral studies; or
(3) Outcomes research and health services research."

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and members of racial and/or ethnic minority groups in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex and racial and/or ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria

- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex, or racial and/or ethnic group
- The proposed sample composition using the "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report" (see Section J, Attachments)

NOTE 1 : *For all proposals, use the ethnic and racial categories and complete the "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report" in accordance with the Office of Management and Budget (OMB) for all Application Packages after January 25, 2018, which may be found at* : https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm .

NOTE 2 : *If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in RFO 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.*

Standards for Collecting Data . When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in Appendix A- Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity at: https://nces.ed.gov/programs/handbook/data/pdf/Appendix_A.pdf . The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials** ***** require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect ((see NIH Guide:

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-131.html, Definitions – D.

Significant Difference).
*The definition of an " **NIH-Defined Phase III clinical trial** " can also be found at this website.) by sex, racial and/or ethnic minority groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex and racial and/or ethnic minority group differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex and/or racial and/or ethnic minority subgroups when prior studies strongly support these significant differences among subgroups,

  OR

- Plans to include and analyze sex and/or racial and/or ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups,

  OR

- Plans to conduct valid analyses of the intervention effect in sex and/or racial and/or ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form entitled, "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report," <u>when preparing your response</u> to the solicitation requirements for inclusion of women and members of racial and/or ethnic minority groups. (See Section J-List of Documents, Exhibits and Other Attachments of the RFP)

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex specific study or a single or limited number of racial and/or ethnic minority population groups. Therefore, the NIH believes that the inclusion of women and racial and/or minority groups is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the form entitled, "PHS Human Subjects and Clinical Trials Information Form/Cumulative Inclusion Enrollment Report," for <u>reporting in the resultant contract</u> .

e. **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are clear and compelling reasons not to include them. (See examples of Justifications for Exclusion of Children below). For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 18 years.

All Offerors proposing research involving human subjects should read the "Inclusion of Children in Clinical Research: Change in NIH Definition " which was published in the NIH guide notice on October 13, 2015 and is available at the following URL address:

https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-010.html

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

1. The objective of the solicitation is not relevant to children.
    a. There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
    b. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
    c. A separate, age-specific study in children is warranted and preferable. Examples include:
        i. The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
        ii. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
        iii. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
        iv. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
        v. Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
        vi. Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 18 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not

address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 18) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

f. **Research Involving Prisoners as Subjects**

A. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: http://www.hhs.gov/ohrp/policy/prisoner.html.

B. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:
    a. to describe the prevalence or incidence of a disease by identifying all cases, or
    b. to study potential risk factor associations for a disease, and
2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2 7) and determined and documented that:
    a. the research presents no more than minimal risk, and

b. no more than inconvenience to the prisoner subjects, and
c. prisoners are not a particular focus of the research.

For more information about this Waiver see http://www.gpo.gov/fdsys/pkg/FR-2003-06-20/html/03-15580.htm.

j. **Human Stem Cell Research**

On March 9, 2009, the President issued Executive Order (EO) 13505: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells. The NIH has published Guidelines on Human Stem Cell Research at: https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research . The Guidelines implement EO 13505 with regard to extramural NIH-funded human stem cell research, establish policy and procedure under which the NIH will fund such research, and help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.

To facilitate research using human embryonic stem cells, the NIH has established a Human Embryonic Stem Cell Registry ("the NIH Registry") that lists the human embryonic stem cells that are currently eligible for use in NIH-funded research. This registry is available at: https://grants.nih.gov/stem_cells/registry/current.htm . Proposed human embryonic stem cell line(s) must be on the NIH Registry at the time of proposal submission. Any possible changes to the proposed cell line must be discussed in the proposal. Offerors wishing to have Human Embryonic Stem Cell Lines added to the NIH Human Embryonic Stem Cell Registry must submit the request on Form NIH 2890 through the following website: https://hescregapp.od.nih.gov/NIH_Form_2890_Login.htm .

See Section H of this solicitation for more details.

k. **Public Health Surveillance Exclusion**

An Offeror may request an exclusion from applicability of the "revised Common Rule"[1] if it believes that NIH-funded or -conducted activities associated with this solicitation should be considered "public health surveillance activities deemed not to be research" for the purposes of the revised Common Rule. All requests for the public health surveillance exclusion from the revised Common Rule for NIH-funded research-whether conducted or supported-must receive NIH approval, as per the process outlined below, to be considered a public health surveillance activity deemed not to be research under the revised Common Rule's Sections §46.102(k), Public health authority, and §46.102(l)(2), Public health surveillance activities. NIH expects that NIH-supported or -conducted research will be determined to be a public health surveillance activity only in extremely rare cases. **Please note that NIH will not consider any NIH-defined clinical trials for a public health surveillance exclusion request. In addition, NIH will not consider studies that contain any activity that does not meet the requirements for an exclusion for a public health surveillance determination, including any intent to store specimens and/or**

data for future use.

Requesting a Determination that NIH-Funded or -Conducted Activities be Considered Public Health Surveillance:

Offerors shall provide a compelling justification as to why NIH-funded or -conducted activities should be considered public health surveillance activities deemed not to be research for the purposes of the revised Common Rule. Refer to the attached template in Section J. All activities for which approval of the exclusion will be sought must be disclosed and described.

The justification shall include information that demonstrates **all three (3)** of the following:

a) The proposed activity is strictly limited to only that necessary for NIH to identify, monitor, assess, or investigate:

i. Potential public health signals; or

ii. Onsets of disease outbreaks; or

iii. Conditions of public health importance (including trends, signals, risk factors, or patterns in diseases).

AND

b) The activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).

AND

c) The activities will directly inform NIH public health decision-making or action.

Note: An Offeror shall submit its compelling justification for exclusion with its technical proposal as a separate attachment, so that the justification can be detached from and evaluated apart from the Offeror's technical proposal. The Government reserves the right to not consider any public health surveillance exclusion requests if the justification is not provided at the time of original proposal submission.

Offerors shall complete and submit the PHS Human Subjects and Clinical Trials Information Form, following instructions in the solicitation, as applicable. Offerors should not assume that approval of an exclusion will be granted when completing the PHS Human Subjects and Clinical Trials Information Form.

Note that the proposed budget in the proposal must reflect all necessary/required costs for the full and proper conduct of research involving human subjects, in complete compliance with all applicable laws, protocols, rules, and/or regulations at all levels, without approval of any exclusion. Offerors should not assume that approval of an exclusion will be granted when considering the costs to include in any proposed budget and therefore, must respond and price accordingly.

Notice of Approval or Disapproval of Request for Exclusion

Exclusion requests will be considered separate from the NIH peer review of technical proposals. Offerors will be issued written notification of approval or denial by the NIH Contracting Officer of any request(s) for exclusion prior to award. Any decision by NIH on an Offeror's request for a Public Health Surveillance Exclusion shall be final.

The award budget may then be adjusted accordingly if approval of an exclusion is granted by NIH.

_____

[1] Code of Federal Regulations (CFR) Title 45, Public Welfare, Department of Health and Human Services, Part 46, Protection of Human Subjects, Revised 19 January 2017, Effective 19 July 2018, with a General Compliance Date of 21 January 2019 (45 CFR part 46)), and not its predecessor, the Pre-2018 Common Rule (Common Rule). The revised Common Rule is also known or referred to as the "2018 Requirements" or the "2018 Rule."

l. **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

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

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be

performed on a regular basis and the conclusions of the monitoring reported to the Contracting Officer Representative (COR).

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

For any proposed clinical trial, NIH requires a data and safety monitoring plan (DSMP) that is commensurate with the risks of the trial, its size, and its complexity. Provide a description of the DSMP, including:

- The overall framework for safety monitoring and what information will be monitored.
- The frequency of monitoring, including any plans for interim analysis and stopping rules (if applicable).
- The process by which Adverse Events (AEs), including Serious Adverse Events (SAEs) such as deaths, hospitalizations, and life threatening events and Unanticipated Problems (UPs), will be managed and reported, as required, to the IRB, the person or group responsible for monitoring, the awarding IC, the NIH Office of Biotechnology Activities, and the Food and Drug Administration.
- The individual(s) or group that will be responsible for trial monitoring and advising the appointing entity. Because the DSMP will depend on potential risks, complexity, and the nature of the trial, a number of options for monitoring are possible. These include, but are not limited to, monitoring by a:
    - PD/PI: While the PD/PI must ensure that the trial is conducted according to the approved protocol, in some cases (e.g., low risk trials, not blinded), it may be acceptable for the PD/PI to also be responsible for carrying out the DSMP.

- Independent safety monitor/designated medical monitor: a physician or other expert who is independent of the study.
- Independent Monitoring Committee or Safety Monitoring Committee: a small group of independent experts.
- Data and Safety Monitoring Board (DSMB): a formal independent board of experts including investigators and biostatisticians. NIH requires the establishment of DSMBs for multi-site clinical trials involving interventions that entail potential risk to the participants, and generally, for all Phase III clinical trials, although Phase I and Phase II clinical trials may also need DSMBs. If a DSMB is used, please describe the general composition of the Board without naming specific individuals.

The NIH Policy for Data and Safety Monitoring at: http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

m. **Registration of and Results Reporting for Applicable Clinical Trials in ClinicalTrials.gov**

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

A. The registration of certain "applicable clinical trials" in ClinicalTrials.gov no later than 21 days after the first subject is enrolled; and
B. The reporting of summary results information (including adverse events) no later than 1 year after the completion date for registered applicable clinical trials involving drugs that are approved under section 505 of the Food, Drug and Cosmetic Act (FDCA) or licensed under section 351 of the PHS Act, biologics, or of devices that are cleared under section 510k of FDCA.

The resultant contract will support one or more applicable clinical trial subject to FDAAA.

The "responsible party" is the entity responsible for registering and reporting trial results in ClinicalTrials.gov.

1. Where the Contractor is the IND/IDE holder, the Contractor will be considered the Sponsor, therefore the "Responsible Party."
2. Where there is no IND/IDE holder or where the Government is the IND/IDE holder, the Government will generally be considered the "Sponsor" and may designate the Contractor's Principal Investigator (PI) as the "Responsible Party."
3. For Multi-Center trials where there is no IND/IDE holder or where the Government is the IND/IDE holder, the "Responsible Party" will be designated at one site (generally the lead clinical site) and all other sites will be responsible for providing necessary data to the "Responsible Party" for reporting in the database.

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

n. **PLAN FOR THE DISSEMINATION OF INFORMATION OF NIH-FUNDED CLINICAL TRIAL**

Offerors are required to submit a plan for the dissemination of NIH-funded clinical trial information in the proposal. At a minimum, the plan must contain sufficient information to assure that:

1. The Contractor shall register and submit results information to https://clinicaltrials.gov/ as outlined in the NIH policy on the Dissemination of NIH-Funded Clinical Trial Information and according to the specific timelines stated in the policy (this can be a brief statement);
2. Informed consent documents for the clinical trial(s) shall include a specific statement relating to posting of clinical trial information at https://clinicaltrials.gov/ ; and
3. The Contractor has an internal policy in place to ensure that clinical trials registration and results reporting occur in compliance with NIH policy on the Dissemination of NIH-Funded Clinical Trial Information requirements.

If the Offerors plan does not meet these minimum standards, or is otherwise not acceptable as determined by the Contracting Officer, the contract award cannot be issued until an approved plan has been submitted.

o. **IDENTIFICATION OF SINGLE INSTITUTIONAL REVIEW BOARD (sIRB)**

Offerors are required to identify the name of the Single Institutional Review Board (sIRB) in an attachment to the technical proposal for each protocol involving more than one domestic site. At a minimum, the Offeror shall provide confirmation of the following:

1. Participating sites will adhere to the sIRB Policy;
2. Sites and the sIRB will adhere to the communication plan described in the authorization/reliance agreement; and

3. If, in the case of restricted award an sIRB has not yet been identified, include a statement that the offeror will follow the sIRB Policy and communicate plans to select a registered IRB of record. This information must be provided to the Contracting Officer prior to initiating recruitment for a multi-site study.

The Offeror may request direct cost funding for the additional costs associated with the establishment and review of the multi-site study by the sIRB, with appropriate justification; all such costs must be reasonable and consistent with cost principles, in accordance with the Federal Acquisition Regulation Part 31, as applicable to your contract.

p. **EXCEPTIONS TO THE SINGLE INSTITUTIONAL REVIEW BOARD (sIRB) POLICY**

In the technical proposal, Offerors may request an exception to the sIRB policy for one or more studies.

1. For sites for which Federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions):
    A. The Offeror shall identify any site that meets the requirements for the Single IRB policy but is required to have local IRB review because of a federal, state, or tribal law, regulation or policy; and
    B. The Offeror shall provide specific citation for policy-based exceptions.
2. Time Limited Exception: ancillary studies to ongoing research without a sIRB-new multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy, but are associated with the ongoing multi-site parent studies, will not be required to use the sIRB of record until the parent study is expected to comply with the sIRB policy. The Offeror shall provide the parent contract number to request an exception.
3. *Other exceptions* when Offeror believes that one or more research sites should be exempt from use of the single IRB of record to conduct local IRB review based on compelling justification:
    A. Offerors should request an exception in the sIRB plan attachment within the contract proposal (section 3.2 in the Study Record: PHS Human Subjects and Clinical Trials Information form).
    B. Offerors must include the name of the site(s) for which an IRB other than the sIRB of record is proposed to review the study for the sites(s).
    C. Offerors must substantiate their exception request with sufficient information that demonstrates a compelling justification for *other exceptions* to the sIRB policy. The rationale should include why the sIRB of record cannot serve as the reviewing IRB for the site(s), and why the local IRB is uniquely qualified to be the reviewing IRB for the specific site(s).

- For instance, the justification may consider ethical or human subjects protections issues, population needs, or other compelling reasons that IRB review for the site(s) cannot be provided by the single IRB of record.

D. Note that the proposed budget in the proposal must reflect all necessary sIRB costs without an approved *other exception* . The Offerors should not assume that *another exception* will be granted when considering what sIRB costs to include in the budget.

Post-Award Exception Requests

For any post-award changes that necessitate an exception request, such as the addition of a new domestic site that may be unable to use the sIRB Contractor shall contact their Contracting Officer (CO). For policy-based exceptions, the Contractor shall provide the appropriate citation to verify the requirement for local IRB review for the newly added site(s) to the CO. For *other exceptions* , the Contractor shall provide compelling justification to the CO to be reviewed by the NIH Exceptions Review Committee (ERC) (see **Steps to Request an *Other Exception* to the sIRB Policy** above). For time limited exceptions, Contractor shall provide the parent contract number to the CO.

Notice of Approval or Disapproval of *Other Exception* Requests

The sIRB exception requests will be considered after peer review for proposals in the competitive range. All requests for *other exceptions* must be reviewed by the NIH ERC. The decision of NIH ERC is final. Offerors will be notified of the final decision by their CO prior to award. Approved exceptions will be incorporated as a term and condition in the contract award. Also, any exception requests submitted after award must be submitted to the CO and reviewed by the NIH ERC. No further revisions of the exception request will be accepted.

The award budget may need to be adjusted if an exception is granted.

q. **PHS HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM**

Offerors shall submit the "PHS Human Subjects and Clinical Trials Information Form" with each technical proposal for work involving human subjects.

FORM SUBMISSION INSTRUCTIONS

1. The PHS Human Subjects and Clinical Trials Information Form must be submitted with your technical proposal.

2. Offerors must use the form and follow the associated instructions posted on the website at: https://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files.

r. **INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS**

Section 2038 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions requiring NIH to address the consideration of age as an inclusion variable in research involving human subjects, to identify criteria for justification for any age-related exclusions in NIH research, and to provide data on the age of participants in clinical research studies. The NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accordance with Sections 101(b) and 401(b) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects.

Effective on all solicitations issued on or after January 25, 2019, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

The proposal for research involving human subjects must address the age-appropriate inclusion or exclusion of individuals in the proposed research project. The Offeror must include a description of plans for including individuals across the lifespan, including a rationale for selecting the specific age range justified in the context of the scientific question proposed. If individuals will be excluded from the research based on age, the Offeror must provide acceptable justification for the exclusion in the proposal.

The Contractor must submit cumulative data as prescribed in the NIH Contracts Age Enrollment Report template Attachment Files - Section J | National Institutes of Health on participant age at enrollment in monthly progress reports. Investigators planning to conduct research involving human subjects should design their studies in such a way that de-identified individual level participant data on sex, race, and/or ethnic minority groups, and age at enrollment may be provided in progress reports. The Contractor must submit cumulative de-identified individual level participant data on sex, race, and/or ethnicity, and age at enrollment annually. The template used for these submissions is https://www.era.nih.gov/sites/default/files/2020-05/ParticipantLevelData-Template.CSV

s. **POSTING CLINICAL TRIAL INFORMED CONSENT FORMS TO CLINICALTRIALS.GOV**

The Revised Common Rule sections 46.102(b) and 46.116(h) requires Contractors with to post one IRB-approved version of an Informed Consent Form that has been used to enroll participants on a public federal website designated for posting such Consent Forms. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database https://clinicaltrials.gov/. Note: ClinicalTrials.gov only accepts Informed Consent Forms written in English; non-English language forms must be submitted to https://www.regulations.gov/.

1. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database https://clinicaltrials.gov/
2. The Informed Consent Form must be posted after recruitment closes, and no later than 60 days after the final study visit.
3. The Contracting Officer (CO) and/or Contracting Officer's Representative (COR) may permit or require redactions as appropriate.
4. Informed Consent Forms for the clinical trial(s) shall include a specific statement relating to posting of clinical trial information at https://clinicaltrials.gov/
5. Informed Consent Forms must be compliant with the HHS Policy for the Protection of Human Research Subjects (45 CFR 46).

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

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, MD 20892-6910 (Email: olaw@od.nih.gov ; Phone: 301-496-7163).

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

(End of provision).

6. **Research Involving Live Vertebrate Animals**

It is intended that live vertebrate animals will be used during performance of this contract. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (authority derived from the Health Research Extension Act of 1985) specifies that certain information is required from offerors in contract proposals submitted to the NIH that will use live vertebrate animals.

The following criteria must be addressed in a separate section of the Technical Proposal titled "Vertebrate Animal Section" (VAS):

1. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
2. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
3. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
4. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

A concise (no more than 1-2 pages), complete description addressing these criteria must be provided. The description must be cohesive and include sufficient information to allow evaluation by reviewers and NIH staff. For more discussion regarding the VAS, see NIH Guide Notice NOT-OD-16-006 at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html.

The Contract Proposal VAS Worksheet is provided as an Attachment in SECTION J of this solicitation to assist in the preparation of the VAS as part of the Technical Proposal. It can be accessed at: https://grants.nih.gov/grants/olaw/vascontracts.pdf.

8. **Enhancing Reproducibility through Rigor and Transparency**

The offeror shall demonstrate compliance with the NIH Policy on enhancing Reproducibility through Rigor and Transparency as described in NIH Guide Notice NOT- OD-15-103 . Specifically, the offeror shall describe in its technical proposal the information described below:

a. Compliance Factors

1. Describe the scientific premise for the Technical Proposal. The scientific premise is the research that is used to form the basis for the proposed research. Offerors should describe the general strengths and weaknesses of the prior research being cited by the offeror as crucial to support the proposal. It is expected that this consideration of general strengths and weaknesses could include attention to the rigor of the previous experimental designs, as well as the incorporation of relevant biological variables and authentication of key resources.
2. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.
3. Explain how relevant biological variables, including sex, [if deemed necessary by the IC, additional variables may be included here] are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for proposals proposing to study only one sex. If your proposal involves human subjects, the sections on Inclusion across the lifespan can be used to expand your discussion and justify the proposed proportions of individuals (such as males and females) in the sample. Refer to NOT-OD-15-102 for further consideration of NIH expectations about sex as a biological variable.
4. If applicable to the proposed science, briefly describe methods to ensure the identity and validity of key biological and/or chemical resources used in the proposal. Key biological and/or chemical resources may or may not be generated with NIH funds and: 1) may differ from laboratory to laboratory or over time; 2) may have qualities and/or qualifications that could influence the research data; and 3) are integral to the proposed research. These include, but are not limited to, cell lines, specialty chemicals, antibodies, and other biologics.

   Standard laboratory reagents that are not expected to vary do not need to be included in the plan. Examples are buffers and other common biologicals or chemicals. If the Technical Proposal does not propose the use of key biological and/or chemical resources, a plan for authentication is not required, and the offeror should so state in its proposal.

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

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

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

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

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

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

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

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

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

If the resultant contract is part of a collaborative program involving multiple sites, all data management and sharing shall be governed by a data management, sharing, and dissemination plan to be jointly developed prior to award. A Coordinating Center's proposal shall describe the methods by which to coordinate such data management, sharing, and dissemination planning and implementation efforts. In its proposal the Coordinating Center shall include a budget with all proposed costs and justification for/of any costs of such collaborative effort(s).

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

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

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

c. **BUSINESS PROPOSAL INSTRUCTIONS**

1. **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. **Proposal Cover Sheet**

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right

to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.

8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with RFO 15.402.

3. **Data Other than Certified Cost or Pricing Data**

a. Data submitted shall be sufficient to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., data to support an analysis of material costs (when sufficient data on labor and overhead rates is already available), or data on prices and quantities at which the offeror has previously sold the same or similar items.

   Data submitted must support the price proposed. The offeror shall include sufficient detail or cross references to clearly establish the relationship of the data provided to the price proposed. The offeror shall support any data provided with explanations or supporting rationale, as needed, to permit the Contracting Officer and authorized representative to evaluate the documentation.

   [Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.]

b. The data submitted shall be at the level of detail described below.

   1. **Direct Labor**

      Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

   2. **Materials**

      Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

   3. **Subcontracted Items**

      Include parts, components, assemblies, and services that are to be

produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $2,500,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by RFO 15.404-8.

4. **Raw Materials**

   Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

5. **Purchased Parts**

   Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

   Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

7. **Indirect Costs**

   Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

   If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

9. **Travel**

   Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

10. **Other Costs**

    List all other costs not otherwise included in the categories described

above (e.g., computer services, consultant services) and provide basis for pricing.

5. **Requirements for Certified Cost or Pricing Data and Data Other than Certified Cost or Pricing Data, RFO Clause 52.215-20 (DEVIATION)** (Nov 2025).

(a) Exceptions from certified cost or pricing data.

(1) In lieu of submitting certified cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following paragraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) *Identification* of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) *Commercial product and commercial service exception*. For a commercial product and commercial service exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include:-

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Schedule contract, proof that an exception has been granted for the schedule item.(2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit

information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

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

(1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-1 of FAR 15.408-2, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-1 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.403-4.

(End of provision).

Alternate I (DEVIATION) (Nov 2025) of **RFO Clause 52.215-20, Requirements for Certified Cost or Pricing Data and Data Other than Cost or Pricing Data** (DEVIATION) (Nov 2025).

Alternate I-DEVIATION (Nov 2025). As prescribed in 15.110(t)(1), substitute the following paragraph (b)(1) for paragraph (b)(1) of the provision:

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

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

6. **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.

9. **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $900,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," RFO Clause No. 52.219-9, incorporated herein by reference in the Solicitation. In accordance with RFO 19.206-2 and RFO Clause 52.219-9, the submission of a subcontracting plan by other than small business offeror(s) is a requirement as a part of the proposal submission process and is to be submitted separately from the technical and cost proposals. An offeror's subcontracting plan must be determined to be acceptable, by the Contracting Officer, prior to the contract award.

1. An offeror is to submit their respective subcontracting plan electronically using the U.S. Department of Health and Human Services (HHS) Small Business Customer Experience (SBCX) system at https://osdbu.hhs.gov . The offeror must follow the instructions outlined in the SBCX Industry Guide instructions outlined in the SBCX Industry Guide at: https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j to successfully submit their subcontracting plan by the proposal submission deadline.
2. The official point of receipt for determining timely submission of an offeror's subcontracting plan is the SBCX system and/or email notification. Once the subcontracting plan is successfully submitted in the SBCX system the offeror should receive an email notification and confirmation message of completion upon submission.
3. If an offeror's subcontracting plan is not confirmed as received within the SBCX system by the proposal submission date specified in the solicitation, it will be

considered late in accordance with subparagraph (c)(3) of RFO Clause 52.215-1, Instructions to Offeror-Competition Acquisition. Disposition of late submittals of a subcontracting plan by an offeror via the SBCX system is at the discretion of the Contracting Officer.

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

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

vi. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:

i. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
ii. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
iii. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
iv. A description of the method used to develop the subcontracting goals.
v. A description of the method used to identify potential sources for solicitation purposes.
vi. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
vii. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
viii. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
ix. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $900,000 adopt a plan similar to the plan agreed upon by the offeror.
x. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government at https://www.SAM.gov/.
xi. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including

establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see RFO Clause 52.219-9, Small Business Subcontracting Plan.

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

32.35% for Small Business; 5.45% for Small Disadvantaged Business; 8.95% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and 3% Service-Disabled Veteran-Owned Small Business.

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

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

3. Mentor-Protege agreements--joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision).

11. **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with RFO Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone .

15. **Other Administrative Data**

a. **Property**

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:

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

2. Government Property

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

a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);

b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to

support prorating the rent;

c. The amount of rent that would otherwise be charged in accordance with RFO 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 RFO 52.245-9.

3. Government-Furnished Property

No Government Furnished Property is offered for this acquisition

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

c. **Submission of Electronic Funds Transfer Information with Offer, RFO Clause 52.232-38** (Jul 2013).

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

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

wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

(End of provision).

d. **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e. **Adequate Accounting System**

RFO Part 16 sets forth the requirements and limitations for consideration of contract type. As stated in Section L.1., General Instructions of this solicitation, the resultant contract will not be Firm-Fixed Price. Therefore, the offeror's/contractor's accounting system and practices must be adequate and suitable for accumulating costs under government contracts.

To be considered for an award under this solicitation, the offeror shall include, in the Business Proposal, the following Certification:

"By submission of its signed offer, the Offeror certifies that its accounting system:

1. Complies with Generally Accepted Accounting Principles (GAAP).
2. Provides for:
    a. Proper segregation of direct costs from indirect costs.
    b. Identification and accumulation of direct costs by contract.
    c. A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
    d. Accumulation of costs under general ledger control.
    e. A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
    f. A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
    g. Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
    h. Exclusion from costs charged to government contracts of amounts that are not allowable in terms of RFO 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 (RFO 52.232-20) or limitation on payments (RFO 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.

f. **Facilities Capital Cost of Money, RFO 52.215-16,** (Jun 2003).

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of provision).

16. **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a. **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b. **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes

overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c. **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d. **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

17. **Subcontractors**

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

a. Willingness to perform as a subcontractor for specific duties (list duties).
b. What priority the work will be given and how it will relate to other work.
c. The amount of time and facilities available to this project.
d. Information on their cognizant field audit offices.
e. How rights to publications and patents are to be handled.
f. A complete cost proposal in the same format as the offeror's cost proposal.

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

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

19. **Travel Costs/Travel Policy**

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

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

c. **Certification of Visas for Non-U.S. Citizens**

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

SECTION M - EVALUATION FACTORS FOR AWARD

2. **GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are more important than cost. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the SOLICITATION. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of

the requirements of the SOLICITATION. Offerors must submit information sufficient to evaluate their proposals based on the detailed factors listed below.

4. **COST/PRICE EVALUATION**

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in RFO 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 RFO 15.404-3. The result of the cost realism analysis will be considered in the making the best value tradeoff decision.]

5. **MULTI-YEAR CONTRACT**

The evaluation will consider the offeror's price and ability to perform the first program year as well as the total multi-year requirement to assess whether the contractor's anticipated costs are unbalanced and to ensure that the proposed costs are consistent with the proposed effort across all program years. Within the context of RFO Subpart 17.1, "program year" has the same meaning as "contract year."

If the Government determines before award that only the first contract year requirements are needed, the Government's evaluation of the offeror's price and ability to perform shall consider only the first year.

6. **HUMAN SUBJECT EVALUATION**

This research project involves human subjects. NIH Policy requires:

i. **Protection of Human Subjects from Research Risks**

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NIAID that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and

under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

ii. **Women and Members of Racial and/or Ethic Minority Groups**

Women and members of racial and/or ethnic minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide Guide Notice NOT-OD-25-131 at https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-131.html, Definitions - Significant Difference) by sex, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups,

  OR

- Plans to include and analyze sex and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged),

OR

- Plans to conduct valid analyses of the intervention effect in sex and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and members of racial and/or ethnic minority groups as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both sexes in adequate representation
- how the offeror addresses the inclusion of women and members racial/ethnic of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for exclusion based on sex, the reviewers will examine the rationale to determine if it is because:
    - the purpose of the research constrains the offeror's selection of study participants by sex (e.g., uniquely valuable stored specimens or existing datasets are single sex; very small numbers of subjects are involved; or
    - overriding factors dictate selection of subjects); or
    - sex representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.
- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
    - inclusion of those groups would be inappropriate with respect to their health; or
    - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and members of racial and/or ethnic minority groups is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed women/minority inclusion plans, or concerns are identified as to the sex or minority representation, or the proposal does not adequately address limited representation of one sex or minority groups; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

iii. **Children**

Children (i.e. individuals under the age of 18) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance with NIH policy

guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

iv. **Data and Safety Monitoring**

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers will rely on the Statement of Work and Section L in the solicitation, as well as any further technical evaluation factors in this Section M, as applicable, for the solicitation's specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will consider the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for data and safety monitoring is still found to be unacceptable, then your proposal may not be considered further for award.

7. **LIVE VERTEBRATE ANIMALS EVALUATION**

The offerors proposal must include, as a separate section of the Technical Proposal titled "Vertebrate Animal Section," (VAS) a complete, concise (no more than 1-2 pages) description addressing the following criteria. (See NIH Guide Notice NOT-OD-16-006 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html):

1. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
2. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
3. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
4. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

As part of the overall technical evaluation of proposals, the reviewers will consider the acceptability of the offeror's description in the VAS of the technical proposal. The discussion of all criteria will be addressed and evaluated. Based on the evaluation of this Section, the VAS may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the description addressing each of the criteria, or no discussion can be found regarding the VAS), or "acceptable." If the reviewers find that this Section of the technical proposal is "unacceptable" they will provide a narrative supporting their findings.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed description under the VAS is still found to be unacceptable, then your proposal may not be considered further for award.

8. PROSPECTIVE CONTRACTOR RESPONSIBILITY AND ELIGIBILITY STANDARDS: SUPPLY CHAIN RISK ASSESSMENT

Revolutionary FAR Overhaul (RFO) Subpart 9.1 sets the standards and procedures for determining prospective contractor and subcontractor responsibility. RFO 9.104-2 allows for special standards of responsibility.

Special standards in the responsibility determination: The government will assess the offeror’s submitted information in provision HHSAR 352.204-74, Supply Chain Risk Assessment (Deviation), any required supporting data, and information from other sources for the purpose of evaluating foreign ownership, control or influence and other areas of supply chain risk, when necessary, and

this information will be treated by HHS, to the extent permitted by law, as business or financial information submitted in confidence.

The Government may request additional information or a mitigation plan from the offeror that addresses risks identified in the supply chain risk assessment. Any requests for additional information resulting from the supply chain risk assessment do not constitute exchanges or discussions as described in RFO 15.306.

Any mitigation plans and amendments determined necessary and required to be implemented and sustained during contract performance will be incorporated into the contract.

In order to manage supply chain risk, the Government may consider information, public and non-public, relating to an offeror's supply chain in determining responsibility. The Government may remove the offeror from further consideration due to a Supply Chain Risk determination, which renders the offeror non-responsible. 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.

Paragraph (A):

Failure by the offeror to affirmatively demonstrate adequate compliance with any special standards established for this acquisition under RFO 9.104-2 may result in a determination of non-responsibility. As with all aspects of prospective contractor responsibility, a finding of non-responsibility can be made at any time prior to contract award. Per RFO 9.103(b), if the prospective contractor is a small business concern, responsibility will be determined in accordance with Subpart 19.6, Certificates of Competency and Determinations of Responsibility. If the prospective contractor is a Section 8(a) participant, see Subpart 19.8.

Paragraph (B):

Failure by the offeror to affirmatively demonstrate adequate compliance with the general standards of prospective contractor responsibility at RFO 9.104-1, and any special standards established for this acquisition under RFO 9.104-2, may result in a determination of non-responsibility. As with all aspects of prospective contractor responsibility, a finding of non-responsibility can be made at any time prior to contract award. Per RFO 9.103(b), if the prospective contractor is a small business concern, responsibility will be determined in accordance with Subpart 19.6, Certificates of Competency and Determinations of Responsibility. If the prospective contractor is a Section 8(a) participant, see Subpart 19.8.

9. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with RFO Clause 52.217-5, Evaluation of Options, (Nov 2025), 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 RFO 17.202 not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

10. EVALUATION OF AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

If the offeror has proposed the use of key biological and/or chemical resources, the offeror's plan for authentication will be reviewed for adequacy.

Any concerns associated with key biological and/or chemical resource authentication raised during the review process will need to be resolved prior to award.

12. 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.

13. TECHNICAL EVALUATION FACTORS

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

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO - Additional Technical Proposal Instructions OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF TECHNICAL PROPOSALS.

CRITERIA	WEIGHT
CRITERION 1: TECHNICAL PLAN/APPROACH A. **Task Area A (25 pts)**: Administrative and Technical Support Appropriateness, feasibility, and adequacy of the proposed technical plan/approach for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation. B. **Task Area B (50 pts)**: Animal Model and New Approach Methodologies (NAMs) Development, and Efficacy Testing of Candidate MCMs	125

CRITERIA	WEIGHT
1. **Task Order B-1 (25 pts):** Adequacy of proposed plans and previous organizational experience for using rodent, large animal (rhesus macaques), other relevant animal models of hematopoietic, gastrointestinal and lung radiation injury, and NAMs for efficacy studies, mechanism of action studies for candidate MCMs, and sample collection for biodosimetry or biomarkers for radiation injury. 2. **Sample Task Order B-2 (25 pts):** Adequacy of the plans for GLP testing of MCMs for gastrointestinal syndrome of the acute radiation syndrome. C. **Task Area C (20 pts):** Non-Clinical Studies in Support of Investigational New Drug (IND)/New Drug Application (NDA)/Biologics License Application (BLA) Submissions Adequacy of the proposed plans and procedures and previous organizational experience for GLP testing of the MCM in animals and in vitro for safety/toxicity and pharmacology to support clinical use in humans of a therapeutic product. D. **Task Area D (15 pts):** Chemistry, Manufacturing and Control (CMC) Support Adequacy of proposed plans and procedures and previous organizational experience to manufacture and test MCM suitable for clinical use." E. **Task Area E (15 pts):** Phase I Clinical Studies and Support Adequacy of the proposed plans and procedures and previous organizational experience to design and conduct Phase I clinical safety study(ies) in normal human subjects under GCP to support approval of a radiological/nuclear medical countermeasure candidate.	
CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL Appropriateness and adequacy of the education, training, experience, expertise, and proposed levels of effort of the Principal Investigator and scientific and technical staff including subcontractors/consultants for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.	25
CRITERION 3: PROJECT MANAGEMENT Appropriateness and adequacy of the Project Management Plan in terms of staffing, organizational structure and lines of	25

CRITERIA	WEIGHT
authority, management of subcontracts/consultants, tracking of project activities, monitoring progress and timelines, and communication with stakeholders.	
CRITERION 4: FACILITIES, EQUIPMENT, AND OTHER RESOURCES Appropriateness and adequacy of facilities, equipment, space, and other resources including those of subcontractors/consultants for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.	25
TOTAL POSSIBLE WEIGHT:	200

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

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

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

15. **PAST PERFORMANCE FACTOR**

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

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

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

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

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

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

PRE-AWARD SITE VISIT OR SITE AUDIT

Offerors determined, upon completion of the scientific/technical peer review, to be in the Competitive Range may be subject to a pre-award site visit or auditing of their facilities and Quality Assurance/Quality Control (QA/QC) capabilities. The decision to conduct a pre-award site visit or audit specific facilities will be made by the Contracting Officer’s Representative. Offerors, including proposed subcontractors, will be requested to make all non-proprietary records, including previous regulatory inspection records, and staff available in response to a pre-award site visit or audit by NIAID or its designee. **Due to timeline requirements, pre-award site visits may be made with short notice. Offerors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.**

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

I. PROPOSAL SUBMISSION

A. eCPS

1. Proposals must be submitted via the electronic Contract Proposal Submission (eCPS) website at https://ecps.nih.gov.
2. Proposals submitted by facsimile or e-mail will not be accepted.
3. Follow the "How to Submit an Electronic Proposal" instructions provided on the eCPS website at: https://ecps.nih.gov/home/howto. Please note that creating an account to submit may take up to three (3) business days. Please apply for a new account early to allow enough time for the registration process.
4. Offerors are solely responsible for submitting proposals and any modifications or revisions so as to reach the Government office designated above by the date and time specified in the solicitation. If your proposal is not received by the date and time specified in the solicitation, it will be considered a "late proposal," in accordance with **HHSAR 352.215-70, Late Proposals and Revisions (December 18, 2015).**

B. Creating and Naming Files:

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

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

   The Business Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned, but must be merged into the Business Proposal PDF file. Additionally, the "Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet" (http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx) must be included in the Business Proposal.

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

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

   Examples:
   Technical Proposal: *XYZ Company_NIHAI2012001_Technical.pdf*
   Business Proposal: *XYZ Company_NIHAI2012001_Business.pdf*
   Excel Workbook: *XYZ Company_NIHAI2012001_Business.xlsx*

II. FORMATTING AND PAGE LIMITATIONS:

A. Formatting for proposals

1. Proposal page layout shall be letter size 8.5” x 11" for all pages.
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 10 to 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. The total page count of the Technical proposal shall not exceed 30 pages.
2. Total page count does not include:
   a. Title and Back Page; Table of Contents; Section Dividers that do not contain information other than title of Section; and
   b. The Human Subject and Clinical Trial Information Form, if required by the solicitation.
3. Each Curriculum Vitae (CV) shall not exceed 5 pages.
4. **Pages exceeding limitations will be removed from the proposal and will not be considered.**

PROPOSAL INTENT RESPONSE FORM

RFP No: 75N93026R00005

RFP Title: RADIOLOGICAL OR NUCLEAR MEDICAL COUNTERMEASURE PRODUCT DEVELOPMENT SUPPORT (PDS)

Please review the Request for Proposal (RFP). Furnish the information requested below and return this page to the Contracting Officer/Contract Specialist identified on **Section A-Solicitation/Contract Form** by the following date: August 31, 2026

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

Choose one of the following Options:

- (●) Do intend to submit a proposal
- ( ) Do Not intend to submit a proposal

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

Please provide the following contact information:

Name (First, Middle Initial, Last):
Title:
Organization:
E-mail:

ATTACHMENT 3: BASE CONTRACT STATEMENT OF WORK

RADIOLOGICAL OR NUCLEAR MEDICAL COUNTERMEASURE PRODUCT DEVELOPMENT SUPPORT (PDS)

RFP NUMBER 75N93026R00005

Template Version 6/30/2020

BACKGROUND AND INTRODUCTION

Nuclear disasters such as the Fukushima Daiichi meltdown on March 11, 2011, have heightened awareness of radiation exposure risks to civilians. Furthermore, global unrest in regions such as Ukraine and the Middle East has intensified concerns about the potential use of chemical, biological, radiological or nuclear weapons. Radiological or nuclear attacks could involve detonation of improvised nuclear devices, assaults on nuclear power plants, discharge of radiological dispersal devices (commonly known as "dirty bombs," which combine radioactive material with conventional explosives), or the placement of radiation sources in public locations, food, or water supplies. These threats underscore the urgent need to develop clinical tools and strategies to treat radiation-induced multi-organ injuries and restore the function of critical organs after exposure.

To help meet this urgent need, the National Institute of Allergy and Infectious Diseases (NIAID) has awarded four Product Development Support contracts since 2005, which have developed in-house capabilities and partnered with subcontractors several treatments for the hematopoietic sub-syndrome of acute radiation syndrome (H-ARS), including Neupogen®, Neulasta®, and Nplate® (Amgen), which have been approved by the U.S. Food and Drug Administration (FDA). As a result of these approvals, seven biosimilars of Neulasta/Neupogen have also now been approved by the FDA. Despite these advancements, significant gaps remain in developing treatments for other acute radiation sub-syndromes (e.g., gastrointestinal (GI)-ARS) and the persistent inflammation that characterizes delayed effects of acute radiation exposure (DEARE), which can manifest months to years later and can include complications for the lungs, kidneys, heart, and skin.

The purpose of the proposed Indefinite Delivery, Indefinite Quantity (IDIQ) contract, titled "Radiological or Nuclear Medical Countermeasure Product Development Support," is to provide the facilities, expertise, and capabilities needed to develop additional radiological or nuclear medical countermeasures (MCMs) and support NIAID's biodosimetry efforts. One IDIQ contract will be awarded to an organization that can provide comprehensive product development services. NIAID will initiate, direct, and fund the work through Task Orders to support the research and development of radiological or nuclear MCMs and biodosimetry approaches along the drug or device development pathway to achieve approval, FDA licensure, or clearance. NIAID expects that the products for screening, testing, and development will come from industry, academia, and government agencies. Both the contractors and their collaborators are to have conducted some of the requested types of studies in accordance with Good Laboratory Practice (GLP) standards (21 CFR 58). Their extensive range of capabilities should include:

- Developing animal models and New Approach Methodologies (NAMs)
- Conducting efficacy tests in rodent and large [nonhuman primates (NHPs] animal models for H- and GI-ARS

- Assessing DEARE in rodent and large animal models (e.g., pigs and NHPs))
- Facilitating large animal sample distribution for testing candidate biodosimetry methods
- Evaluating radionuclide decorporation agents in rodent and canine models
- Performing animal safety studies, including pharmacokinetic and pharmacodynamic assessments
- Managing manufacturing and formulation processes
- Overseeing quality assurance activities
- Conducting Phase I Clinical Safety Studies

The Government intends to award one IDIQ contract to support these activities. Task Orders will be issued in the following areas:

- Task Area A: Administrative and Technical Support
- Task Area B: Animal Model and New Approach Methodologies (NAMs) Development, and Efficacy Testing of Candidate MCMs
- Task Area C: Non-Clinical Studies in Support of Investigational New Drug (IND)/New Drug Application (NDA)/Biologics License Application (BLA) Submissions
- Task Area D: Chemistry, Manufacturing, and Control (CMC) Support
- Task Area E: Phase I Clinical Safety Studies and Support

SCOPE

The Contractor shall establish a robust research and development framework to facilitate the progression of candidate MCMs towards obtaining FDA approval, licensure, or clearance. This infrastructure should focus on the following key areas: 1) mitigation and treatment of ARS and DEARE; 2) management and treatment of internal radionuclide contamination; and 3) support for biodosimetry efforts. This comprehensive approach will ensure that promising MCMs and biodosimetry tools are effectively developed, rigorously tested, and made available for public health medical preparedness and response use.

This IDIQ will be administered and used primarily to support NIAID Radiation and Nuclear Countermeasures Program (RNCP). However, Task Orders under this IDIQ may be initiated to support other NIAID medical countermeasure programs as necessary to help accomplish their mission.

GENERAL TASK ORDER REQUIREMENTS

The following requirements shall apply to each Task Order:

The activities carried out under this contract will adhere to the product development pathway outlined by the FDA Animal Rule, unless it is more appropriate to follow the traditional product development pathway. The FDA Animal Rule is typically used when it is not feasible or ethical to test the efficacy of certain products in humans. Therefore, the FDA will likely rely on data and information from adequate and well-controlled or GLP pivotal animal efficacy studies conducted under the Animal Rule. This is detailed in the Code of Federal Regulations (CFR) Title 21, Parts 314.600 (Subpart I) for drugs (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-D/part-314/subpart-I) and 601.90 (Subpart H) for biologics (https://www.ecfr.gov/current/title-21/chapter-I/subchapter-F/part-601/subpart-H). For further guidance, the FDA has developed a document titled "Product Development under the Animal Rule" (https://www.fda.gov/downloads/drugs/guidances/ucm399217.pdf) and an Animal Model Qualification

Program https://www.fda.gov/drugs/drug-development-tool-ddt-qualification-programs/animal-model-qualification-program-amqp).

A. All Task Orders involving animals shall be conducted in compliance with the Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals, including environmental enrichment (https://olaw.nih.gov/policies-laws/phs-policy.htm). Furthermore, animal facilities utilized by the Contractor must maintain:

1. Full and continuous accreditation by the Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC; https://www.aaalac.org/accreditation-program/rules-of-accreditation/) or equivalent;
2. Current licensure with the U.S. Department of Agriculture for animals covered under the Animal Welfare Act, or equivalent; and
3. Current Animal Welfare Assurance number on file with the Office of Laboratory Animal Welfare (OLAW; https://olaw.nih.gov/), or equivalent.

B. The Contractor must be capable of satisfying GLP (21 CFR 58), current Good Manufacturing Practice (cGMP, 21CFR 210, 211, 314, 600, 610, 801, 803, 807, 812, 814, 820, 1270, 1271 and ICH Q1-Q12) and Good Clinical Practice (GCP, 21 CFR 11, 50, 54, 56, 812, 814, and ICH E6) requirements to address the need for submission of data and reports to the FDA. Potential sources must demonstrate and document the following in their capability statements.

1. GLP-compliant facilities that can perform radiation exposure in large animals (non-human primates, dogs) and rodents;
2. Facilities capable of manufacturing MCM candidates in compliance with cGMP guidelines;
3. GLP-compliant facilities capable of performing non-clinical safety testing;
4. GCP-compliant facilities capable of performing human safety studies.

C. Capability statements submitted as a result of this announcement should demonstrate the offerors' qualifications and experience, specifically providing evidence as to their capability to perform this requirement, with particular attention to the following:

1. Development and refinement of rodent and large animal (NHP) models for hematopoietic, gastrointestinal, and lung radiation injury;
2. The performance of GLP efficacy studies for hematopoietic and gastrointestinal acute radiation syndromes in rodents and large animals (NHPs);
3. Development and refinement of a large animal (pig) model for skin radiation injury.
4. Personnel/Management: adequacy, appropriateness, and relevance of expertise, experience, qualifications, and availability of the key professional and technical staff with a project of similar size, scope, and complexity;
5. Past Performance: Past performance is considered essential. In addition to demonstrating that they have met the above qualifications, interested parties must identify at least three other projects of similar size and complexity.

D. The below-described Task Area E: Phase I Clinical Studies and Support will involve the use of human subjects. The rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and HHSAR 352.270-4 Protection of Human Subjects.

DESCRIPTION FOR INDIVIDUAL TASK AREAS

A. TASK AREA A: Administrative and Technical Support

1. **Scope of Task Area A:** Conduct administrative and technical activities on a recurring basis to support all Task Orders awarded under the base contract.

2. **Requirements for Task Area A:** The contractor shall have the capability to manage the various activities and units, including subcontractors, required for the execution of work performed under this contract. This includes Task Order and financial management, general administration, quality assurance and quality control, communications, data management, study specimen and document management, and regulatory activities.

B. TASK AREA B: Animal Model and New Approach Methodologies (NAMs) Development, and Efficacy Testing of Candidate MCMs

1. **Scope of Task Area B:** Develop, refine, and maintain animal and NAMs models of radiation injury and perform MCM efficacy studies (e.g., evaluation, characterization, optimization, and GLP protocols) and other supporting work, such as mechanism of action studies for candidate MCMs in models relevant for radiation exposure studies.

2. **Requirements for Task Area B:** The contractor shall provide facilities, expertise, and scientific oversight necessary for performing model development, efficacy studies, and other supporting studies as directed by NIAID. Facilities where animal studies are performed must have the necessary accreditation, licensure, or assurance listed in section 3A1-3. Facilities where irradiations are performed must have the necessary national, state, and local licensure or the equivalent. Facilities proposed for GLP studies must document GLP capabilities.

C. TASK AREA C: Non-Clinical Studies in Support of Investigational New Drug (IND)/New Drug Application (NDA)/Biologics License Application (BLA) Submissions

1. **Scope of Task Area C:** Test candidate MCMs for safety and/or toxicity and perform pharmacology studies as required to support their clinical use in humans.

2. **Requirements for Task Area C:** The contractor shall provide facilities and staff capable of performing studies in compliance with Good Laboratory Practice (21 CFR Part 58).

D. TASK AREA D: Chemistry, Manufacturing, and Control (CMC) Support

1. **Scope of Task Area D:** Manufacture candidate MCMs to support clinical use, including formulation development (including pediatric and special population formulations), stability testing, and current cGMP manufacture of drug candidates.

2. **Requirements for Task Area D:** The contractor shall provide facilities and staff capable of drug and biologics manufacturing, testing, and formulation in compliance with current Good Manufacturing Practice (21CFR 210, 211, 314, 600, 1270, 1271 and ICH Q1-Q12).

E. TASK AREA E: Phase I Clinical Safety Studies and Support

1. **Scope of Task Area E:** Conduct Phase I safety (including safety, tolerability, pharmacokinetic, pharmacodynamic, absorption, distribution, metabolism, and excretion) studies on candidate MCMs.

2. **Requirements for Task Area E:** The contractor shall provide facilities and staff capable of performing studies in human volunteers in compliance with Good Clinical Practice (21 CFR 11, 50, 54, 56, 812, 814, and ICH E6).

ATTACHMENT 4: TASK ORDER

RADIOLOGICAL OR NUCLEAR MEDICAL COUNTERMEASURE PRODUCT DEVELOPMENT SUPPORT (PDS)

RFP NUMBER 75N93026R00005

TASK ORDER A-1

Administrative and Technical Support

[Associated with Task Area A]

NOTE: NIAID anticipates issuing Task Order A-1 on the effective date of the contract. Offerors are to include in their proposals a response that specifies the methods by which this Task Order will be accomplished and the project management plan, with associated costs. Offerors should refer to the Additional Technical Proposal Instructions and Additional Business Proposal Instructions for guidance regarding preparation of their proposals.

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

a. **The estimated cost of the Base Period of this Task Order is $ TBD**

b. **If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the total estimated cost of the Task Order will be increased as follows:**

	Estimated Cost ($)	Estimated Cost ($)
Base Period	$TBD	$TBD
Option Period(s):	$TBD	$TBD
Total [Base Period and Option(s)]	$TBD	$TBD

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

STATEMENT OF WORK

I. BACKGROUND AND INTRODUCTION

The Department of Health and Human Services (HHS) charged the National Institute of Allergy and Infectious Diseases (NIAID) within the National Institutes of Health (NIH) with building and managing a program to develop products for the mitigation or treatment of radiation injuries resulting from exposures due to nuclear and radiological attacks.
Previous contract numbers and incumbent contractors are:

- 2005: HHSN266200500043C to the University of Maryland School of Medicine

- 2010: HHSN272201000046C to the University of Maryland School of Medicine.
- 2015: HHSN272201500013, to SRI International
- 2020: 75N93020D00011 to SRI International

II. SCOPE

The Contractor shall conduct administrative and technical activities on a recurring basis, to support all Task Orders awarded under the base contract.

III. TECHNICAL REQUIREMENTS

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

The requirements for Task Area A defined in the base Statement of Work apply to all work performed under this Task Order.

In addition to the requirements laid out in the base Statement of Work, the Contractor shall:

1. Project Management

   Plan, initiate, implement, manage, and coordinate the activities of this contract. Provide administrative and technical support for the evaluation of new Task Order Requests and for all planning activities associated with Task Orders prior to their award. Coordinate the management of all awarded Task Orders and monitor the overall progress of each Task Order to ensure that activities are on time and on budget. Provide a schedule of activities being performed under the contract. Task Order-specific project management activities will be incorporated into the Statements of Work for each Task Order.

2. Quality Assurance and Quality Control

   Provide a Quality Assurance Unit (QAU) to ensure that study reports, products, and other deliverables can be provided in compliance with Good Laboratory Practice (GLP), Good Clinical Practice (GCP), and current Good Manufacturing Practice (cGMP) guidelines when required in Task Orders. The QAU shall develop, implement and monitor adherence to a Quality Assurance/Quality Control (QA/QC) Management Plan designed to: (i) standardize contract processes, (ii) ensure that the conduct of all contract activities complies with approved standard operating procedures (SOPs), and (iii) provide for an assessment of Contractor and subcontractor performance and the quality of work provided. Specifically, the Contractor shall:

   a. Within 6 weeks of the contract effective date, develop and submit, for Contracting Officer's Representative (COR) review and approval, a Draft QA/QC Management Plan detailing the following:

      i. standard processes to be used to ensure internal QA/QC with respect to the timeliness, accuracy, and completeness of the work performed

      ii. metrics to be used to assess performance and the quality of assessment activities

iii. process for vetting subcontractors for QA/QC suitability

iv. plans and process for establishing Quality Agreements with NIAID and with subcontractors in accordance with U.S. FDA Guidance for Industry "Contract Manufacturing Arrangements for Drugs: Quality Agreements," dated November 2016 (http://www.fda.gov)

v. example of quality agreement language (such as a QA template) to be implemented with any subcontract

vi. plans for monitoring and reviewing work done by Contractor and subcontractors

vii. approaches and/or methods for implementing Quality Investigations, Corrective and Preventive Action (CAPA), and to document and address problems and deficiencies identified, including improvements in the internal QA/QC Management Plan

viii. plans for the training of Contractor and subcontractor staff on standard processes and study-related activities and measures used for internal QA/QC

ix. plans for the documentation of training and maintenance of training records

x. plans and processes for document management, including generation, change control, retention, archival, and obsolescence.

xi. plans for addressing regulatory agency inspections and audits

COR comments on the Draft QA/QC Management Plan will be provided within 2 months of receipt, and the Final QA/QC Management Plan shall be submitted to the COR within 1 month of receipt of COR comments.

b. Arrange for independent audits of Contractor and subcontractor facilities, equipment, other resources, safety training, and SOPs to ensure standardization and compliance with NIH, Federal (including Food and Drug Administration (FDA) and Occupational Safety and Health Administration (OSHA), state, and local requirements and guidelines. NIAID reserves the right to arrange for independent audits of Contractor and subcontractor facilities, equipment, other resources, safety training, and SOPs. The Contractor and any subcontractors shall comply with NIAID audits and make all necessary facilities and personnel available for any such audits.

3. Communications:

a. Participate in a one-day Contract Initiation Meeting to be held in Rockville, Maryland. The COR will schedule the meeting and will take place within two months following the effective date of the base contract, and shall be attended by the Principal Investigator and other relevant key Contractor technical and business staff, the Contracting Officer (CO), and the COR.

b. Hold an Annual Meeting at the Contractor's site to discuss the status of ongoing Task Orders, data, plans, and any other information that could assist in the evaluation and planning of the contract work. The COR and other NIAID staff will participate in this meeting.

c. At the request of NIAID or the contractor, convene regular (monthly) and ad hoc meetings or teleconferences between contract personnel and NIAID staff to review and discuss the status

of ongoing Task Orders and any technical problems or issues requiring resolution. Provide minutes to the COR within three working days of the conclusion of the meeting or teleconference.

d. In addition to the required Technical and QA/QC reports listed under Task Order deliverables, provide contract-related information and updates of Task Order activities to the CO and COR, upon request.

e. Establish a plan to collaborate with other NIH-funded researchers, private organizations, and companies conducting related research on radiation and nuclear countermeasures. Submit all proposed public presentations, publications, and disclosures containing contract-generated data to the COR at least 10 business days in advance.

4. Databases, Data, Documents, Product and Specimen, and Reagent and Inventory Management

a. Provide the capabilities to support the data requirements for all studies to be carried out under the various Task Orders, including data collection, analysis, and transfer to statistical analysis programs. The system for overall data management must be integrated into one system and be 21 CFR Part 11 compliant.

b. Provide the capabilities to securely store and retrieve documents and other files related to contract activities. The system shall be capable of maintaining confidentiality of data received from NIAID or third parties, as well as data generated within the scope of the contract. Proprietary information contained in the database shall not be used for data-mining purposes by the Contractor or subcontractors. The document management system shall be integrated and part of one system.

c. Provide the capabilities to communicate electronically between the Contractor, NIAID Division of Allergy, Immunology, and Transplantation (DAIT) staff, subcontractors, and consultants, including email, word processing, and data files. All communications must be secure, including protections against unauthorized access.

d. Provide the capabilities to manage documents and study materials for all non-clinical and pre-clinical studies. The requirements include capabilities to: 1) document receipt of compound or test article shipments from a source designated by the COR, inventory their identifiers, available amounts, and storage locations; and 2) retain and store all records, drug candidate materials, biological samples and histopathology slides and make them available to NIAID staff as indicated under all applicable FDA regulations and guidance (e.g., Good Laboratory Practice (GLP) guidelines (21 CFR 58), Investigational New Drug (IND) regulations (21 CFR 312.57), Good Clinical Practice (GCP) and/or as requested by the COR. The required system must be 21 CFR 11 compliant.

5. Regulatory Activities

Provide technical and administrative regulatory support to the Radiation/Nuclear Countermeasure Product (RNCP), inclusive of relevant DAIT program staff and contractors, investigators at NIAID-supported sites, and industry collaborators. These functions are to support Investigational

New Drug (IND), New Drug Application (NDA), Biologics License Application (BLA), Investigational Device Exemption (IDE) applications, 510(k) or Pre-Market Notification (PMN) submissions, or amendments to an existing application(s) held by NIAID, companies, and NIAID-supported investigators. The Contractor shall have the capability to provide the support activities delineated below, though NIAID may only require a subset of these regulatory support functions at any point in time.

a. Regulatory Submissions and Reports.

   i. Assist in preparing materials (e.g., information briefing packages) for, and participate in, meetings and teleconferences with officials of Regulatory Health Authorities to address questions and provide additional information pertinent to regulatory submissions. Work with the COR or his or her designee to prepare and submit written summaries of major decisions and action items resulting from all such meetings and teleconferences within 5 business days of meeting or teleconference completion, or in accordance with Regulatory Health Authority requirements.

   ii. Assist in the preparation and submission of responses to inquiries from Regulatory Health Authorities relating to Drug Master Files, INDs, IDEs, and/or other regulatory submissions held by NIAID, companies, and NIAID-supported investigators.

   iii. Assist in the preparation of Annual Reports relating to IND, IDE, and other applications held by NIAID, companies, and NIAID-sponsored investigators, as required by Regulatory Health Authorities and in accordance with appropriate regulations and guidance.

   iv. Provide for the appropriate labeling, storage, handling, and disposal of sensitive or confidential data, media, and output. Work with the COR to ensure that an accurate file-related regulatory correspondence and submissions system will be maintained.

   v. Participate as necessary and as directed by the COR in discussions with the FDA during pre-IND, IND animal qualification, pre-NDA/BLA, and other meetings.

b. Support the preparation and submission of study protocols, statistical analysis plans (SAP), data management, study reports, IND applications, IND, NDA, or BLA Amendments or Supplements to the FDA, or other supporting documentation prepared for submission to Health Authorities in support of applications held by NIAID, companies, and NIAID-sponsored investigators.

c. Maintain current knowledge of the developing regulatory environment regarding requirements for animal research and the FDA regulatory guideline for animal studies in support of approval, licensure, or clearance.

d. Maintain a log of study personnel and their involvement in the conduct of studies.

e. Section 306(k) of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 335a(k)), as amended by the Generic Drug Enforcement Act of 1992 (GDEA), requires that drug product applicants certify that they did not and will not use in any capacity the services of any debarred persons in connection with a drug product application. Contract Manufacturing Organization (CMO) warrants and represents that it did not and shall not use in any capacity the services of any person debarred under the 21 U.S.C. §335a(k)(1), and further, did not use any person who has been convicted of a crime as defined under the GDEA in connection with the services rendered to NIAID. Therefore, the Contractor shall provide written assurance that debarred, disqualified, or restricted individuals do not participate in the conduct of any studies. The FDA Debarment List may be found at: https://www.fda.gov/ICECI/EnforcementActions/FDADebarmentList.

6. Transition activities

a. Initial Transition: The Contractor shall ensure an orderly, secure, and efficient transition of Task Order-related materials and activities from the successor contractor or from the Government. A description of transition activities, timelines, and assigned staff shall be provided in a Draft and Initial Transition Plan, which will be reviewed and approved by the Contracting Officer's Representative. The Draft Transition Plan shall be submitted with the proposal, and the Initial Transition Plan (approved by the Contracting Officer's Representative and Contracting Officer) shall be submitted [Insert Number] months prior to the start date of the Task Order.
b. Final Transition: The Contractor shall ensure an orderly, secure, and efficient transition of Task Order-related materials and activities to the successor contractor or to the Government. A description of transition activities, timelines, and assigned staff shall be provided in a Draft and Final Transition Plan, which will be reviewed and approved by the Contracting Officer's Representative. The Draft Transition Plan shall be submitted [Insert Number] months prior to the completion date of the Task Order, and the Final Transition Plan (approved by the Contracting Officer's Representative and Contracting Officer) shall be submitted [Insert Number] months prior to the completion date of the contract.

Option(s)

In addition to the services/quantities outlined above to be provided for the base requirement, Options(s) for additional services/quantities under the Task Order may be exercised at the discretion of the Government and are defined as follows:

Option 1 - 6: Extend the Term of the Task Order: The Government may include options to extend the period of the performance. The total period of performance resulting from the base period plus all potential Term Options is 7 years. If Options 1-6 are exercised, the services required will be the same as provided during the base year.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional D. clauses applicable to this Task Order beyond those in the base contract.

SECTION E – INSPECTION AND ACCEPTANCE

There are no additional E. clauses applicable to this Task Order beyond those in the base contract.

SECTION F – DELIVERIES OR PERFORMANCE

a. The period of performance of this contract shall be from TBD through TBD (*not to exceed 1 year from task order award date*).
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 1	TBD (not to exceed 1 year)
Option 2	TBD (not to exceed 1 year)
Option 3	TBD (not to exceed 1 year)
Option 4	TBD (not to exceed 1 year)
Option 5	TBD (not to exceed 1 year)
Option 6	TBD (not to exceed 1 year)

c. In the performance of this Task Order, the Contractor shall provide TBD direct labor hours annually during the base period and Options 1 through 6 if exercised by the Government.

TASK ORDER REPORTING REQUIREMENTS AND DELIVERABLES

TASK ORDER REPORTING REQUIREMENTS

Technical Reports

All reports required herein shall be submitted in electronic format via NIAID's electronic Report Deliverable Submission (eRDS) system, with a copy sent to the COR via email at the time of eRDS submission.

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

Technical Reports
In addition to those reports required by the other terms of this task order, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this task order:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH-funded research.]

a) **Quarterly Progress Report**
This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

b) **Annual Progress Report**
This report shall include a summation of the results of the entire task order work for the period covered. An annual report will not be required for the period when the Final Report is due. A Quarterly Report shall not be submitted when an Annual Report is due.

c) **Final Report**
This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved and will include a summary (not to exceed 200 words) of salient results achieved during the performance of all Task Order work. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this task order. An Annual Report will not be required for the period when the Final Report is due.

TASK ORDER DELIVERABLES

Technical Progress Reports

Item	Reports	Recipients	Delivery Schedule
a.	Quarterly Progress Report	eRDS submission plus 1 email copy to COR and CO	Each report is due on the 15th of the month following each reporting period. The report for the Administrative Task Order will include reports from all ongoing Task Orders.
b.	Annual Progress Report	eRDS submission plus 1 email copy to COR and CO	Each report is due on the 15th of the month following each anniversary date of the Task Order. The report for the Administrative Task Order will include reports from all ongoing Task Orders.
c.	Annual Utilization Report	eRDS submission plus 1 email copy to COR and CO	Due on the 30th of the month following each anniversary date of the Task Order.

Item	Reports	Recipients	Delivery Schedule
d.	Final Invention Statement	eRDS submission plus 1 email copy to COR and CO	Due on expiration date of the Task Order.
e.	All reports and documentation including the invention disclosure report, the confirmatory license, and the government support certification	1 copy to OPERA	As required by FAR Clause 52.227-11.
f.	Final Report	eRDS submission plus 1 email copy to COR and CO	Final Report is due on the expiration date of the last Task Order.

Other Reports and Deliverables (Delivery Schedule)

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
a.	Draft QA/QC Management Plan	III.2.a	eRDS submission plus 1 email copy to COR and CO	Six weeks after Contract effective date
b.	Final QA/QC Management Plan	III.2.a	eRDS submission plus 1 email copy to COR and CO	One month after COR comments are received.
c.	Audit Reports	III.2.b	eRDS submission plus 1 email copy to COR and CO	One month after receipt of response to audit report
d.	Meeting Minutes	III.3.c	eRDS submission plus 1 email copy to COR and CO	Three business days after meeting or teleconference

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
e.	Materials for Submission to FDA	III.5.a., b	eRDS submission plus 1 email copy to COR and CO	As requested by COR

SECTION G – TASK ORDER ADMINISTRATION DATA

There are no additional G. clauses applicable to this Task Order beyond those in the base contract.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

There are no additional H. clauses applicable to this Task Order beyond those in the base contract.

ATTACHMENT 5: TASK ORDER

RADIOLOGICAL OR NUCLEAR MEDICAL COUNTERMEASURE PRODUCT DEVELOPMENT SUPPORT (PDS)

RFP NUMBER 75N93026R00005

TASK ORDER B-1

Animal Model and New Approach Methodologies (NAMs) Development, and Efficacy Testing of Candidate Medical Countermeasures (MCMs)

[Associated with Task Area B]

NOTE: NIAID anticipates issuing Task Order B-1 on the effective date of the contract. Offerors are to include in their proposals a response that specifies the methods by which this Task Order will be accomplished and the project management plan, with associated costs. Offerors should refer to the Additional Technical Proposal Instructions and Additional Business Proposal Instructions for guidance regarding preparation of their proposals.

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

The estimated cost of this task order is $ TBD

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

STATEMENT OF WORK

I. BACKGROUND AND INTRODUCTION

The Department of Health and Human Services (HHS) charged the National Institute of Allergy and Infectious Diseases (NIAID) within the National Institutes of Health (NIH) with building and managing a program to develop products for the mitigation or treatment of radiation injuries from exposures due to nuclear and radiological attacks.

II. SCOPE

The Contractor shall develop, maintain, and use animal models and New Approach Methodologies (NAMs) as standards that provide quantifiable and comparable data to 1) screen candidate medical countermeasures (MCMs) for initial activity; and 2) further evaluate the efficacy of selected candidate MCMs to optimize the dose; obtain comparative, mechanistic, and pharmacological information. Animal efficacy studies and mechanism of action studies for candidate MCMs shall be performed in rodents as well as large animals. NIAID will work with various commercial, academic, and government collaborators who will provide material for testing.

III. TECHNICAL REQUIREMENTS

Independently, and not as an agent of the Government, the Contractor shall furnish qualified personnel, materials, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Work below.

The requirements for Task Area B defined in the base Statement of Work apply to all work performed under this Task Order.

Specifically, the Contractor shall:

1. Fulfill all administrative requirements outlined in Task Order A, as appropriate for the work to be conducted in this Task Order.

2. As directed by the Contracting Officer's Representative (COR), provide animal models and NAMs that are relevant to the human radiation response. For example, these models need to:

    a. Quantitatively assess primary endpoints (survival and/or selected indicators of radiation-induced morbidity) to detect statistically significant differences between treatment and control groups;

    b. Evaluate secondary parameters such as mechanistic, molecular, physicochemical, biological, pharmacokinetic, pharmacodynamic, and immunological parameters;

    c. Include supportive care or medical management elements as appropriate to simulate medical management expected in a mass casualty incident;

    d. Perform validated tests such as dosimetry and/or bioassays to quantify and document radiation exposure levels (Note that facilities in which animals will be irradiated will be expected to participate in a NIAID radiation program-wide dosimetry harmonization effort);

    e. As appropriate, observe and measure general toxicity, including body weight, food consumption, body temperature, behavior, and other indicators of general health; determination, observation, and recording of toxicity; and

    f. As appropriate, perform gross pathology and histopathology upon necropsy following death or euthanasia.

3. Perform efficacy evaluation and comparison studies of candidate MCMs to further product development as requested by the COR. These activities could include:

    a. Mechanism of action

    b. Candidate MCM formulation

    c. Route of administration

    d. Effective dose levels and dose schedules

    e. Timing of administration post-irradiation

    f. Pharmacokinetics and pharmacodynamics.

4. For the studies described in sections III.2 and III.3, above, submit Protocols, Amendments, and Outcome Reports to the COR, receive approval by the COR prior to initiation of each study,

and file approved Protocols, Amendments, and reports to the DAIT Regulatory Management Center. Include the appropriate statistics in planning and performing data analysis.

5. Develop and maintain Protocols and standard operating procedures (SOPs) for activities specific to this Task Order, including protocols for IACUC review and approval. Work with the COR and other NIAID staff to communicate with NIAID and the collaborator through teleconferences, meetings, or email. For teleconferences or meetings, provide minutes to the COR within three working days of the conclusion of the teleconference or meeting.

6. Work with the COR and his or her designee to qualify animal models and NAMs with the FDA under the Animal Models Qualification Program (https://www.fda.gov/drugs/drug-development-tool-ddt-qualification-programs/animal-model-qualification-program-amqp).

7. Prepare meeting abstracts, posters, manuscripts and other experimental summaries and reports, as requested by the COR.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional D. clauses applicable to this Task Order beyond those in the base contract.

SECTION E – INSPECTION AND ACCEPTANCE

There are no additional E. clauses applicable to this Task Order beyond those in the base contract.

SECTION F – DELIVERIES OR PERFORMANCE

The period of performance of this contract shall be from TBD through TBD.

TASK ORDER REPORTING REQUIREMENTS AND DELIVERABLES

TASK ORDER REPORTING REQUIREMENTS

Technical Reports

All reports required herein shall be submitted in electronic format via NIAID's electronic Report Deliverable Submission (eRDS) system, with a copy sent to the COR via email at the time of eRDS submission.

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

1) **Technical Reports**

In addition to those reports required by the other terms of this Task Order, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this Task Order:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH funded research.]

a) **Quarterly Progress Report**
This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

b) **Annual Progress Report**
This report shall include a summation of the results of the entire Task Order work for the period covered. A Quarterly Report will not be required when the Annual Progress Report is due.

c) **Final Report**
This report is to include a summation of the work performed and results obtained for the entire contract period of performance and will include a summary (not to exceed 200 words) of salient results achieved during the performance of all Task Order work. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this task order. An Annual Report will not be required for the period when the Final Report is due.

TASK ORDER DELIVERABLES

1. Technical Progress Reports

Item	Reports	Recipients	Delivery Schedule
a.	Quarterly Progress Report	eRDS submission plus 1 email copy to COR and CO	Each report is due on the 15th of the month following each reporting period.
b.	Annual Progress Report	eRDS submission plus 1 email copy to COR and CO	Each report is due on the 15th of the month following each anniversary date of the Task Order.
c.	Final Report	eRDS submission plus 1 email copy to COR and CO	Final Report is due on the completion date of the Task Order.

2. Other Reports and Deliverables (Delivery Schedule)

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
a.	Schedules of studies planned, in progress and completed.	III.1	eRDS submission plus 1 email copy to COR and CO	To be updated at least monthly.
b.	Study Protocols	III.2-5	eRDS submission plus 1 email copy to COR and CO	Prior to study initiation.
c.	Draft Study Reports	III.2-5	eRDS submission plus 1 email copy to COR and CO	Within 30 calendar days after completion of each study.
d.	Final Study Reports	III.2-5	eRDS submission plus 1 email copy to COR and CO	Within 30 calendar days after completion of NIAID review.
e.	Meeting Minutes	III.5	eRDS submission plus 1 email copy to COR and CO	Three business days after meeting or teleconference
f.	Abstracts, posters, manuscripts, animal model letter of intent and qualification plan, press releases, other experimental summaries and reports	III.6-7	eRDS submission plus 1 email copy to COR and CO	For outside communications, prior approval from COR.

There are no additional E. clauses applicable to this Task Order beyond those in the base contract.

SECTION G – TASK ORDER ADMINISTRATION DATA

There are no additional G. clauses applicable to this Task Order beyond those in the base contract.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

There are no additional H. clauses applicable to this Task Order beyond those in

ATTACHMENT 6: SAMPLE TASK ORDER

RADIOLOGICAL OR NUCLEAR MEDICAL COUNTERMEASURE PRODUCT DEVELOPMENT SUPPORT (PDS)

RFP NUMBER 75N93026R00005

SAMPLE TASK ORDER B-2

Pivotal Efficacy Studies for Gastrointestinal Medical Countermeasure in Mouse and Nonhuman Primate

[Associated with Task Area B]

NOTE: The following Sample Task Order indicated in this Attachment is provided to assess the Offeror's capabilities to conduct and fulfill the requirements of the Statement of Work for projects of similar scope and size to be issued under contracts awarded in response to this solicitation. Although the Sample Task Order will NOT be executed nor will awards be made for the Sample Task Order, Offerors are to include in their proposals a response that specifies the methods by which each Sample Task Order will be accomplished and the project management plan, with associated costs. Offerors should refer to the Additional Technical Proposal Instructions and Additional Business Proposal Instructions for guidance regarding preparation of their proposal

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

The estimated cost of this task order is $ TBD.

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

STATEMENT OF WORK

I. BACKGROUND AND INTRODUCTION

The Department of Health and Human Services (HHS) charged the National Institute of Allergy and Infectious Diseases (NIAID) within the National Institutes of Health (NIH) with building and managing a program to develop products for the mitigation or treatment of radiation injuries from exposures due to nuclear and radiological attacks.

II. SCOPE

The Contractor shall generate efficacy data in Good Laboratory Practice (GLP) pivotal animal efficacy studies in rodent and non-human (NHP) models for a given medical countermeasure (MCM) suitable for submission to the FDA to satisfy the requirement for well-controlled efficacy studies under the "Animal Rule" (21 CFR 314.600-650 (pharmaceuticals) and 21 CFR 601.90-95 (biologics)).

Note: For purposes of preparing a technical and business response, assume that the Contractor is tasked with developing and executing protocols to evaluate the efficacy of a novel small molecule as part of the product development leading to licensure by the Food and Drug Administration (FDA). Assume that preliminary studies using the medical countermeasure have shown 30% efficacy (LD_{50} to LD_{20}) over 30 days in mouse and rhesus macaque gastrointestinal radiation injury models with 2.5% bone marrow

shielding. In these studies, the drug was administered subcutaneously at 5 mg/kg (in mice) or 1.3 mg/kg (in rhesus macaques), given twice daily for 5 days, starting 24 hours after radiation exposure. No toxicity was observed in those studies aside from that typical of radiation injury. The medical countermeasure will be provided by the manufacturer as Good Manufacturing Practice (GMP)-produced liquid in sterile multi-dose vials. It is stored at room temperature. A vehicle control will be provided that is identical in appearance except for the label.

III. TECHNICAL REQUIREMENTS

Independently, and not as an agent of the Government, the Contractor shall furnish qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work below.

The requirements for Task Area B defined in the base Statement of Work apply to all work performed under this Task Order.

Specifically, the Contractor shall

1. Fulfill all administrative requirements outlined in Task Order A, as appropriate for the work to be conducted in this Task Order.

1. Perform GLP pivotal animal studies in mouse and NHP to obtain data to demonstrate efficacy of a radiological or nuclear MCM for the gastrointestinal syndrome of the acute radiation syndrome (GI-ARS). Include the appropriate statistics in planning and data analysis. Specify interim analyses for futility or efficacy to justify stopping the study at predetermined times. Provide Interim Analysis reports to NIAID Data Monitoring Committee, as designated by the Contracting Officer's Representative (COR). Receive approval of Study Protocols and Amendments from the COR prior to initiation of the study. Quantitatively assess primary endpoints (survival and/or selected indicators of radiation-induced morbidity) to detect statistically significant differences between treatment and control groups of animals.

3. The animal studies shall include:
   a. Quantitative assessments of primary endpoints to detect statistically significant differences between treatment and control groups of animals;
   b. Inclusion of supportive care or medical management elements as appropriate to simulate medical management expected in a mass casualty incident and as required by the Institutional Animal Care and Use Committee (IACUC);
   c. Performance of validated tests such as dosimetry and/or bioassays in order to quantify and document radiation exposure levels to animals;
   d. As appropriate, observation and measurement of general toxicity, including body weight, food consumption, body temperature, behavior, and other indicators of general health, as appropriate, and determination, observation, and recording of adverse events; and
   e. As appropriate, gross pathology and histopathology upon necropsy following death or euthanasia.

4. Prepare meeting abstracts, posters, manuscripts, and other experimental summaries and reports, as requested by the COR.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional D. clauses applicable to this Task Order beyond those in the base contract.

SECTION E – INSPECTION AND ACCEPTANCE

There are no additional E. clauses applicable to this Task Order beyond those in the base contract.

SECTION F – DELIVERIES OR PERFORMANCE

The period of performance of this contract shall be from TBD through TBD.

TASK ORDER REPORTING REQUIREMENTS AND DELIVERABLES

TASK ORDER REPORTING REQUIREMENTS

Technical Reports

All reports required herein shall be submitted in electronic format via NIAID's electronic Report Deliverable Submission (eRDS) system, with a copy sent to the COR via email at the time of eRDS submission.

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

1. **Technical Reports**
   In addition to those reports required by the other terms of this Task Order, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this Task Order:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH-funded research.]

a) **Quarterly Progress Report**
   This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance, including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

b) **Annual Progress Report**
   This report shall include a summation of the results of the entire Task Order work for the period covered. A Quarterly Report will not be required when the Annual Progress Report is due.

c) **Final Report**
   This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved and will include a summary (not to exceed 200 words) of salient results achieved

during the performance of all Task Order work. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this task order. An Annual Progress Report will not be required for the period when the Final Report is due.

TASK ORDER DELIVERABLES

1. Technical Progress Reports

Item	Reports	Recipients	Delivery Schedule
a.	Quarterly Progress Report	eRDS submission plus 1 email copy to COR and CO	Each report is due on the 15th of the month following each reporting period.
b.	Annual Progress Report	eRDS submission plus 1 email copy to COR and CO	Each report is due on the 15th of the month following each anniversary date of the Task Order.
c.	Final Report	eRDS submission plus 1 email copy to COR and CO	Final Report is due on the completion date of the Task Order.

2. Other Reports and Deliverables (Delivery Schedule)

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
a.	Study Protocols	III.1-2	eRDS submission plus 1 email copy to COR and CO	Prior to study initiation.
b.	Interim Analysis	III.1-2	eRDS submission plus 1 email copy to COR and CO	As requested by COR and upon completion and audit.

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
c.	Draft Study Report	III. 1-2	eRDS submission plus 1 email copy to COR and CO	Within 30 calendar days after completion of each study.
d.	Final Study Report	III.1-2	eRDS submission plus 1 email copy to COR and CO	Within 30 calendar days after acceptance of the Draft Study Report.
e.	Abstracts, posters, manuscripts, press releases, other experimental summaries and reports	III.1, 2, 4	eRDS submission plus 1 email copy to COR and CO	Submit for approval to the COR 10 business days before planned public release/submission.

SECTION G – TASK ORDER ADMINISTRATION DATA

There are no additional G. clauses applicable to this Task Order beyond those in the base contract.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

There are no additional H. clauses applicable to this Task Order beyond those in the base contract.

ATTACHMENT 7: SAMPLE TASK ORDER

RADIOLOGICAL OR NUCLEAR MEDICAL COUNTERMEASURE PRODUCT DEVELOPMENT SUPPORT (PDS)

RFP NUMBER 75N93026R00005

SAMPLE TASK ORDER C-1

Non-Clinical Studies in Support of Investigational New Drug (IND)/New Drug Application (NDA)/Biologics License Application (BLA) Submissions -

[Associated with Task Area C]

NOTE: The following Sample Task Order indicated in this Attachment is provided to assess the Offeror's capabilities to conduct and fulfill the requirements of the Statement of Work for projects of similar scope and size to be issued under contracts awarded in response to this solicitation. Although the Sample Task Order will NOT be executed nor will awards be made for the Sample Task Order, Offerors are to include in their proposals a response that specifies the methods by which each Sample Task Order will be accomplished and the project management plan, with associated costs. Offerors should refer to the Additional Technical Proposal Instructions and Additional Business Proposal Instructions for guidance regarding preparation of their proposals.

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

The estimated cost of this task order is $ TBD

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

STATEMENT OF WORK

I. BACKGROUND AND INTRODUCTION

The Department of Health and Human Services (HHS) charged the National Institute of Allergy and Infectious Diseases (NIAID) within the National Institutes of Health (NIH) with building and managing a program to develop products for the mitigation or treatment of radiation injuries from exposures due to nuclear and radiological attacks.

II. SCOPE

The Contractor shall test candidate medical countermeasures (MCMs) for safety and toxicity and perform pharmacology studies as required to support clinical use in humans of a therapeutic product.

Note: For purposes of preparing a technical and business response, assume that the Contractor is tasked with developing a strategy for nonclinical studies to evaluate the pharmacology and toxicology of a novel MCM as part of the product development leading to licensure by the Food and Drug Administration (FDA). Assume that the MCM has shown efficacy regarding hematopoietic radiation injury in preliminary studies in mice when administered Intramuscular (IM) at 5 mg/kg per dose given twice daily for 5 days. No toxicity was observed in those studies aside from that typical of radiation injury. The medical countermeasure is currently available as a current Good Manufacturing Practice (cGMP)-

produced liquid solution and is available to the offeror in sterile multi-dose vials. It is stored at room temperature. Validated methods for testing pharmacodynamics are available. A vehicle control will be provided that is identical in appearance except for the label.

III. TECHNICAL REQUIREMENTS

Independently, and not as an agent of the Government, the Contractor shall furnish qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work below.

The requirements for Task Area B defined in the base Statement of Work apply to all work performed under this Task Order.

Specifically, the Contractor shall:

1. Fulfill all administrative requirements outlined in Task Order A, as appropriate for the work to be conducted in this Task Order.

2. Work with the Contracting Officer's Representative (COR) and his or her designee to develop a non-clinical strategy and plan for the medical countermeasure. The plan shall include the strategy and list the pharmacologic and toxicological protocols appropriate for Investigational New Drug (IND), New Drug Application (NDA), or Biological License Application (BLA) submission.

3. Provide a schedule for studies with milestones and go/no-go decision points.

4. Perform tests required to qualify the medical countermeasure for human administration including the list below. Such testing shall also include tests required for an IND application. All studies shall be performed in accordance with Good Laboratory Practices (GLP) regulations (21 CFR 58) unless otherwise specified by the COR in writing. These shall include the development of validated analytical methods for assessing concentrations of test article or active metabolite in biological fluids, such as blood, for testing of pharmacokinetics, validated methods for testing pharmacodynamics, and other parameters, such as immunogenicity.

    a. Nonclinical toxicity safety pharmacology evaluations of the MCM in animals, to include:

        i. Determination of the maximum tolerated dose (MTD);

        ii. Determination of acute and subchronic systemic toxicity;

        iii. Determination of relevant pharmacokinetic (PK), toxicokinetic and pharmacodynamic (PD) parameters;

        iv. Bioavailability studies; and

        v. Absorption, distribution, metabolism, and excretion (ADME) studies.

    b. Other nonclinical toxicity/safety studies, using appropriate animal and *in vitro* assays to include:

i. Genetic toxicity of candidate drugs or test articles;

ii. Carcinogenicity studies that may be appropriate under certain conditions; for example, compounds expected to be administered for extended periods of time;

iii. Reproductive toxicity studies, as appropriate. Such studies shall include fertility, general reproductive performance, teratology, and developmental toxicity;

iv. Immunotoxicity studies to determine the toxicity of candidate drugs to the immune system, or other specialized target organ system;

v. Biotransformation assays: assays conducted *in vitro* to evaluate the potential of candidate drugs to undergo biotransformation in test animals and humans;

vi. Additional pharmacologic assays: assays and studies to determine additional pharmacologic parameters of candidate drugs such as tissue distribution, and mass balance; and

vii. Other safety and pharmacology assays and studies that NIAID may require for a particular drug candidate, such as pharmacodynamics and immunogenicity testing.

5. Additional tasks:

a. Evaluate the data resulting from the conduct of the above studies and draw relevant conclusions about pharmacokinetics, organ toxicity, and potential human adverse reactions to the evaluated candidate drugs;

b. Acquire, validate, and utilize assay and/or organism-specific standardized reagents and controls to the extent possible;

c. As requested by the COR, participate in discussions with the Food and Drug Administration (FDA) during pre-IND, IND, and pre-NDA/BLA meetings.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional D. clauses applicable to this Task Order beyond those in the base contract.

SECTION E – INSPECTION AND ACCEPTANCE

There are no additional E. clauses applicable to this Task Order beyond those in the base contract.

SECTION F – DELIVERIES OR PERFORMANCE

The period of performance of this contract shall be from TBD through TBD

TASK ORDER REPORTING REQUIREMENTS AND DELIVERABLES

TASK ORDER REPORTING REQUIREMENTS

Technical Reports

All reports required herein shall be submitted in electronic format via NIAID's electronic Report Deliverable Submission (eRDS) system, with a copy sent to the COR via email at the time of eRDS submission.

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

1. **Technical Reports**
In addition to those reports required by the other terms of this Task Order, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this Task Order:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH-funded research.]

a) Quarterly Progress Report
This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance, including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

b) Annual Progress Report
This report shall include a summation of the results of the entire Task Order work for the period covered. A Quarterly Report will not be required when the Annual Progress Report is due.

c) Final Report
This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved and will include a summary (not to exceed 200 words) of salient results achieved during the performance of all Task Order work. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this task order. An Annual Progress Report will not be required for the period when the Final Report is due.

TASK ORDER DELIVERABLES

1. Technical Progress Reports

Item	Reports	Recipients	Delivery Schedule
a.	Quarterly Progress Report	eRDS submission plus 1 email copy to COR and CO	Each report is due on the 15th of the month following each reporting period.
b.	Annual Progress Report	eRDS submission plus 1 email copy to COR and CO	Each report is due on the 15th of the month following each anniversary date of the Task Order.
c.	Final Report and Summary of Salient Results	eRDS submission plus 1 email copy to COR and CO	Final Report is due on the completion date of the Task Order.

2. Other Reports and Deliverables (Delivery Schedule)

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
a.	Schedules of studies planned, in progress and completed.	III.2-4	eRDS submission plus 1 email copy to COR and CO	To be updated at least monthly.
b.	Draft Plan for nonclinical development	III.2, 3	eRDS submission plus 1 email copy to COR and CO	Within 30 calendar days of Task Order initiation.
c.	Final Plan	III.2, 3	eRDS submission plus 1 email copy to COR and CO	Within 30 calendar days of receipt of COR comments.

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
d.	Study Protocols	III.4	eRDS submission plus 1 email copy to COR and CO	Prior to study initiation.
e.	Draft and Final Study Reports	III.4, 5	eRDS submission plus 1 email copy to COR and CO	Within 30 calendar days after completion of each study.

SECTION G – TASK ORDER ADMINISTRATION DATA

There are no additional G. clauses applicable to this Task Order beyond those in the base contract.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

There are no additional H. clauses applicable to this Task Order beyond those in the base contract.

ATTACHMENT 8: SAMPLE TASK ORDER

RADIOLOGICAL OR NUCLEAR MEDICAL COUNTERMEASURE PRODUCT DEVELOPMENT SUPPORT (PDS)

RFP NUMBER 75N93026R00005

SAMPLE TASK ORDER D-1

Chemistry, Manufacturing and Control (CMC) Support

[Associated with Task Area D]

NOTE: The following Sample Task Order indicated in this Attachment is provided to assess the Offeror's capabilities to conduct and fulfill the requirements of the Statement of Work for projects of similar scope and size to be issued under contracts awarded in response to this solicitation. Although the Sample Task Order will NOT be executed nor will awards be made for the Sample Task Order, Offerors are to include in their proposals a response that specifies the methods by which each Sample Task Order will be accomplished and the project management plan, with associated costs. Offerors should refer to the Additional Technical Proposal Instructions and Additional Business Proposal Instructions for guidance regarding preparation of their proposals.

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

The estimated cost of this task order is $ TBD

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

STATEMENT OF WORK

I. BACKGROUND AND INTRODUCTION

The Department of Health and Human Services (HHS) charged the National Institute of Allergy and Infectious Diseases (NIAID) within the National Institutes of Health (NIH) with building and managing a program to develop products for the mitigation or treatment of radiation injuries from exposures due to nuclear and radiological attacks.

II. SCOPE

The Contractor shall manufacture candidate medical countermeasures (MCMs) to support clinical use, including formulation development (including pediatric and special population formulations), stability testing, and current Good Manufacturing Practice (cGMP) manufacture of drug candidates.

Note: For purposes of preparing a technical and business response, assume that the Contractor is tasked with the production of a medical countermeasure for use in Phase 1 and non-Good Laboratory Practice (GLP) animal efficacy studies. Assume that the medical countermeasure is a novel biological substance that has been purified from *Escherichia coli* in a basic research lab, using standard methods. All available information about the purification process and biological properties of the medical countermeasure will be provided by the inventor. The research lab has produced 1 gram of material. The target dose of the medical countermeasure is 1 mg, administered subcutaneously once daily for 5 days. The medical

countermeasure is stable at ambient temperature, and shipment will not require the use of a controlled temperature environment.

III. TECHNICAL REQUIREMENTS

Independently, and not as an agent of the Government, the Contractor shall furnish qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below.

The requirements for Task Area D defined in the base Statement of Work apply to all work performed under this Task Order.

Specifically, the Contractor shall:

1. Fulfill all administrative requirements outlined in Task Order A, as appropriate for the work to be conducted in this Task Order.

2. Conduct cGMP-compliant manufacturing processes and procedures (in accordance with 21 CFR parts 312.23, 211, 210, 600-680, 1270, 1271, applicable sections of International Council for Harmonisation (ICH) guidelines Q1-Q12, applicable U.S. Food and Drug Administration (FDA) Guidance for Industry, and other laws and regulations as appropriate) including manufacture of master and cell banks, manufacture of bulk products and formulated products including sterilization, packaging, labeling, storage and distribution that meet all FDA and NIAID standards and requirements. The activities shall include:

    a. Development of pilot-scale manufacturing plans and activities for the biologic substance and biologic product;

    b. Production of batches and lots of the medical countermeasure. Produce 500 vials containing 25 mg each of the medical countermeasure for the conduct of GLP safety studies, GLP animal efficacy studies, and clinical safety studies; and additional MCM for stability studies;

    c. Performance of necessary tests on each batch for the assessments of concentration, identity, integrity, purity, potency, and contamination for cGMP bulk substance and formulated product characterization tests required for release for clinical use;

    d. Cooperation with independent audits and inspections of facilities;

    e. Collection of information and materials for regulatory submissions.

3. Perform stability studies in compliance with cGMP to support regulatory submissions.

4. Provide oversight and audits of facilities and studies to ensure personnel, equipment, and facilities are compliant with appropriate regulatory requirements.

5. Collect information and prepare reports and materials for regulatory submissions.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional D. clauses applicable to this Task Order beyond those in the base contract.

SECTION E – INSPECTION AND ACCEPTANCE

There are no additional E. clauses applicable to this Task Order beyond those in the base contract.

SECTION F – DELIVERIES OR PERFORMANCE

The period of performance of this contract shall be from TBD through TBD.

TASK ORDER REPORTING REQUIREMENTS AND DELIVERABLES

TASK ORDER REPORTING REQUIREMENTS

Technical Reports

All reports required herein shall be submitted in electronic format via NIAID's electronic Report Deliverable Submission (eRDS) system, with a copy sent to the COR via email at the time of eRDS submission.

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

1. **Technical Reports**
   In addition to those reports required by the other terms of this Task Order, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this Task Order:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH-funded research.]

a) **Quarterly Progress Report**
   This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance, including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

b) **Annual Progress Report**
   This report shall include a summation of the results of the entire Task Order work for the period covered. A Quarterly Report will not be required when the Annual Progress Report is due.

c) **Final Report**
   This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved and will include a summary (not to exceed 200 words) of salient results achieved during the performance of all Task Order work. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this task order. An Annual Progress Report will not be required for the period when the Final Report is due.

TASK ORDER DELIVERABLES

1. Technical Progress Reports

Item	Reports	Recipients	Delivery Schedule
a.	Quarterly Progress Report	eRDS submission plus 1 email copy to COR and CO	Each report is due on the 15th of the month following each reporting period.
b.	Annual Progress Report	eRDS submission plus 1 email copy to COR and CO	Each report is due on the 15th of the month following each anniversary date of the Task Order.
c.	Annual Utilization Report	eRDS submission plus 1 email copy to COR and CO	Due on/before the 15th of the month following each anniversary date of the task order.
d.	Final Report	eRDS submission plus 1 email copy to COR and CO	Final Report is due on the completion date of the Task Order.

2. Other Reports and Deliverables (Delivery Schedule)

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
a.	Draft Stability Study Protocols	III.3	eRDS submission plus 1 email copy to COR and CO	15 calendar days prior to initiating study

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
b.	Final Stability Study Report	III.3	eRDS submission plus 1 email copy to COR and CO	Within 30 calendar days after completion of each study.
c.	Manufactured Product	III.2.b	To be specified 60 days prior to task order completion	At or before task order completion
d.	Reports for Regulatory Submissions	III.5	eRDS submission plus 1 email copy to COR and CO	As requested by COR

SECTION G – TASK ORDER ADMINISTRATION DATA

There are no additional G. clauses applicable to this Task Order beyond those in the base contract.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

There are no additional H. clauses applicable to this Task Order beyond those in the base contract.

ATTACHMENT 9: SAMPLE TASK ORDER

RADIOLOGICAL OR NUCLEAR MEDICAL COUNTERMEASURE PRODUCT DEVELOPMENT SUPPORT (PDS)

RFP NUMBER 75N93026R00005

SAMPLE TASK ORDER E-1

Phase I Clinical Safety Studies and Support

[Associated with Task Area E]

NOTE: The following Sample Task Order indicated in this Attachment is provided to assess the Offeror's capabilities to conduct and fulfill the requirements of the Statement of Work for projects of similar scope and size to be issued under contracts awarded in response to this solicitation. Although the Sample Task Order will NOT be executed nor will awards be made for the Sample Task Order, Offerors are to include in their proposals a response that specifies the methods by which each Sample Task Order will be accomplished and the project management plan, with associated costs. Offerors should refer to the Additional Technical Proposal Instructions and Additional Business Proposal Instructions for guidance regarding preparation of their proposals.

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

The estimated cost of this task order is $ TBD.

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

STATEMENT OF WORK

I. BACKGROUND AND INTRODUCTION

The Department of Health and Human Services (HHS) charged the National Institute of Allergy and Infectious Diseases (NIAID) within the National Institutes of Health (NIH) with building and managing a program to develop products for the mitigation or treatment of radiation injuries from exposures due to nuclear and radiological attacks.

II. SCOPE

The Contractor shall conduct Phase I safety (including pharmacokinetic, pharmacodynamic, absorption, distribution, metabolism, and excretion) studies on candidate medical countermeasures (MCMs) provided to the Contractor by NIAID.

Note: For purposes of preparing a technical and business response, assume that the Contractor is tasked with designing and performing one study to evaluate the pharmacokinetics of a novel small molecule in 20 normal human volunteers. Provide details about the study tolerability and pharmacokinetics of the MCM, establish a clinical site, arrange site assessment visits, identify and recruit subjects, and conduct of all such safety testing of candidate products required to support a New Drug Application (NDA) and conducted according to good clinical practice (GCP). Standard blood tests will be performed, and pharmacokinetic analysis will be conducted. Provide route of administration and dosing details for a

single escalating dose trial. All appropriate non-clinical studies will have been performed and submitted to the FDA under an existing Investigational New Drug (IND). The medical countermeasure will be provided to the offeror as a Good Manufacturing Practice (GMP)-produced liquid product in sterile vials at an agreed concentration in the vehicle background and stored at the proper temperature. A vehicle control identical in appearance will be provided for the medical countermeasure, except for the label.

III. TECHNICAL REQUIREMENTS

Independently, and not as an agent of the Government, the Contractor shall furnish qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below.

The requirements for Task Area E-1 defined in the base Statement of Work apply to all work performed under this Task Order.

Specifically, the Contractor shall:

1. Fulfill all administrative requirements outlined in Task Order A-1, as appropriate for the work to be conducted in this Task Order.

2. Design and conduct a Phase I clinical safety study in normal human subjects to support the approval of a radiological/nuclear medical countermeasure. This activity includes establishing clinical sites, arranging site assessment visits, identifying and recruiting subjects, and conducting all such safety testing of candidate products required to support a New Drug Application (NDA), and is conducted according to GCP.

   These activities include the following:

   a. Develop and submit to the Contracting Officer's Representative (COR) for review and approval, a clinical study proposal for the evaluation of the MCM for the conduct of Phase I clinical safety and pharmacokinetic studies.
   b. Develop and submit to the COR for review, clinical protocols and protocol-related documents. This shall include, but not be limited to, Case Report Forms, subject informed consent forms, and any materials as requested by the COR.
   c. Work with COR to submit materials for review by the applicable Division of Allergy, Immunology, and Transplantation (DAIT) review committees, and provide written responses to comments within 10 days received from review.
   d. Provide sufficient information to COR for DAIT to complete ClinicalTrials.gov entries and updates to fulfill the Food and Drug Administration Amendments Act Section 801 (FDAAA 801), as required by law and DAIT Policy.
   e. Perform clinical site monitoring. This shall include:
      i. Provide study-specific monitoring plans for review and approval by the COR.
      ii. Provide the COR with comprehensive monitoring reports for each site visit as per monitoring plan and applicable regulations.
   f. At the conclusion of each Phase I clinical safety study, the Contractor shall prepare a final report (as per 21 CFR 312.32, 312.64(b), 320.31(d)(3) and applicable International Conference on Harmonization – ICH guidelines) that captures all Phase I clinical safety study results. The report shall include data summary, analysis (total analysis as well as site-specific analysis if multiple sites are chosen), and interpretation, as well as final

conclusions and recommendations. Provide a draft report to the COR for review and comment prior to finalization.

g. Prepare meeting abstracts, posters, manuscripts, and other experimental summaries and reports.

3. Provide the capabilities for centralized reporting, tracking, and archiving of Serious Adverse Event (SAE) Reports. This shall include an internet-based data entry system for submission of SAE Reports from clinical sites. Paper forms for the submission of SAE Reports shall be used for sites that do not have internet access and as a "back-up system" for the paperless remote data entry and capture systems for SAE Reports in cases where the paperless systems are unavailable for periods exceeding 12 hours.

SECTION D – PACKAGING, MARKING, AND SHIPPING

There are no additional D. clauses applicable to this Task Order beyond those in the base contract.

SECTION E – INSPECTION AND ACCEPTANCE

There are no additional E. clauses applicable to this Task Order beyond those in the base contract.

SECTION F – DELIVERIES OR PERFORMANCE

The period of performance of this contract shall be from TBD through TBD.

TASK ORDER REPORTING REQUIREMENTS AND DELIVERABLES

TASK ORDER REPORTING REQUIREMENTS

Technical Reports

All reports required herein shall be submitted in electronic format via NIAID's electronic Report Deliverable Submission (eRDS) system, with a copy sent to the COR via email at the time of eRDS submission.

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

1. **Technical Reports**
In addition to those reports required by the other terms of this Task Order, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this Task Order:

[Note: Beginning May 25, 2008, the Contractor shall include, in any technical progress report submitted, the applicable PubMed Central (PMC) or NIH Manuscript Submission reference number when citing publications that arise from its NIH-funded research.]

a) Quarterly Progress Report

This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance, including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

b) Annual Progress Report

This report shall include a summation of the results of the entire Task Order work for the period covered. A Quarterly Report will not be required when the Annual Progress Report is due.

c) Final Report

This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved and will include a summary (not to exceed 200 words) of salient results achieved during the performance of all Task Order work. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this task order. An Annual Progress Report will not be required for the period when the Final Report is due.

d) Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this task order. The Contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in SECTION J of the base contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report.

The Contractor shall submit the report in accordance with the DELIVERIES Article in SECTION F of this task order.

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001 (NOT-OD-02-001) and November 2017 (NOT-OD-18-014) apply. The Guidelines may be found at the following website:

https://grants.nih.gov/grants/funding/women_min/guidelines.htm

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

TASK ORDER DELIVERABLES

1. Technical Progress Reports

Item	Reports	Recipients	Delivery Schedule
a.	Quarterly Progress Report	eRDS submission plus 1 email copy to COR and CO	Each report is due on the 15th of the month following each reporting period.
b.	Annual Progress Report	eRDS submission plus 1 email copy to COR and CO	Each report is due on the 15th of the month following each anniversary date of the Task Order.
c.	Annual Utilization Report	eRDS submission plus 1 email copy to COR and CO	Due on/before the 15th of the month following each anniversary date of the task order.
d.	Final Report	eRDS submission plus 1 email copy to COR and CO	Final Report is due on the completion date of the Task Order.

2. Other Reports and Deliverables (Delivery Schedule)

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
a.	Schedules of studies planned, in progress and completed.	III.2.a	eRDS submission plus 1 email copy to COR and CO	To be updated at least monthly.
b.	Study Protocols	III.2.b	eRDS submission plus 1 email copy to COR and CO	Prior to study initiation.
c.	Clinical Site Monitoring Plans, Visits and reports	III.2.e	eRDS submission plus 1 email copy to COR and CO	As per Protocol
d.	Draft Final Clinical Study Report	III.2.f	eRDS submission plus 1 email copy to COR and CO	As per Protocol

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
e.	Final Clinical Study Reports	III.2.f	eRDS submission plus 1 email copy to COR and CO	Within 30 calendar days after completion of each study.
f.	Abstracts, posters, manuscripts, press releases, other experimental summaries and reports	III.2.g	eRDS submission plus 1 email copy to COR and CO	For outside communications, prior approval from COR

SECTION G – TASK ORDER ADMINISTRATION DATA

There are no additional G. clauses applicable to this Task Order beyond those in the base contract.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

There are no additional H. clauses applicable to this Task Order beyond those in the base contract.

ATTACHMENT 10: ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS, FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS

RADIOLOGICAL OR NUCLEAR MEDICAL COUNTERMEASURE PRODUCT DEVELOPMENT SUPPORT (PDS)

RFP NUMBER 75N93026R00005

It is strongly recommended that offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

These additional Technical Proposal instructions reflect the requirements of the solicitation and provide specific instructions and formatting for the Technical Proposal. While Section L of the solicitation provides a generic set of Technical Proposal instructions applicable to all NIH R&D solicitations, these instructions are tailored to the specific requirements of the RFP. The information requested in these instructions should be used to format and prepare the Technical Proposal and should be used as a Table of Contents for your Technical Proposal. Offerors should follow the instructions in Section L of the solicitation and include the information requested here.

Offerors are advised to give careful consideration to the Statement of Work, all reference materials, and attachments, the Technical Evaluation Criteria in Section M, and the solicitation as a whole in the development of their Technical Proposals.

Offerors proposing subcontracts to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration/coordination between the prime Contractor and all proposed subcontractors, and the expected advantages of such an approach.

Offerors must refer to the solicitation Attachment entitled "Packaging and Delivery of the Proposal," which details strict guidelines, including page limitations, formatting, and layout of proposals, and prohibits the offerors use of links to internet website addresses (URLs) to direct readers to alternate sources of information.

Include the Attachment "Packaging and Delivery of the Proposal" with the SP.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

GENERAL NOTES:

The Government anticipates awarding a single Indefinite Delivery, Indefinite Quantity (IDIQ) contract that provides a guaranteed minimum award to the organization or consortium that best meets the overall qualifications needed to fulfill the technical requirements of this solicitation. The contract awardee must be capable of carrying out Task Orders in each of the five Task Areas identified in the Statement of Work for the base contract.

Upon award of the base contract, the Government intends to issue Task Order awards under Task Areas A [Administrative and Technical Support] and B [Animal Model and New Approach Methodologies (NAMs) Development, and Efficacy Testing of Candidate Medical Countermeasures (MCMs)]. The

award for Task Order A-1 will be a cost-reimbursement, term (level of effort) type task order with a Base Period of 12 months and Options to extend the Task Order in 12-month periods for a total Period of Performance of seven years. It is anticipated that Task Order B-1 will be a non-severable cost-reimbursement, completion-type task order and have a 1-year period of performance.

If the need arises, additional Task Orders may be awarded in Task Area B, Task Area C (Non-Clinical Studies in Support of Investigational New Drug (IND), New Drug Application (NDA), and Biologics License Application (BLA) submissions), Task Area D (Chemistry, Manufacturing and Control (CMC) Support), and Task Area E (Phase I Clinical Studies and Support) after award of the base contract. It is anticipated that these Task Orders will be non-severable cost-reimbursement, completion-type task orders. Sample Task Orders (B-2, C-1, D-1, E-1) are provided in this solicitation to assist the Government in evaluating Offeror capabilities but will not immediately lead to specific Task Order awards.

Offerors will be evaluated on their ability to address all technical requirements in the general Task Area SOW, as well as the technical requirements in each Task Order. Offerors lacking the expertise to address all of the technical requirements are encouraged to identify collaborations and partnerships that, through combined expertise, can address all of these technical requirements.

SECTION 1:

1) PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, Unique Entity Identifier (UEI), and identify if the proposal is an original or a copy. 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 also include the legend regarding Restriction on Disclosure and Use of Data prescribed by FAR 52.215-1 (e)].

2) TABLE OF CONTENTS

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested 3-page maximum)

Provide a brief overview of the Technical Proposal, including:

1) A brief description of the activities proposed by the offeror and all proposed subcontractors, including identification of all proposed subcontractors and a list of key personnel for the offeror and the proposed subcontractors with degrees, titles, and roles in the project.

2) By area of expertise, provide the total number of staff, the number available to be assigned to the contract for the offeror and all proposed subcontractors, and total number of additional staff to be hired and trained.

3) A brief description of the facilities and equipment to be made available by the offeror and all proposed subcontractors.

SECTION 3: TECHNICAL PLAN/APPROACH FOR EACH TASK AREA

A. **Task Area A:** Administrative and Technical Support (Task Order A-1, SOW Section C.III):

1) Describe the Project Management Plan for the overall organization that addresses the planning, initiation, implementation, conduct, monitoring, and completion of tasks identified in the Statement of

Work. Describe the project management systems that will be used to track activities and to keep multiple activities on time and on budget. If consultants and/or subcontractors are proposed, describe the plan to solicit, manage, coordinate, and oversee the work performed by consultants and/or subcontractor(s). Include the plan to identify and remediate problems in subcontractor performance.

a) Describe the Staffing Plan that describes roles, responsibilities, and level of effort for all scientific and technical personnel, including all proposed subcontractors and consultants. Describe the administrative and technical framework, indicating clear lines of authority and responsibility for all proposed personnel. Include a chart of the proposed organizational/management structure for the project and provide a plan to ensure that no one participating in studies is debarred, disqualified, or restricted from participating in pivotal trials to establish safety and efficacy.

b) Include in the discussion relevant organizational experience, problems or obstacles encountered, and approaches implemented to resolve or correct identified problems.

2) Describe the organization's Quality Assurance/Quality Control (QA/QC) Management Plan and how the plan will harmonize activities across multiple departments and across organizations. Include in the Plan the organization and reporting structure of any QA units and testing facility managers. The plan must include a description of the QC methods that will be used to ensure the effective and efficient initiation, implementation, management, and oversight of contract requirements. Include documentation of Good Laboratory Practice (GLP), current Good Manufacturing Practice (cGMP) or Good Clinical Practice (GCP) compliance (e.g., Food and Drug Administration (FDA)- inspection reports). Include in the discussion relevant organizational experience, problems or obstacles encountered, and approaches implemented to resolve or correct identified problems.

3) Describe plans for the Contract Initiation Meeting, Annual Meetings, Task Order update meetings or teleconferences, project development team meetings, and other regular and ad hoc meetings with the Contracting Officer's Representative (COR).

4) Outline how the Principal Investigator (PI) (or Project Manager) will communicate with the COR and Contracting Officer and how the PI (or Project Manager) will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

5) Describe how the Contractor will disseminate and/or present data and reports of funded research and development studies to outside organizations, including companies, academic organizations, and other government agencies.

6) Describe the equipment and resources available to store, retrieve, and analyze the technical data related to the contract. Include a description of the systems for managing test and control articles for testing and samples generated from studies performed under the contract.

7) Describe the plans to provide support for regulatory activities including technical and administrative assistance to the radiation/nuclear countermeasures program, in particular, the COR, the Division of Allergy, Immunology and Transplantation (DAIT) Office of Regulatory Affairs (ORA), other DAIT program staff, investigators at DAIT-supported sites and industry collaborators in carrying out the functions relating to the sponsor's responsibilities for an IND/NDA/BLA and Investigational Device Exemption (IDE) application or amendment to an existing application.

8) OPTIONS 1 through 6: Extend the Term of the Task Order – Discuss plans and procedures for continuing and providing the same services indicated in the Statement of Work beyond the Task Order

base period. To address this option, offerors should describe the methods and procedures to maintain the operations specified in the Statement of Work beyond the base period, including retaining or recruiting necessary staff, and maintaining and/or acquiring required equipment and facility space.

B. **Task Area B:** Animal Model and New Approach Methodologies (NAMs) Development, and Efficacy Testing of Candidate MCMs (Task Order B-1 and Sample Task Order B-2, SOW Section C.III for each):

1) Task Order B-1:

   a) Describe capabilities, past experience, and proposed plans and procedures for maintenance, refinement, and characterization of radiation exposure animal models and NAMs, including sample collection for radiation injury biomarkers, referenced in the Statement of Work (hematopoietic, gastrointestinal, and lung injury in mice, rhesus macaques, and other relevant species). Describe capabilities and plans for non-GLP animal efficacy studies using the animal models and NAMs.

   b) Describe how animals will be procured, housed, and transported to and from the irradiation facilities (if required), irradiated (include dosimetry), and provided with medical management during the conduct of the studies. Describe primary endpoints that will support efficacy and the secondary endpoints that will support mechanism of action and other animal health. Also, describe the statistical analyses used to justify group sizes and to determine significance of the primary and secondary endpoints and any descriptive analyses.

2) Sample Task Order B-2: Describe how GLP animal efficacy and mechanism of action studies for a candidate gastrointestinal acute radiation syndrome medical countermeasure (MCM) would be performed in rodents and rhesus macaques. Describe irradiation (include dosimetry), medical management, primary endpoints that will support, and other animal health indicators. Also include the statistical analyses used to justify group sizes and to analyze data.

C. **Task Area C:** Non-Clinical Studies in Support of IND/NDA/BLA submissions (Sample Task Order C-1, SOW Section C.III):

Sample Task Order C-1: Describe the proposed plans and procedures for GLP testing of candidate MCMs for safety/toxicity and the performance of pharmacology studies, which may be required to support clinical use of a therapeutic product in humans. Describe a strategy for development of a non-clinical safety/pharmacology plan, capabilities for performing standard GLP non-clinical safety/pharmacology studies, and sample analysis. Include capabilities for performing standard in vitro safety tests. Include relevant past organizational experience.

D. **Task Area D:** Chemistry, Manufacturing and Control (CMC) Support (Sample Task Order D-1, SOW Section C.III):

Sample Task Order D-1: Describe the proposed plans and procedures for the manufacture of a candidate MCM which will support clinical use, including formulation development, development of the manufacturing processes, stability testing, and current cGMP manufacture of biologics substance and final formulated biologics product at laboratory and pilot scales. Include testing of drug, biologics, and/or cell products for composition, identity, and purity. Describe oversight of the drug manufacturing and

testing processes. Describe relevant organizational experience with manufacturing products used in clinical trials.

E. **Task Area E:** Phase I Clinical Safety Studies and Support (Sample Task Order E-1, SOW Section C.III):

Sample Task Order E-1: Describe the proposed plans and procedures for the design and conduct of Phase I safety studies in normal human subjects under GCP conditions, which will support approval of a radiological/nuclear medical countermeasure candidate. Describe GCP compliance and previous human safety testing experience. Describe the objectives, patient population, primary and secondary endpoints, statistical evaluations, and study subject follow-up. Describe the protocol development and submission processes, coordination with institutional and DAIT review boards, and generation and delivery of the final report. Describe the clinical monitoring plans and systems for serious adverse event recording and reporting. Offerors may reference information that is duplicated in the Human Subjects and Clinical Trials section.

SECTION 4: SCIENTIFIC AND TECHNICAL PERSONNEL

Provide information relevant to document individual training, experience, qualifications, and expertise necessary for the successful completion of all Task Order requirements. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the Task Order

1) **Principal Investigator (PI):** Describe the experience, training, expertise, and qualifications, and level of effort of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract. In particular, address scientific and technical expertise in: managing clinical trials, directing contracts, managing subcontractors, directing research under GLP regulations, developing drug, biologics, and/or cell products, developing protocols, conducting research and development in support of FDA submissions, effects of radiation on mammalian systems, radiobiology, mitigation or treatment of radiation effects by drug products and experience in developing animal models for radiation exposure.

2) **Other Key Scientific and Technical Personnel:** Describe the education, experience, training, expertise, and qualifications, as well as the level of effort, for all proposed key scientific and technical personnel. Include experience in conducting clinical trials, radiobiology, the development of animal models and NAMs for the treatment of radiation exposure; efficacy and other nonclinical testing, including GLP pivotal animal efficacy studies; statistics; preparation and submission of essential regulatory documents; cGMP manufacture; technical writers; quality assurance/quality control programs; GLP, cGMP, and GCP compliance; information technology; and data/document management.

SECTION 5: PROJECT MANAGEMENT

1) Provide a Project Management Plan for the overall organization that addresses the planning, initiation, implementation, conduct, monitoring, and completion of tasks identified in the Statement of Work. If consultants and/or subcontractors are proposed, include a plan to manage, coordinate, and oversee the work performed by consultants and/or subcontractor(s).

2) Provide a Staffing Plan that describes roles, responsibilities, and level of effort for all scientific and technical personnel, including all proposed subcontractors and consultants. Provide an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel. Include a chart of the proposed organizational/management structure for the project.

3) Describe the project management systems that will be used to track activities and to keep multiple activities on time and budget. The plan must include a description of the quality control methods that will be used to ensure the effective and efficient initiation, implementation, management, and oversight of contract requirements.

4) Outline how the PI (or Project Manager) will communicate with the Contracting Officer's Representative and Contracting Officer and how the PI (or Project Manager) will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

SECTION 6: FACILITIES, EQUIPMENT, AND OTHER RESOURCES

The Technical Proposal should document availability and adequacy of facilities, equipment, space, and other resources necessary to carry out the Statement of Work, including:

1) Location and features of facilities, including a floor plan and a list of equipment and resources dedicated to the project for the prime contractor and any proposed subcontractors (lease or ownership information should be provided).

2) Identification and description of ALL support resources (including Information Technology systems) that will be required to effectively complete the SOW, including capability to obtain, store, collate, and arrange data and information in regulatory formats and to keep all information secure.

3) Plans and procedures for GLP, cGMP and GCP compliance, Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation and Quality Controls and Quality Assurance including equipment validation and maintenance, standard operating procedures for the operation of the equipment, protocol and performance of experiments, protocol and report generation and oversight of the GLP program, including regular and ad hoc inspections and plans for addressing non-compliant items. Describe the support systems available to collect and store data, information and test articles and sample reserve samples for the required duration of time, in a manner that ensures preservation. Include a description of how the security of stored information and samples will be ensured.

ATTACHMENT 11: ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

RADIOLOGICAL OR NUCLEAR MEDICAL COUNTERMEASURE PRODUCT DEVELOPMENT SUPPORT (PDS)

RFP NUMBER 75N93026R00005

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

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as attachments, the Technical Evaluation Criteria, and the RFP as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your Business Proposal. Offerors should consider and include the information requested here, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL – TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVER SHEET (use form NIH 2043 identified in Section J of the solicitation)

SECTION 2 – COST OR PRICE SUPPORT

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related sort. All related documentation should be included in a clearly marked section of the proposal.

SECTION 3 – UNIFORM COST ASSUMPTIONS

1) Technical Cost Assumptions

A. Contract Value

This contract will have a Minimum Guaranteed Award of $50,000 and a Maximum Potential Value of $100,000,000. The Maximum Potential Value is not guaranteed but represents the potential for additional funding through Task Order awards under the contract during the ordering period, up to the Maximum Potential Value.

B. Scope of Activities

In order to provide a general indication of the overall scope and volume of this project, the Government anticipates awarding the following estimated number of Tasks Orders during the performance period of the resulting contract:

Task Area	Title	Estimated No. of Task Orders

A	Administrative and Technical Support	1 with 6 options for additional 12-months each
B	Animal Model and New Approach Methodologies (NAMs) Development, and Efficacy Testing of Candidate Medical Countermeasures MCMs	2 per year
C	Non-Clinical Studies in Support of Investigational New Drug (IND)/New Drug Application (NDA)/Biologics License Application (BLA) Submissions	4 over the course of the contract's total 7-year performance period
D	Chemistry, Manufacturing and Control (CMC) Support	2 over the course of the contract's total 7-year performance period
E	Phase I Clinical Safety Studies and Support	1 over the course of the contract's total 7-year performance period

C. **Cost Proposal for Task Order A-1**: Please submit a separate cost estimate (budget spreadsheet in MS Excel format) for the Base Period and all Option Periods. A Summary budget that includes all Options for all periods shall be submitted. When developing your cost proposal, please adhere to the following uniform cost assumptions:

Concurrent with award of the base contract, the Government intends to issue a Task Order award in Task Area A- Administrative and Technical Support. The proposed Task Order will be a cost-reimbursement, term (level of effort) Task Order with a Base Period of 12 months (July 1, 2027 through June 30, 2028) and Options to extend the Task Order term, on an annual basis, for a total Task Order period of performance up to 7 years.

Required Level of Effort for the Base Period and Options 1-6: The required level of effort is stated in terms of FTEs. The labor effort includes consultants/subcontractor labor effort. To assist you in the preparation of your proposal, the Government considers the effort to be 0.85 FTEs per year for the Base Period and 4.1 FTEs per year for Options 1-6. The labor mix is provided as an estimate and are not meant to be restrictive. The Contractor may propose the labor mix deemed most appropriate for carrying out the SOW of the Task Order.

Labor Categories	FTE Per Year
PI/Management III	0.18
Management II	0.33
Management I	0.42
Research Scientist	0.83
Research Associate II	1.33
Research Associate I	0.83
Technician	0.18

Options 1 through 6 to extend the Term of the Task Order: For estimating purposes, please submit separate cost estimates for Options 1 through 6. The Government may exercise Options to extend the period of performance of the Task Order beyond the Base Period (year 1), annually, for a total Task Order period of up to 7 years. Assume that the scope and types of activities outlined herein (i.e., for year 1 of the Task Order would be continued for each succeeding annual Task Order period, for a total period of performance of 7 years.

Provide a Cost Proposal for this Task Order using the following assumptions:

1. Administrative, general Quality Assurance (QA), Data and Document Management, and Project Management to support the activities described in Task Orders B-1, B-2, C-1, D-1 and E-1.

2. Travel:
   a. **Contract Initiation Meeting:** Assume one meeting in Bethesda, Maryland within three months after the effective date of the contract to discuss contract initiation. Assume that this meeting will require a two-night stay and shall be attended by the appropriate personnel from the Contractor and subcontractors (five people total).

   b. **Annual Meeting:** Assume one meeting/year at the Contractor's site to discuss contract progress. Assume that this meeting will require a two-night stay and shall be attended by the appropriate personnel from the Contractor and subcontractors (five people total).

   c. **Subcontractor Site Visits:** Assume one two-day site visit per year to each subcontractor (U.S. and non-U.S.); four contract personnel per visit.

3. Assist the NIAID Office of Regulatory Affairs with the preparation of one IND submission to the Food and Drug Administration (FDA), i.e., provide nonclinical data, assist in drafting and reviewing documents.

D. Cost Proposal for Task Order B-1

When developing your cost proposal, please adhere to the following uniform cost assumptions:

Concurrent with award of the base contract, the Government intends to issue a Task Order award in Task Area B- Animal Model and New Approach Methodologies (NAMs) Development, and Efficacy Testing of Candidate MCMs. The proposed Task Order will be a cost-reimbursement, completion type Task Order with a Base of 12 months (July 1, 2027, through June 30, 2028).

Estimated Level of Effort for the Base: The estimated level of effort is stated in terms of FTEs. The labor effort includes consultants/subcontractor labor effort. To assist you in the preparation of your proposal, the Government considers the effort to be 0.5 FTEs. The effort and labor mix is provided as an estimate and are not meant to be restrictive. The Contractor may propose the labor mix deemed most appropriate for carrying out the SOW of the Task Order.

Labor Categories	**FTE Per Year**
PI/Management III	0.05
Management II	0.05
Management I	0.04
Research Scientist	0.09
Research Associate II	0.09
Research Associate I	0.09
Technician	0.09

Support and management activities, such as administrative, data, and document management, are described in Task A-1 and are not to be included here. Include statistical analysis, radiation dosimetry as well as all administrative tasks that are specific to this task order. For Task Order B-1:

1. Screen six candidate compounds for efficacy against hematopoietic acute radiation syndrome (ARS) in mice and optimize dose and dose schedule of three candidates. (9 total studies)

2. Screen four candidate compounds for efficacy against gastrointestinal ARS in mice and

optimize dose and dose schedule of two candidates. (6 total studies)

3. Screen two candidate compounds for efficacy against radiation-induced lung injury in mice.

4. Design and initiate a non-Good Laboratory Practice (GLP), non-clinical efficacy study for gastrointestinal ARS in non-human primates for one therapeutic compound.

5. Design and initiate a non-GLP, non-clinical efficacy study for lung ARS in non-human primates for one therapeutic compound. Include monitoring of hematopoietic recovery as a secondary endpoint.

E. **Cost Proposal for Sample Task Order B-2**

Task Area B- . The proposed sample Task Order will be a cost-reimbursement, completion type Task Order with a Base of 12 months (July 1, 2027, through June 30, 2028). Estimated Level of Effort for the Base: The estimated level of effort is stated in terms of FTEs. The labor effort includes consultants/subcontractor labor effort. To assist you in the preparation of your proposal, the Government considers the effort to be 3.53 FTEs. The effort and labor mix is provided as an estimate and are not meant to be restrictive. The Contractor may propose the labor mix deemed most appropriate for carrying out the SOW of the Task Order.

Labor Categories	**FTE Per Year**
PI/Management III	0.08
Management II	0.15
Management I	0.40
Research Scientist	0.50
Research Associate II	1.40
Research Associate I	0.50
Technician	0.50

Include statistical analysis, radiation dosimetry, and QA specific to this task order.

1. Design and perform a non-clinical, GLP efficacy study for gastrointestinal ARS in mice for one therapeutic compound. Include monitoring of appropriate secondary endpoints.

2. Design and initiate a non-clinical, GLP efficacy study for gastrointestinal ARS in non-human primates (Rhesus macaque) for one therapeutic compound. Include monitoring of appropriate secondary endpoints.

F. **Cost Proposal for Sample Task Order C-1**

Task Area C- Non-Clinical Studies in Support of IND/NDA/BLA Submissions. The proposed sample Task Order will be a cost-reimbursement, completion-type Task Order with a Base of 12 months (July 1, 2027 through June 30, 2028). Estimated Level of Effort for the Base: The estimated level of effort is stated in terms of FTEs. The labor effort includes consultants/subcontractor labor effort. To assist you in the preparation of your proposal, the Government considers the effort to be 6.4 FTEs. The effort and labor mix is provided as an estimate and are not meant to be restrictive. The Contractor may propose the labor mix deemed most appropriate for carrying out the SOW of the Task Order.

Labor Categories	**FTE Per Year**
PI/Management III	0.25
Management II	0.40
Management I	0.50
Research Scientist	1.00
Research Associate II	1.25
Research Associate I	1.33
Technician	1.67

Assume one 14-day GLP dose-escalation safety study in rats using a total of 80 animals (40 male, 40 female), with test article administered subcutaneously.

G. **Cost Proposal for Sample Task Order D-1**

Task Area D- Chemistry, Manufacturing and Control (CMC) Support. The proposed sample Task Order will be a cost-reimbursement, completion type Task Order with a Base of 12 months (July 1, 2027 through June 30, 2028). Estimated Level of Effort for the Base: The estimated level of effort is stated in terms of FTEs. The labor effort includes consultants/subcontractor labor effort. To assist you in the preparation of your proposal, the Government considers the effort to be 1.0 FTEs.

The effort and labor mix is provided as an estimate and are not meant to be restrictive. The Contractor may propose the labor mix deemed most appropriate for carrying out the SOW of the Task Order.

Labor Categories	**FTE Per Year**
PI/Management III	0.03
Management II	0.04
Management I	0.42
Research Scientist	0.33
Research Associate II	0.00
Research Associate I	0.09
Technician	0.09

Assume pilot-scale manufacture of one drug in solution form for subcutaneous injection. Assume shipment of final packaged pharmaceutical products (500 vials of 25 mg/vial of the MCM) to Bethesda, MD, will not require use of a controlled temperature environment.

H. **Cost Proposal for Sample Task Order E-1**

Task Area E- Phase I Clinical Safety Studies and Support. The proposed sample Task Order will be a cost-reimbursement, completion type Task Order with a Base of 12 months (July 1, 2027 through June 30, 2028). Estimated Level of Effort for the Base: The estimated level of effort is stated in terms of FTEs. The labor effort includes consultants/subcontractor labor effort. To assist you in the preparation of your proposal, the Government considers the effort to be 1.85 FTEs. The effort and labor mix is provided as an estimate and are not meant to be restrictive. The Contractor may propose the labor mix deemed most appropriate for carrying out the SOW of the Task Order.

Labor Categories	FTE Per Year
PI/Management III	0.25
Management II	0.34
Management I	0.42
Research Scientist	0.17
Research Associate II	0.25
Research Associate I	0.17
Technician	0.25

Assume one Phase I clinical study using twenty healthy human volunteers, with test article administered subcutaneously. Include blood draws as appropriate for pharmacokinetic analysis and standard blood tests.

2) Government Furnished Property

Check the appropriate box.

☐ Government Furnished Property is offered for this acquisition.

☒ No Government Furnished Property is offered for this acquisition.

☒ The purchase of Government Furnished Property will not be authorized as a direct charge under the resultant Task Order.

SECTION 4 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

Refer to Section L of the solicitation for documentation requirements. All relevant documentation should be included in a clearly marked section of the proposal.

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REGISTER OF WAGE DETERMINATIONS UNDER THE SERVICE CONTRACT ACT
By direction of the Secretary of Labor

U.S. DEPARTMENT OF LABOR
EMPLOYMENT STANDARDS ADMINISTRATION
WAGE AND HOUR DIVISION
WASHINGTON D.C. 20210

Daniel W. Simms
Director

Division of Wage Determinations

Wage Determination No.: 2015-5637
Revision No.: 32
Date Of Last Revision: 5/13/2026

State: California

Area: California Counties of San Francisco and San Mateo

Fringe Benefits Required Follow the Occupational Listing

OCCUPATION CODE - TITLE	FOOTNOTE	RATE
01000 - Administrative Support And Clerical Occupations		
01011 - Accounting Clerk I		24.69
01012 - Accounting Clerk II		27.71
01013 - Accounting Clerk III		31.00
01020 - Administrative Assistant		48.62
01035 - Court Reporter		62.05
01041 - Customer Service Representative I		22.14
01042 - Customer Service Representative II		24.16
01043 - Customer Service Representative III		27.12
01051 - Data Entry Operator I		23.38
01052 - Data Entry Operator II		25.51
01060 - Dispatcher, Motor Vehicle		29.13
01070 - Document Preparation Clerk		22.21
01090 - Duplicating Machine Operator		22.21
01111 - General Clerk I		21.90
01112 - General Clerk II		23.89
01113 - General Clerk III		26.82
01120 - Housing Referral Assistant		31.71
01141 - Messenger Courier		23.05
01191 - Order Clerk I		22.55
01192 - Order Clerk II		24.61
01261 - Personnel Assistant (Employment) I		24.85
01262 - Personnel Assistant (Employment) II		27.79
01263 - Personnel Assistant (Employment) III		30.98
01270 - Production Control Clerk		35.73
01290 - Rental Clerk		22.10
01300 - Scheduler, Maintenance		25.43
01311 - Secretary I		25.43
01312 - Secretary II		28.45
01313 - Secretary III		31.71
01320 - Service Order Dispatcher		28.67
01410 - Supply Technician		48.62
01420 - Survey Worker		29.45
01460 - Switchboard Operator/Receptionist		23.11
01531 - Travel Clerk I		24.40
01532 - Travel Clerk II		26.57
01533 - Travel Clerk III		29.01
01611 - Word Processor I		26.14
01612 - Word Processor II		29.33
01613 - Word Processor III		32.81
05000 - Automotive Service Occupations		
05005 - Automobile Body Repairer, Fiberglass		31.75
05010 - Automotive Electrician		33.13
05040 - Automotive Glass Installer		31.35
05070 - Automotive Worker		31.35
05110 - Mobile Equipment Servicer		27.64
05130 - Motor Equipment Metal Mechanic		34.94
05160 - Motor Equipment Metal Worker		31.35
05190 - Motor Vehicle Mechanic		34.94
05220 - Motor Vehicle Mechanic Helper		25.54
05250 - Motor Vehicle Upholstery Worker		29.57
05280 - Motor Vehicle Wrecker		31.35
05310 - Painter, Automotive		33.13
05340 - Radiator Repair Specialist		31.35
05370 - Tire Repairer		22.14
05400 - Transmission Repair Specialist		34.94
07000 - Food Preparation And Service Occupations		
07010 - Baker		21.93
07041 - Cook I		23.04

07042 - Cook II		26.13
07070 - Dishwasher		19.32
07130 - Food Service Worker		19.17
07210 - Meat Cutter		22.28
07260 - Waiter/Waitress		18.03
09000 - Furniture Maintenance And Repair Occupations		
09010 - Electrostatic Spray Painter		29.90
09040 - Furniture Handler		16.69
09080 - Furniture Refinisher		26.00
09090 - Furniture Refinisher Helper		20.04
09110 - Furniture Repairer, Minor		23.20
09130 - Upholsterer		27.81
11000 - General Services And Support Occupations		
11030 - Cleaner, Vehicles		20.86
11060 - Elevator Operator		20.93
11090 - Gardener		30.13
11122 - Housekeeping Aide		20.93
11150 - Janitor		20.93
11210 - Laborer, Grounds Maintenance		23.18
11240 - Maid or Houseman		21.96
11260 - Pruner		20.86
11270 - Tractor Operator		27.85
11330 - Trail Maintenance Worker		23.18
11360 - Window Cleaner		23.26
12000 - Health Occupations		
12010 - Ambulance Driver		24.06
12011 - Breath Alcohol Technician		39.18
12012 - Certified Occupational Therapist Assistant		46.60
12015 - Certified Physical Therapist Assistant		46.74
12020 - Dental Assistant		30.33
12025 - Dental Hygienist		72.69
12030 - EKG Technician		44.07
12035 - Electroneurodiagnostic Technologist		44.07
12040 - Emergency Medical Technician		24.06
12071 - Licensed Practical Nurse I		35.02
12072 - Licensed Practical Nurse II		39.18
12073 - Licensed Practical Nurse III		43.66
12100 - Medical Assistant		28.80
12130 - Medical Laboratory Technician		39.13
12160 - Medical Record Clerk		31.45
12190 - Medical Record Technician		35.18
12195 - Medical Transcriptionist		27.36
12210 - Nuclear Medicine Technologist		87.76
12221 - Nursing Assistant I		18.84
12222 - Nursing Assistant II		21.19
12223 - Nursing Assistant III		23.13
12224 - Nursing Assistant IV		25.96
12235 - Optical Dispenser		29.43
12236 - Optical Technician		32.23
12250 - Pharmacy Technician		29.80
12280 - Phlebotomist		28.78
12305 - Radiologic Technologist		65.74
12311 - Registered Nurse I		50.96
12312 - Registered Nurse II		62.32
12313 - Registered Nurse II, Specialist		62.32
12314 - Registered Nurse III		75.40
12315 - Registered Nurse III, Anesthetist		75.40
12316 - Registered Nurse IV		90.40
12317 - Scheduler (Drug and Alcohol Testing)		48.52
12320 - Substance Abuse Treatment Counselor		32.85
13000 - Information And Arts Occupations		
13011 - Exhibits Specialist I		28.27
13012 - Exhibits Specialist II		35.02
13013 - Exhibits Specialist III		42.83
13041 - Illustrator I		29.13
13042 - Illustrator II		36.10
13043 - Illustrator III		44.14
13047 - Librarian		47.43
13050 - Library Aide/Clerk		30.01
13054 - Library Information Technology Systems Administrator		42.82
13058 - Library Technician		30.82
13061 - Media Specialist I		30.91
13062 - Media Specialist II		34.57
13063 - Media Specialist III		38.53
13071 - Photographer I		26.05
13072 - Photographer II		29.14
13073 - Photographer III		36.09
13074 - Photographer IV		44.14
13075 - Photographer V		53.40
13090 - Technical Order Library Clerk		35.93
13110 - Video Teleconference Technician		34.36
14000 - Information Technology Occupations		
14041 - Computer Operator I		30.61
14042 - Computer Operator II		34.24
14043 - Computer Operator III		38.19
14044 - Computer Operator IV		42.44
14045 - Computer Operator V		46.99
14071 - Computer Programmer I	(see 1)	
14072 - Computer Programmer II	(see 1)	
14073 - Computer Programmer III	(see 1)	
14074 - Computer Programmer IV	(see 1)	
14101 - Computer Systems Analyst I	(see 1)	

14102 - Computer Systems Analyst II	(see 1)	
14103 - Computer Systems Analyst III	(see 1)	
14150 - Peripheral Equipment Operator		30.61
14160 - Personal Computer Support Technician		42.44
14170 - System Support Specialist		47.43
15000 - Instructional Occupations		
15010 - Aircrew Training Devices Instructor (Non-Rated)		48.20
15020 - Aircrew Training Devices Instructor (Rated)		58.32
15030 - Air Crew Training Devices Instructor (Pilot)		69.92
15050 - Computer Based Training Specialist / Instructor		48.20
15060 - Educational Technologist		47.99
15070 - Flight Instructor (Pilot)		69.92
15080 - Graphic Artist		44.41
15085 - Maintenance Test Pilot, Fixed, Jet/Prop		69.92
15086 - Maintenance Test Pilot, Rotary Wing		69.92
15088 - Non-Maintenance Test/Co-Pilot		69.92
15090 - Technical Instructor		36.32
15095 - Technical Instructor/Course Developer		44.42
15110 - Test Proctor		29.32
15120 - Tutor		29.32
16000 - Laundry, Dry-Cleaning, Pressing And Related Occupations		
16010 - Assembler		22.08
16030 - Counter Attendant		22.08
16040 - Dry Cleaner		25.23
16070 - Finisher, Flatwork, Machine		22.08
16090 - Presser, Hand		22.08
16110 - Presser, Machine, Drycleaning		22.08
16130 - Presser, Machine, Shirts		22.08
16160 - Presser, Machine, Wearing Apparel, Laundry		22.08
16190 - Sewing Machine Operator		26.28
16220 - Tailor		27.33
16250 - Washer, Machine		23.14
19000 - Machine Tool Operation And Repair Occupations		
19010 - Machine-Tool Operator (Tool Room)		33.25
19040 - Tool And Die Maker		39.92
21000 - Materials Handling And Packing Occupations		
21020 - Forklift Operator		27.53
21030 - Material Coordinator		35.73
21040 - Material Expediter		35.73
21050 - Material Handling Laborer		23.18
21071 - Order Filler		21.46
21080 - Production Line Worker (Food Processing)		27.53
21110 - Shipping Packer		23.56
21130 - Shipping/Receiving Clerk		23.56
21140 - Store Worker I		21.04
21150 - Stock Clerk		27.31
21210 - Tools And Parts Attendant		27.53
21410 - Warehouse Specialist		27.53
23000 - Mechanics And Maintenance And Repair Occupations		
23010 - Aerospace Structural Welder		48.51
23019 - Aircraft Logs and Records Technician		39.06
23021 - Aircraft Mechanic I		46.16
23022 - Aircraft Mechanic II		48.51
23023 - Aircraft Mechanic III		50.56
23040 - Aircraft Mechanic Helper		33.75
23050 - Aircraft, Painter		43.78
23060 - Aircraft Servicer		39.06
23070 - Aircraft Survival Flight Equipment Technician		43.78
23080 - Aircraft Worker		41.42
23091 - Aircrew Life Support Equipment (ALSE) Mechanic I		41.42
23092 - Aircrew Life Support Equipment (ALSE) Mechanic II		46.16
23110 - Appliance Mechanic		28.11
23120 - Bicycle Repairer		25.04
23125 - Cable Splicer		61.77
23130 - Carpenter, Maintenance		38.92
23140 - Carpet Layer		31.96
23160 - Electrician, Maintenance		50.38
23181 - Electronics Technician Maintenance I		39.74
23182 - Electronics Technician Maintenance II		42.02
23183 - Electronics Technician Maintenance III		44.30
23260 - Fabric Worker		37.83
23290 - Fire Alarm System Mechanic		36.67
23310 - Fire Extinguisher Repairer		35.04
23311 - Fuel Distribution System Mechanic		50.23
23312 - Fuel Distribution System Operator		39.73
23370 - General Maintenance Worker		30.52
23380 - Ground Support Equipment Mechanic		46.16
23381 - Ground Support Equipment Servicer		39.06
23382 - Ground Support Equipment Worker		41.42
23391 - Gunsmith I		35.04
23392 - Gunsmith II		39.73
23393 - Gunsmith III		44.29
23410 - Heating, Ventilation And Air-Conditioning Mechanic		36.90
23411 - Heating, Ventilation And Air Contidioning Mechanic (Research Facility)		38.78
23430 - Heavy Equipment Mechanic		44.36

23440 - Heavy Equipment Operator		56.42
23460 - Instrument Mechanic		41.91
23465 - Laboratory/Shelter Mechanic		42.01
23470 - Laborer		23.18
23510 - Locksmith		31.85
23530 - Machinery Maintenance Mechanic		41.41
23550 - Machinist, Maintenance		31.89
23580 - Maintenance Trades Helper		22.11
23591 - Metrology Technician I		41.91
23592 - Metrology Technician II		44.04
23593 - Metrology Technician III		45.91
23640 - Millwright		51.65
23710 - Office Appliance Repairer		30.30
23760 - Painter, Maintenance		30.71
23790 - Pipefitter, Maintenance		41.14
23810 - Plumber, Maintenance		39.02
23820 - Pneudraulic Systems Mechanic		44.29
23850 - Rigger		46.00
23870 - Scale Mechanic		39.73
23890 - Sheet-Metal Worker, Maintenance		47.18
23910 - Small Engine Mechanic		28.19
23931 - Telecommunications Mechanic I		41.19
23932 - Telecommunications Mechanic II		43.29
23950 - Telephone Lineman		49.79
23960 - Welder, Combination, Maintenance		32.75
23965 - Well Driller		36.77
23970 - Woodcraft Worker		44.29
23980 - Woodworker		35.04
24000 - Personal Needs Occupations		
24550 - Case Manager		27.51
24570 - Child Care Attendant		21.62
24580 - Child Care Center Clerk		26.95
24610 - Chore Aide		17.24
24620 - Family Readiness And Support Services Coordinator		27.51
24630 - Homemaker		27.51
25000 - Plant And System Operations Occupations		
25010 - Boiler Tender		59.67
25040 - Sewage Plant Operator		54.98
25070 - Stationary Engineer		59.67
25190 - Ventilation Equipment Tender		43.63
25210 - Water Treatment Plant Operator		54.98
27000 - Protective Service Occupations		
27004 - Alarm Monitor		50.29
27007 - Baggage Inspector		22.47
27008 - Corrections Officer		48.34
27010 - Court Security Officer		53.32
27030 - Detection Dog Handler		25.35
27040 - Detention Officer		48.34
27070 - Firefighter		58.08
27101 - Guard I		22.47
27102 - Guard II		25.35
27131 - Police Officer I		58.36
27132 - Police Officer II		64.84
28000 - Recreation Occupations		
28041 - Carnival Equipment Operator		25.07
28042 - Carnival Equipment Repairer		27.12
28043 - Carnival Worker		18.78
28210 - Gate Attendant/Gate Tender		25.96
28310 - Lifeguard		19.37
28350 - Park Attendant (Aide)		29.03
28510 - Recreation Aide/Health Facility Attendant		21.19
28515 - Recreation Specialist		35.96
28630 - Sports Official		23.12
28690 - Swimming Pool Operator		30.76
29000 - Stevedoring/Longshoremen Occupational Services		
29010 - Blocker And Bracer		42.43
29020 - Hatch Tender		42.43
29030 - Line Handler		42.43
29041 - Stevedore I		39.97
29042 - Stevedore II		44.83
30000 - Technical Occupations		
30010 - Air Traffic Control Specialist, Center (HFO)	(see 2)	57.59
30011 - Air Traffic Control Specialist, Station (HFO)	(see 2)	39.72
30012 - Air Traffic Control Specialist, Terminal (HFO)	(see 2)	43.73
30021 - Archeological Technician I		24.86
30022 - Archeological Technician II		27.80
30023 - Archeological Technician III		34.44
30030 - Cartographic Technician		34.44
30040 - Civil Engineering Technician		46.48
30051 - Cryogenic Technician I		38.13
30052 - Cryogenic Technician II		42.12
30061 - Drafter/CAD Operator I		24.86
30062 - Drafter/CAD Operator II		27.80
30063 - Drafter/CAD Operator III		30.99
30064 - Drafter/CAD Operator IV		38.15
30081 - Engineering Technician I		20.77
30082 - Engineering Technician II		23.30
30083 - Engineering Technician III		26.07

30084 - Engineering Technician IV		32.30
30085 - Engineering Technician V		39.51
30086 - Engineering Technician VI		47.80
30090 - Environmental Technician		35.57
30095 - Evidence Control Specialist		34.43
30210 - Laboratory Technician		33.89
30221 - Latent Fingerprint Technician I		45.41
30222 - Latent Fingerprint Technician II		50.16
30240 - Mathematical Technician		57.81
30361 - Paralegal/Legal Assistant I		27.05
30362 - Paralegal/Legal Assistant II		33.51
30363 - Paralegal/Legal Assistant III		40.98
30364 - Paralegal/Legal Assistant IV		49.58
30375 - Petroleum Supply Specialist		42.12
30390 - Photo-Optics Technician		35.89
30395 - Radiation Control Technician		42.12
30461 - Technical Writer I		42.52
30462 - Technical Writer II		52.00
30463 - Technical Writer III		62.91
30491 - Unexploded Ordnance (UXO) Technician I		36.61
30492 - Unexploded Ordnance (UXO) Technician II		44.29
30493 - Unexploded Ordnance (UXO) Technician III		53.08
30494 - Unexploded (UXO) Safety Escort		36.61
30495 - Unexploded (UXO) Sweep Personnel		36.61
30501 - Weather Forecaster I		38.13
30502 - Weather Forecaster II		46.38
30620 - Weather Observer, Combined Upper Air Or Surface Programs	(see 2)	30.99
30621 - Weather Observer, Senior	(see 2)	34.43
31000 - Transportation/Mobile Equipment Operation Occupations		
31010 - Airplane Pilot		44.29
31020 - Bus Aide		27.47
31030 - Bus Driver		38.19
31043 - Driver Courier		21.91
31260 - Parking and Lot Attendant		20.34
31290 - Shuttle Bus Driver		23.14
31310 - Taxi Driver		19.72
31361 - Truckdriver, Light		23.70
31362 - Truckdriver, Medium		25.36
31363 - Truckdriver, Heavy		30.87
31364 - Truckdriver, Tractor-Trailer		30.87
99000 - Miscellaneous Occupations		
99020 - Cabin Safety Specialist		21.59
99030 - Cashier		19.00
99050 - Desk Clerk		21.46
99095 - Embalmer		33.15
99130 - Flight Follower		36.61
99251 - Laboratory Animal Caretaker I		22.61
99252 - Laboratory Animal Caretaker II		24.46
99260 - Marketing Analyst		56.47
99310 - Mortician		29.47
99410 - Pest Controller		24.35
99510 - Photofinishing Worker		25.62
99710 - Recycling Laborer		38.67
99711 - Recycling Specialist		46.45
99730 - Refuse Collector		34.80
99810 - Sales Clerk		20.43
99820 - School Crossing Guard		28.29
99830 - Survey Party Chief		58.41
99831 - Surveying Aide		33.76
99832 - Surveying Technician		39.83
99840 - Vending Machine Attendant		20.98
99841 - Vending Machine Repairer		25.74
99842 - Vending Machine Repairer Helper		20.98

Note: Executive Order (EO) 13706, Establishing Paid Sick Leave for Federal Contractors, applies to all contracts subject to the Service Contract Act for which the contract is awarded (and any solicitation was issued) on or after January 1, 2017. If this contract is covered by the EO, the contractor must provide employees with 1 hour of paid sick leave for every 30 hours they work, up to 56 hours of paid sick leave each year. Employees must be permitted to use paid sick leave for their own illness, injury or other health-related needs, including preventive care; to assist a family member (or person who is like family to the employee) who is ill, injured, or has other health-related needs, including preventive care; or for reasons resulting from, or to assist a family member (or person who is like family to the employee) who is the victim of, domestic violence, sexual assault, or stalking. Additional information on contractor requirements and worker protections under the EO is available at www.dol.gov/whd/govcontracts.

Note: Executive Order 13658 generally applies to contracts subject to the Service Contract Act that were awarded on or between January 1, 2015 and January 29, 2022, and that have not been renewed or extended on or after January 30, 2022. If a contract is subject to Executive Order 13658, the contractor must pay all covered workers at least $13.65 per hour (or the applicable wage rate listed on this wage determination, if it is higher) for all hours spent performing on the cor
Additional information on contractor requirements and worker protections under Executive Order 13658 is available at www.dol.gov/whd/govcontracts.

ALL OCCUPATIONS LISTED ABOVE RECEIVE THE FOLLOWING BENEFITS:

HEALTH & WELFARE: $5.55 per hour, up to 40 hours per week, or $222.00 per week or $962.00 per month

HEALTH & WELFARE EO 13706: $5.09 per hour, up to 40 hours per week, or $203.60 per week, or $882.27 per month*

*This rate is to be used only when compensating employees for performance on an SCA-

covered contract also covered by EO 13706, Establishing Paid Sick Leave for Federal Contractors. A contractor may not receive credit toward its SCA obligations for any paid sick leave provided pursuant to EO 13706.

VACATION: 2 weeks paid vacation after 1 year of service with a contractor or successor; 3 weeks after 5 years, and 4 weeks after 12 years. Length of service includes the whole span of continuous service with the present contractor or successor, wherever employed, and with the predecessor contractors in the performance of similar work at the same Federal facility. (Reg. 29 CFR 4.173)

HOLIDAYS: A minimum of eleven paid holidays per year: New Year's Day, Martin Luther King Jr.'s Birthday, Washington's Birthday, Memorial Day, Juneteenth National Independence Day, Independence Day, Labor Day, Columbus Day, Veterans' Day, Thanksgiving Day, and Christmas Day. (A contractor may substitute for any of the named holidays another day off with pay in accordance with a plan communicated to the employees involved.) (See 29 CFR 4.174)

THE OCCUPATIONS WHICH HAVE NUMBERED FOOTNOTES IN PARENTHESES RECEIVE THE FOLLOWING:

1) JANITOR: The rate listed on this WD for the """"Janitor"""" occupation applies only to Marin and San Mateo counties. Please refer to WD 1974-1257 to obtain the wage rate and fringe benefits applicable to the """"Janitor"""" occupation in San Francisco County.

2) COMPUTER EMPLOYEES: This wage determination does not apply to any individual employed in a bona fide executive, administrative, or professional capacity, as defined in 29 C.F.R. Part 541. (See 41 C.F.R. 6701(3)). Because most Computer Systems Analysts and Computer Programmers who are paid at least $27.63 per hour (or at least $684 per week if paid on a salary or fee basis) likely qualify as exempt computer professionals under 29 U.S.C. 213(a)(1) and 29 U.S.C. 213(a)(17), this wage determination may not include wage rates for all occupations within those job families. In such instances, a conformance will be necessary if there are nonexempt employees in these job families working on the contract.

Job titles vary widely and change quickly in the computer industry, and are not determinative of whether an employee is an exempt computer professional. To be exempt, computer employees who satisfy the compensation requirements must also have a primary duty that consists of:

(1) The application of systems analysis techniques and procedures, including consulting with users, to determine hardware, software or system functional specifications;

(2) The design, development, documentation, analysis, creation, testing or modification of computer systems or programs, including prototypes, based on and related to user or system design specifications;

(3) The design, documentation, testing, creation or modification of computer programs related to machine operating systems; or

(4) A combination of the aforementioned duties, the performance of which requires the same level of skills. (29 C.F.R. 541.400).

Any computer employee who meets the applicable compensation requirements and the above duties test qualifies as an exempt computer professional under both section 13(a)(1) and section 13(a)(17) of the Fair Labor Standards Act. (Field Assistance Bulletin No. 2006-3 (Dec. 14, 2006)). Accordingly, this wage determination will not apply to any exempt computer employee regardless of which of these two exemptions is utilized.

3) AIR TRAFFIC CONTROLLERS AND WEATHER OBSERVERS - NIGHT PAY & SUNDAY PAY: If you work at night as part of a regular tour of duty, you will earn a night differential and receive an additional 10% of basic pay for any hours worked between 6pm and 6am. If you are a full-time employed (40 hours a week) and Sunday is part of your regularly scheduled workweek, you are paid at your rate of basic pay plus a Sunday premium of 25% of your basic rate for each hour of Sunday work which is not overtime (i.e. occasional work on Sunday outside the normal tour of duty is considered overtime work).

** HAZARDOUS PAY DIFFERENTIAL **

An 8 percent differential is applicable to employees employed in a position that represents a high degree of hazard when working with or in close proximity to ordnance, explosives, and incendiary materials. This includes work such as screening, blending, dying, mixing, and pressing of sensitive ordnance, explosives, and pyrotechnic compositions such as lead azide, black powder and photoflash powder. All dry-house activities involving propellants or explosives. Demilitarization, modification, renovation, demolition, and maintenance operations on sensitive ordnance, explosives and incendiary materials. All operations involving re-grading and cleaning of artillery ranges.

A 4 percent differential is applicable to employees employed in a position that represents a low degree of hazard when working with, or in close proximity to ordnance, (or employees possibly adjacent to) explosives and incendiary materials which involves potential injury such as laceration of hands, face, or arms of the employee engaged in the operation, irritation of the skin, minor burns and the like; minimal damage to immediate or adjacent work area or equipment being used. All operations involving, unloading, storage, and hauling of ordnance, explosive, and incendiary ordnance material other than small arms ammunition. These differentials are only applicable to work that has been specifically designated by the agency for ordnance, explosives, and incendiary material differential pay.

** UNIFORM ALLOWANCE **

If employees are required to wear uniforms in the performance of this contract

(either by the terms of the Government contract, by the employer, by the state or local law, etc.), the cost of furnishing such uniforms and maintaining (by laundering or dry cleaning) such uniforms is an expense that may not be borne by an employee where such cost reduces the hourly rate below that required by the wage determination. The Department of Labor will accept payment in accordance with the following standards as compliance:

The contractor or subcontractor is required to furnish all employees with an adequate number of uniforms without cost or to reimburse employees for the actual cost of the uniforms. In addition, where uniform cleaning and maintenance is made the responsibility of the employee, all contractors and subcontractors subject to this wage determination shall (in the absence of a bona fide collective bargaining agreement providing for a different amount, or the furnishing of contrary affirmative proof as to the actual cost), reimburse all employees for such cleaning and maintenance at a rate of $3.35 per week (or $.67 cents per day). However, in those instances where the uniforms furnished are made of """"wash and wear"""" materials, may be routinely washed and dried with other personal garments, and do not require any special treatment such as dry cleaning, daily washing, or commercial laundering in order to meet the cleanliness or appearance standards set by the terms of the Government contract, by the contractor, by law, or by the nature of the work, there is no requirement that employees be reimbursed for uniform maintenance costs.

** SERVICE CONTRACT ACT DIRECTORY OF OCCUPATIONS **

The duties of employees under job titles listed are those described in the """"Service Contract Act Directory of Occupations"""", Fifth Edition (Revision 1), dated September 2015, unless otherwise indicated.

** REQUEST FOR AUTHORIZATION OF ADDITIONAL CLASSIFICATION AND WAGE RATE, Standard Form 1444 (SF-1444) **

Conformance Process:

The contracting officer shall require that any class of service employee which is not listed herein and which is to be employed under the contract (i.e., the work to be performed is not performed by any classification listed in the wage determination), be classified by the contractor so as to provide a reasonable relationship (i.e., appropriate level of skill comparison) between such unlisted classifications and the classifications listed in the wage determination (See 29 CFR 4.6(b)(2)(i)). Such conforming procedures shall be initiated by the contractor prior to the performance of contract work by such unlisted class(es) of employees (See 29 CFR 4.6(b)(2)(ii)). The Wage and Hour Division shall make a final determination of conformed classification, wage rate, and/or fringe benefits which shall be paid to all employees performing in the classification from the first day of work on which contract work is performed by them in the classification. Failure to pay such unlisted employees the compensation agreed upon by the interested parties and/or fully determined by the Wage and Hour Division retroactive to the date such class of employees commenced contract work shall be a violation of the Act and this contract. (See 29 CFR 4.6(b)(2)(v)). When multiple wage determinations are included in a contract, a separate SF-1444 should be prepared for each wage determination to which a class(es) is to be conformed.

The process for preparing a conformance request is as follows:

1) When preparing the bid, the contractor identifies the need for a conformed occupation(s) and computes a proposed rate(s).

2) After contract award, the contractor prepares a written report listing in order the proposed classification title(s), a Federal grade equivalency (FGE) for each proposed classification(s), job description(s), and rationale for proposed wage rate(s), including information regarding the agreement or disagreement of the authorized representative of the employees involved, or where there is no authorized representative, the employees themselves. This report should be submitted to the contracting officer no later than 30 days after such unlisted class(es) of employees performs any contract work.

3) The contracting officer reviews the proposed action and promptly submits a report of the action, together with the agency's recommendations and pertinent information including the position of the contractor and the employees, to the U.S. Department of Labor, Wage and Hour Division, for review (See 29 CFR 4.6(b)(2)(ii)).

4) Within 30 days of receipt, the Wage and Hour Division approves, modifies, or disapproves the action via transmittal to the agency contracting officer, or notifies the contracting officer that additional time will be required to process the request.

5) The contracting officer transmits the Wage and Hour Division's decision to the contractor.

6) Each affected employee shall be furnished by the contractor with a written copy of such determination or it shall be posted as a part of the wage determination (See 29 CFR 4.6(b)(2)(iii)).

Information required by the Regulations must be submitted on SF-1444 or bond paper.

When preparing a conformance request, the """"Service Contract Act Directory of Occupations"""" should be used to compare job definitions to ensure that duties requested are not performed by a classification already listed in the wage determination. Remember, it is not the job title, but the required tasks that determine whether a class is included in an established wage determination. Conformances may not be used to artificially split, combine, or subdivide classifications listed in the wage determination (See 29 CFR 4.152(c)(1))""
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