SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

<table>
<tr><td colspan="3">1. Requisition or other Purchase Authority: 81-692</td></tr>
<tr><td>2. Request for Proposal Number:
BAA-75N93026R00008</td><td>3. Issue Date:
6/2/2026</td><td>4. Set Aside:
[X] No
[] Yes See Part IV Section L</td></tr>
<tr><td colspan="3">5. Title: Immune Mechanisms of Protection Against Mycobacterium Tuberculosis Centers</td></tr>
<tr><td colspan="2">6. ISSUED BY:
Office of Acquisitions
National Institute of Allergies and Infectious Disease
National Institutes of Health
5601 Fishers Lane
Rockville, MD 20952</td><td>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.</td></tr>
<tr><td colspan="3">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 9/01/2026. 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.</td></tr>
<tr><td colspan="3">9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS.

IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of RFO Clause 52.215-1, Instructions to Offerors--Competitive Acquisition," LOCATED IN SECTION L.1. OF THIS SOLICITATION.</td></tr>
<tr><td colspan="3">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 http://www.sam.gov</td></tr>
<tr><td colspan="3">11. FOR INFORMATION CALL: Christopher Ray
PHONE: 240-627-3365
e-MAIL:chris.ray@nih.gov
COLLECT CALLS WILL NOT BE ACCEPTED.</td></tr>
<tr><td colspan="2">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.</td><td>Christopher Ray

Contracting Officer
Office of R&D and
Professional Services,
OALM, NIH</td></tr>
</table>

PART I - THE SCHEDULE

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

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

SECTION B - Supplies or Services and Prices/Costs

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The objective of this solicitation is to accelerate tuberculosis (TB) vaccine development by supporting research that characterizes both tissue-specific and systemic protective immune responses that prevent or contain *Mycobacterium tuberculosis* (Mtb) infection, and the advancement of tools and resources that facilitate TB vaccine development (*e.g.*, biological models, new approach methodologies [NAMs] such as organoids and *in vitro* systems, computational and modeling platforms). This program will continue to support the comprehensive understanding of protective immunity to Mtb and the impact of Human Immunodeficiency Virus/Simian Immunodeficiency Virus (HIV/SIV) infection on responses to Mtb and TB vaccines. This solicitation also requires the use of human samples and/or clinical studies, at least one animal model, and computational data integration and modeling for cross-comparative analyses of the human and animal studies. In addition, investigators may consider using organoids or other *ex-vivo* systems to assess human immunity to Mtb or TB vaccines. These requirements are in alignment with NIH's initiative to prioritize human-based research.

ARTICLE B.2. ESTIMATED COST - OPTION

a. The estimated cost of the Base Period of this contract is $ TBD.

b. The fixed fee for the Base Period of this contract is $ TBD. The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer. Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.

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

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

	Estimated Cost ($)	**Fixed Fee ($)**	**Estimated Cost Plus Fixed Fee ($)**
Base period	TBD	TBD	TBD
Option Period 1	TBD	TBD	TBD
Option Period 2	TBD	TBD	TBD
Total Base Period and Option(s)	TBD	TBD	TBD

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.

"Confidential Information" is scientific, business, or financial information provided by the Supplier or the NIAID Contract Officer's Representative (COR) and marked "Confidential." Oral Disclosures of Confidential Information will be reduced to writing, marked "Confidential;" and sent to Contractor within 10 days of disclosure to be considered Confidential Information. Confidential Information may not be revealed without written permission from the COR. Similarly, designated Materials are to be considered confidential. In cases where it is not clear whether information or Materials are to be considered confidential, the Contractor should contact the COR to obtain a determination. All materials supplied to the Contractor shall be utilized solely for contract-related research purposes and no unauthorized use or distribution of these materials shall be permitted.

Any Publication containing data generated under this contract ("Results") must be submitted for review by the COR and Supplier before submission for public presentation or publication. A "Publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, for example a manuscript or abstract. The purpose of this review is to ensure that Publications do not contain any of NIAID's or Supplier's proprietary Confidential Information and to allow Supplier time to

file patent applications, if so desired. Contract support shall be acknowledged in all Publications of Results. The COR and Supplier will review all Publications containing Results submitted to the COR and Supplier in a period of time not to exceed 120 calendar days from receipt of Results by both the COR and Supplier, and will either agree to the publication/disclosure, recommend changes and, as applicable, refer the document to the Supplier of the compound for their review. Publication of results earlier than 120 days after submission will require Supplier's written approval. When the Supplier does not consent to publication of the manuscript or abstract on the basis that Supplier's Confidential Information is included in the Publication, the COR shall notify the Contractor and the NIAID Contracting Officer. The COR is responsible for ensuring that all parties adhere to the terms and conditions of any existing Material Evaluation Agreement or other appropriate document between NIAID and the Supplier. NIAID will use its best efforts to assist and expedite the review process by the Supplier.

Should patents arise from this contract, they shall be subject to federal law governing inventions. Every patent applicant (individual or institutional) is required to provide the Government with a non-exclusive, irrevocable, paid-up license to the invention.

135 USC 201(e): The term ''subject invention'' means any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement: Provided, that in the case of a variety of plant, the date of determination (as defined in section 41(d) of the Plant Variety Protection Act (7U.S.C. 2401(d)) must also occur during the period of contract performance.

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.

1. Offerors proposing to conduct clinical trials within the IMPAc-TB program will be the IND sponsor or include a subcontractor(s) that serves as the IND sponsor. However, NIAID reserves the right to serve as the IND sponsor on a clinical trial, if in the best interest of the IMPAc-TB program and the Government.

2. NIAID will work with IMPAc-TB Contractors after award to foster information, data and resource sharing amongst the funded investigators. In addition, while offerors may not include government furnished resources in their proposals, NIAID reserves the right to foster collaborations between the IMPAc-TB Contractors and government employees (e.g., NIAID intramural researchers) and provide access to government facilities after award.

SECTION C - Description/Specifications/Work Statement

ARTICLE C.1. STATEMENT OF WORK

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

Offeror(s) are required to develop their own SOW based on the information provided in the Attachment titled, "Research and Technical Objectives." Offeror(s) are advised to limit the amount of proprietary data or markings in their SOW. The final negotiated SOW will be incorporated into the contract upon award and may be subject to release to the public. If the SOW does include proprietary data or markings, offeror(s) are advised to clearly mark these portions and provide an explanation why this data/marking is proprietary."

ARTICLE C.2. REPORTING REQUIREMENTS

All reports shall be submitted electronically.

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

a. **Technical Progress Reports**

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

For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s) hard copies of these reports will be required as follows:

[ ] Monthly
[ ] Quarterly
[X] Semi-Annually
[ ] Annually
[X] 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)

b. **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.

c. **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.

d. **Reporting on Select Agents or Toxins and/or Highly Pathogenic Agents**

For work involving the possession, use, or transfer of a Select Agent or Toxin and/or a Highly Pathogenic Agent, the following information shall also be included in each Semi-Annual Progress Report:

1. Any changes in the use of the Select Agent or Toxin including initiation of "restricted experiments," and/or a Highly Pathogenic Agent, that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or institutional biosafety official.

2. If work with a new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent will be conducted in the upcoming reporting period, provide:

    a. A list of each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent that will be studied;

b. A brief description of the work that will be done with each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent and whether or not the work is a Select Agent or Toxin restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b https://www.selectagents.gov/regulations/index.htm) or listed on the U.S. Federal Select Agents Registry restricted experiments website (https://www.selectagents.gov/compliance/guidance/restricted/index.htm);

c. The name and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or institutional biosafety official. It must be noted if the work is being done in a new location or different location.

d. For work with Select Agents performed in the U.S. provide documentation of registration status of all domestic organizations where Select Agent(s) will be used. For work with Select Agents performed in a non-U.S. country prior NIAID approval is required.

If the IBC or equivalent body or institutional biosafety official has determined, for example, by conducting a risk assessment, that the work that has been performed or is planned to be performed under this contract may be conducted at a biocontainment safety level that is lower than BSL3, a statement to that affect shall be included in each Semi-Annual Progress Report.

If no work involving a Select Agent or Toxin and/or a Highly Pathogenic Agent has been performed or is planned to be performed under this contract, a statement to that affect shall be included in each Semi-Annual Progress Report.

e. **Other Reports/Deliverables**

1. **Reporting of Financial Conflict of Interest (FCOI)**

All reports and documentation required by 45 CFR Part 94, Responsible Prospective Contractors including, but not limited to, the New FCOI Report, Annual FCOI Report, Revised FCOI Report, and the Mitigation Report, shall be submitted to the Contracting Officer in Electronic format. Thereafter, reports shall be due in accordance with the regulatory compliance requirements in 45 CFR Part 94. 45 CFR Part 94 is available at: https://www.ecfr.gov/current/title-45/part-94.

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

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

2. **Section 508 Annual Report**

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

3. **Multiple Principal Investigators Leadership Plan**

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

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

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

Contracting Officer
Office of Acquisition and Logistics Management
Research & Development and Professional Services, Division A
6701 Rockledge Dr
Bethesda, MD 20817-7786

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, TBD 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
Bethesda, Maryland 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

a. The period of performance of this contract shall be from TBD through TBD.

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

Option	Option Period
Option Period 1	TBD
Option Period 2	TBD

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 date(s) specified in Attachment 4 and specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract.

b. 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 24, 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 one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this 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.

(End of clause)

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 in the contract 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 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. 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 with a copy of the invoice to the approving official, 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 shall 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 Email Address- 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 FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is Office of Acquisition and 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: To be specified in the contract.

g. Contract Line Items as follows:

Line Item #	Line Item Description
TBD	TBD

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

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

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

ARTICLE G.3. 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 Contracting Officer Representative 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.4. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with 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.

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

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

a. Electronic Access to Contractor Performance Evaluations

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

End of clause.

ARTICLE G.5. GOVERNMENT PROPERTY

If this BAA will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, 'HHS Contracting Guide for Contract of Government Property,' Appendix Q, which can be found at: https://oamp.od.nih.gov/sites/default/files/DGS/HHS%20Contracting%20Guide%20for%20Contract%20of%20Government%20Property-Appendix%20Q.pdf

ARTICLE G.6. 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.7. HHSAR 352.237-75 Key Personnel. (DEC 2015)

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

(End of Clause)

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

Name	Title
TBD	TBD

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. 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.5. 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.6. 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.7. 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.8. 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.9. 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.10. PUBLIC HEALTH SURVEILLANCE EXCLUSION

The Contractor may request an exclusion from applicability of the "revised Common Rule"* 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.

*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.11. 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.12. 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.13. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

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

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

ARTICLE H.14. 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.15. LIMITATION ON USE OF FUNDS FOR PROMOTION OF LEGALIZATION OF CONTROLLED SUBSTANCES

The Contractor shall not use contract funds to support activities that promote the legalization of any drug or other substance included in schedule I of the schedules of controlled substances established under section 202 of the Controlled Substances Act, except for normal and recognized executive-congressional communications. This limitation shall not apply when the Government determines that there is significant medical evidence of a therapeutic advantage to the use of such drug or other substance or that federally sponsored clinical trials are being conducted to determine therapeutic advantage.

ARTICLE H.16. 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.17. 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.18. 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.19. 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.20. GUN CONTROL

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

ARTICLE H.21. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item 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.22. 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/Contract Specialist/title of alternate designee] must be included as a contact for notification purposes at the following e- mail address:

[TBD]
[Contracting Officer/Contract Specialist]

ARTICLE H.23. 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

(2) The reason(s) for restricting the types of information identified in subparagraph (d)(1) is/are: TBD

(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.24. 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.25. 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. TBD "

a. **Advanced Copies of Press Releases**

Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall 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.26. 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.27. 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.

A. Sharing of Model Organisms for Biomedical Research

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

ARTICLE H.28. SHARING RESEARCH DATA

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.29. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

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

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

ARTICLE H.30. 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.31. 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.32. HHSAR 352.224-70 Privacy Act. (DEC 2015)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations.

The term *system of records* means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual. Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)).

The Contractor shall ensure that each of its employees knows the prescribed rules of conduct in 45 CFR part 5b and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as Department of Health and Human Services employees. These provisions also apply to all subcontracts the Contractor awards under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a(m)(1)). The contract work statement:

(a) Identifies the system(s) of records and the design, development, or operation work the Contractor is to perform; and

(b) Specifies the disposition to be made of such records upon completion of contract performance.

(End of clause)

ARTICLE H.33. 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.34. 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.35. INFORMATION AND COMMUNICATION TECHNOLOGY ACCESSIBILITY NOTICE, 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.36. 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.37. 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.38. 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).

SECTION I - Contract Clauses

1. GENERAL CLAUSES

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

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

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

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

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically as follows: FAR Clauses at: https://www.acquisition.gov/browse/index/far *. 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 SUBSTITUTION OF CLAUSES

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

It is expected that the following substitutions will be made part of the resultant contract:

a. **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.

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

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

ARTICLE I.3. ADDITIONAL RFO CONTRACT CLAUSES IN FULL TEXT

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

Clause Database	Clause Number	Clause Title
RFO	52.203-13	Contractor Code of Business Ethics and Conduct. (NOV 2021)
RFO	52.203-14	Display of Hotline Poster(s). (NOV 2021)
RFO	52.204-14	Service Contract Reporting Requirements (DEVIATION)(Nov 2016).
RFO	52.240-93	Basic Safeguarding of Covered Contractor Information Systems. (DEVIATION) (NOV 2025)
RFO	52.209-10	Prohibition on Contracting With Inverted Domestic Corporations. (DEVIATION) (NOV 2025)
RFO	52.210-1	Market Research. (DEFIATION)(JUL 2025)
RFO	52.219-9	Small Business Subcontracting Plan (DEVIATION) (RFO FEB 2026)
RFO	52.219-4	Notice of Price Evaluation Preference for HUBZone Small Business Concerns (DEVIATION) (Nov 2025)
RFO	52.219-28	Post-Award Small Business Program Representation. (DEVIATION) (NOV 2025)
RFO	52.227-14	Rights in Data-General. (MAY 2014) - Alternate II (DEC 2007)
RFO	52.227-16	Additional Data Requirements. (JUN 1987)
RFO	52.230-2	Cost Accounting Standards (DEVIATION) (Nov 2025)
RFO	52.230-6	Administration of Cost Accounting Standards (DEVIATION) (Nov 2025)
RFO	52.237-3	Continuity of Services. (JAN 1991)

Clause Database	Clause Number	Clause Title
RFO	52.246-25	Limitation of Liability - Services. (FEB 1997)
RFO	52.247-63	Preference for U.S.-Flag Air Carriers. (JUN 2003)
HHSAR	352.208-70	Printing and Duplication. (FEB 2026)(RFO DEVIATION)
HHSAR	352.211-3	Paperwork Reduction Act. (NOV 2025) (RFO DEVIATION)
HHSAR	352.223-70	Safety and Health. (DEC 2015)
HHSAR	352.231-70	Salary Rate Limitation (December 2015).
HHSAR	352.232-71	Electronic Submission of Payment Requests (FEB 2026) (RFO DEVIATION)

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

This contract incorporates the following clauses in full text:

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

*A. **RFO 52.209-9 Updates of Publicly Available Information Regarding Responsibility Matters**. (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)

*B. RFO **52.217-7 Option for Increased Quantity - Separately Priced Line Item**. (MAR 1989)*

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

(End of clause)

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)

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 4 Wage Determination No.: 2015-4187

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).

SECTION J - List of Documents, Exhibits and Other Attachments

The following documents are incorporated into this BAA:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (R&D)	See Attachment Section at the end of this BAA.
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at the end of this BAA.
Attachment 3:	Broad Agency Announcement Description	See Attachment Section at the end of this BAA.
Attachment 4:	Background and Introduction	See Attachment Section at the end of this BAA.
Attachment 5:	Research and Technical Objectives	See Attachment Section at the end of this BAA.
Attachment 6:	Reporting Requirements and Deliverables	See Attachment Section at the end of this BAA.
Attachment 7:	Additional Technical Proposal Instructions	See Attachment Section at the end of this BAA.
Attachment 8:	Additional Business Proposal Instructions	See Attachment Section at the end of this BAA.
Attachment 9:	Section K - Representations, Certifications, and Other Statements of Offerors	See Attachment Section at the end of this BAA.

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 10:	Technical Proposal Cost Summary	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf
Attachment 11:	Summary of Related Activities	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf
Attachment 12:	Voluntary Product Accessibility	hhttps://www.section508.gov/sell/vpat
Attachment 13:	Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310)	https://oamp.od.nih.gov/sites/default/files/DGS/Section%20J%20Protection%20of%20Human%20Subjects%20Form-0990-0263%202-22.pdf
Attachment 14:	Contract Proposal Vertebrate Animal Section (VAS) Worksheet	https://grants.nih.gov/grants/olaw/vascontracts.pdf

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 15:	Proposal Summary and Data Record, NIH-2043	https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf
Attachment 16:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	https://oamp.od.nih.gov/content/breakdown- proposed-estimated-cost-plus-fee-and- labor-hours https://oamp.od.nih.gov/sites/default/files/DFASDocs/buscntrctprpslsprdsht08-2014_508.xlsx
Attachment 17:	Offeror's Points of Contact	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf
Attachment 18:	Certificate of Current Cost or Pricing Data	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/cert-current-cost.pdf
Attachment 19:	Wage Rate Determination	See Attachment Section at the end of this BAA.
Attachment 20:	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 21:	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 22:	Privacy Act System of Records	https://www.hhs.gov/foia/privacy/sorns/nih-sorns.html
Attachment 23:	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 24:	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 25:	eRDS Quick Reference Guide	See Attachment Section at the end of this BAA.
Attachment 26:	Commitment to Protect Non-Public Information Contractor Agreement	https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j

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

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

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

3. 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).

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 Bidders

*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.”

ARTICLE L.1. GENERAL INFORMATION

a. DEFINITION [FAR 2.101]

"Broad agency announcement" means a general announcement of an agency's research interest including criteria for selecting proposals and soliciting the participation of all offerors capable of satisfying the Government's needs (see 6.102(d)(2))."

BROAD AGENCY ANNOUNCEMENT [FAR Provision 35.016]

(a) *General.* This paragraph prescribes procedures for the use of the broad agency announcement (BAA) with Peer or Scientific Review (see 6.102(d)(2)) for the acquisition of basic and applied research and that part of development not related to the development of a specific system or hardware procurement. BAAs may be used by agencies to fulfill their requirements for scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution. The BAA technique shall only be used when meaningful proposals with varying technical/scientific approaches can be reasonably anticipated.

(b) The BAA, together with any supporting documents, shall -

(1) Describe the agency's research interest, either for an individual program requirement or for broadly defined areas of interest covering the full range of the agency's requirements;

(2) Describe the criteria for selecting the proposals their relative importance, and the method of evaluation;

(3) Specify the period of time during which proposals submitted in response to the BAA will be accepted; and

(4) Contain instructions for the preparation and submission of proposals.

(c) The availability of the BAA must be publicized through the Governmentwide point of entry (GPE) and, if authorized pursuant to subpart 5.5, may also be published in noted scientific, technical, or engineering periodicals. The notice must be published no less frequently than annually.

(d) Proposals received as a result of the BAA shall be evaluated in accordance with evaluation criteria specified therein through a peer or scientific review process. Written evaluation reports on individual proposals will be necessary but proposals need not be evaluated against each other since they are not submitted in accordance with a common work statement.

(e) The primary basis for selecting proposals for acceptance shall be technical, importance to agency programs, and fund availability. Cost realism and reasonableness shall also be considered to the extent appropriate.

(f) Synopsis under subpart 5.2, Synopses of Proposed Contract Actions, of individual contract actions based upon proposals received under the BAA is not required. The notice published pursuant to subparagraph (c), of this section, fulfills the synopsis requirement.

b. INSTRUCTIONS TO OFFERORS-- BROAD AGENCY ANNOUNCEMENT

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

Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

In writing, "writing," or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

Proposal modification is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

Proposal revision is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

Time, if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

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

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

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

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

(i) The solicitation number;

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

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

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

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

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

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

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

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

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

(3) It is the only proposal received.

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

(iv) 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.

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

to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

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

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

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

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

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

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

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

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

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

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

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

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

(f) Contract award.

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

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

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

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

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

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

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

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

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

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

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

> (i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
>
> (ii) The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.

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

(iv) A summary of the rationale for award.

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

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

(End of provision).

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

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

c. **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 BAA), 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 1,000 employees.

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

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

1. It is anticipated that two to three will be made from this solicitation and that the award will be made on/about September 29, 2027.

2. It is anticipated that the awards from this solicitation will be multiple-year Cost-Reimbursement type completion contracts with a Base of 1 year and up to four (4) option periods, (See Section L.2.c. Business Proposal Instructions).

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.

e. **ESTIMATE OF EFFORT**

In accordance with the Broad Agency Announcement (BAA) design, the Government has issued a general announcement of the agency's research interest. Submissions in response to this BAA will represent each offeror's creative and innovative approach to the specific research. Therefore, the Government is unable to provide an estimate of effort but reminds all offerors that they shall propose effort that is consistent with the nature and complexity of their proposed research.

f. **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.

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

h. **RELEASE OF INFORMATION**

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

i. **PREPARATION COSTS**

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

j. **SERVICE OF PROTEST** RFO 52.233-2 (DEVIATION)(NOV 2025).

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

Contracting Officer
Office of Acquisition and Logistics Management
Research & Development and Professional Services, Division A
6701 Rockledge Dr
Bethesda, MD 20817-7786

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

(End of provision).

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

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

(End of provision).

ARTICLE L.2. INSTRUCTIONS TO OFFERORS

a. **GENERAL INSTRUCTIONS**

INTRODUCTION

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

1. **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement completion 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 BAA. 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 BAA title, number, name of organization, UEI No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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 BAA.

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 BAA, 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 FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.

f. The 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 3 years and all 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. **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.

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

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board

Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

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

c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility. In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site http://www.hhs.gov/web/508. In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

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

(End of provision).

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

19. **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).

20. **Information and Communication Technology Accessibility Notice,** 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).

21. **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.

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

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

d. Limitations on Pass-Through Charges--Identification of Subcontract Effort, RFO Provision 52.215-22, (DEVIATION)(NOV 2025).

e. 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 Broad Agency Announcement indicates that the stipulated schedules are mandatory, they shall be treated as desired or recommended schedules. In this event, proposals based upon the offeror's best alternative schedule, involving no overtime, extra shift or other premium, will be accepted for consideration.

b. **Personnel**

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

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

1. Single Principal Investigator/Project Director

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

2. Other Investigators

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

3. Additional Personnel

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

1. The specific items or expertise they will provide.

2. Their availability to the project and the amount of time anticipated.

3. Willingness to act as a consultant.

4. How rights to publications and patents will be handled.

4. Resumes

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

2. **Other Considerations**

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

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

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

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

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

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

3. **Technical Evaluation**

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

4. **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 of Requirements, 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) Web site at: http://www.hhs.gov/ohrp/index.html .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 46.101(b)(1)-(6) 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 shall 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 shall 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 shall document in its proposal the approved FWA from OHRP, related to the designated Institutional Review Board (IRB) reviewing and overseeing the research. If the offeror does not have an approved FWA from OHRP, the offeror must obtain an FWA before the deadline for proposal submission. When possible, the offeror shall 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. 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).

As prescribed in HHSAR 370.303(a), the Contracting Officer shall substitute the following paragraph (g) for paragraph (g) of the basic clause.

(g) The offeror's proposal shall document that it has an approved or active FWA from OHRP, related to the designated IRB reviewing and overseeing the research. When possible the offeror shall also certify the IRB has reviewed and approved the research. If the offeror cannot make this certification at the time of proposal submission, its proposal must include an explanation. Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB. If the offeror does not have an active FWA from OHRP, the offeror shall take all necessary steps to obtain an FWA prior to the deadline for proposal submission. If the offeror cannot obtain an FWA before the proposal submission date, the proposal shall indicate the steps/actions the offeror will take to obtain OHRP approval within (Contracting Officer must 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.

1. 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.

2. 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. Pregnant Women, Fetuses, and Neonates or Children - 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. The University of Rochester manual, entitled, "Protecting Study Volunteers in Research," can be obtained through CenterWatch, Inc. at: https://www.centerwatch.com/products/category/1060-training-guides .

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 Minorities 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 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 Minorities as Subjects in Clinical Research, Amended November 2017," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(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. Patient-oriented

research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research."

e**. 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 minorities 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/gender and racial/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, national and local demography, 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/gender or racial/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 FAR 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/policy/inclusion/women-and-minorities/guidelines.htm, Glossary/Definitions - Significant Difference). *The definition of an " **NIH-Defined Phase III clinical trial** " can also be found at this website.) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity 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/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups,

OR

• Plans to include and analyze sex/gender and/or racial/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/gender 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.

Use the form entitled, "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report," when preparing your response to the solicitation requirements for

inclusion of women and minorities. (See Section J-List of Documents, Exhibits and Other Attachments of the BAA)

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this BAA 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 reporting in the resultant contract.

f. **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 BAA.

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.

g. **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.

h. **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.

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[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."

i. **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.

j. **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.

k. **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 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/gender, race, ethnicity, and age at enrollment may be provided in progress reports.

l. **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).

m. **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).

n. **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 Broad Agency Announcement (BAA) 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.

o. **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, are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for proposals proposing to study only one sex. If your proposal involves human subjects, the sections on the Inclusion of Women and Minorities and Inclusion of Children can be used to expand your discussion and justify the proposed proportions of individuals (such as males and females) in the sample. Refer to 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.

p. **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.

q. **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).

r. **Sharing of Model Organisms for Biomedical Research**

The NIH Research Tools Policy (https://grants.nih.gov/policy/sharing.htm) also referred to as NIH Principles and Guidelines for Sharing of Biomedical Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042 at: (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html), dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066 at: (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html), the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Offerors must include in their technical proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources, OR provide appropriate reasons why such sharing is restricted or not possible. A reasonable time frame for periodic disposition of material and associated data must be specified in the proposal. In addition, the plan must address if, or how, offerors will exercise their intellectual property rights while making model organisms and research resources available to the broader scientific community. At a minimum, the plan should address the following:

1. Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) at: https://www.ott.nih.gov/sites/default/files/documents/pdfs/slaform.pdf ; for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (https://autm.net/surveys-and-tools/agreements/material-transfer-agreements/mta-toolkit/uniform-biological-material-transfer-agreement)

2. How will inappropriate "reach-through" requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?

3. How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

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

s. **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:

See https://www.hhs.gov/web/policies-and-standards/index.html.

c. **BUSINESS PROPOSAL INSTRUCTIONS**

1. **Basic Cost/Price Information**

The business proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit.

2. **Proposal Cover Sheet**

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation, contract, and/or modification number;

2. Name and address of Offeror;

3. Name and telephone number of point of contact;

4. Name, address, and telephone number of Contract Administration Office, (if available);

5. Name, address, and telephone number of Audit Office (if available);

6. Proposed cost and/or price; profit or fee (as applicable); and total;

7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.

8. Date of submission; and

9. Name, title and signature of authorized representative.

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

3. **Data Other than Certified Cost or Pricing Data**

a. Data submitted shall be sufficient to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., data to support an analysis of material costs (when sufficient data on labor and overhead rates is already available), or data on prices and quantities at which the offeror has previously sold the same or similar items.

Data submitted must support the price proposed. The offeror shall include sufficient detail or cross references to clearly establish the relationship of the data provided to the price proposed. The offeror shall support any data provided with explanations or supporting rationale, as needed, to permit the Contracting Officer and authorized representative to evaluate the documentation.

Unless otherwise stated in this solicitation, the information may be submitted in the offeror's own format.

b. The data submitted shall be at the level of detail described below.

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 $750,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

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.

4. 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 FAR 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.

5. **Salary Rate Limitation**

Offerors are advised that no NIH funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level II* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the Contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the Contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level II*. The Executive Schedule, Level II* annual salary rate limitation also applies to individuals proposed under subcontracts and to consultants. **LINK TO EXECUTIVE SCHEDULE RATES OF PAY:**

https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/

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

***Note to Offerors** : The current Fiscal Year Executive Level II Salary Rate shall be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year Executive Level II Salary rates.

6. **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $9000,000 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.

4. Each plan must contain the following:

i. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

ii. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

iii. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

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

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

vi. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

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

viii. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

ix. Assurances that the offeror will include in all subcontracts the contract clause 'Utilization of Small Business Concerns.' Assure that all subcontractors, other than small businesses, in excess of $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.esrs.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 BAA 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% for Service-Disabled Veteran-Owned Small Business.

7. 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).

h. **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone .

8. **Other Administrative Data**

a. **Property**

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below, the proposal must include a comprehensive justification addressing the following items:

a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.

b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. Government Property

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

a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);

b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used

concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;

c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and

d. A description of the offeror's property management system, plan, and any customary commercial practices, voluntary consensus standards, or industry-leading practices and standards to be used in the offeror in managing Government property.

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

b. **Royalties**

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

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.

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**

FAR Part 16 sets forth the requirements and limitations for consideration of contract type. As stated in Section L.1., General Instructions of this solicitation, the resultant contract will not be Firm-Fixed Price. Therefore, the offeror's/contractor's accounting system and practices must be adequate and suitable for accumulating costs under government contracts.

To be considered for an award under this solicitation, the offeror shall include, in the Business Proposal, the following Certification:

"By submission of its signed offer, the Offeror certifies that its accounting system:

1. Complies with Generally Accepted Accounting Principles (GAAP).

2. Provides for:

    a. Proper segregation of direct costs from indirect costs.

    b. Identification and accumulation of direct costs by contract.

    c. A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.

    d. Accumulation of costs under general ledger control.

    e. A timekeeping system that identifies employees' labor by intermediate or final cost objectives.

    f. A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.

    g. Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.

    h. Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions.

    i. Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.

    j. Segregation of preproduction costs from production costs, if applicable.

3. Accounting system provides financial information:

a. Required by contract clause concerning limitation of cost (FAR 52.232-20) or limitation on payments (FAR 52.216-16).

b. Required to support requests for progress payments.

4. Accounting system was designed, and records are maintained in such a manner that adequate, reliable data are developed for use in pricing follow-on acquisitions.

5. Accounting system is currently in full operation.

The Contracting Officer reserves the right to request, with the Final Proposal Revision (FPR), a current (within 18 months) CPA opinion confirming that the Offeror's accounting system is compliant as certified above.

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).

If the offeror elects to claim this cost, the offeror shall specifically identify or propose it in the cost proposal for the contract by checking the appropriate box below.

[ ] Fac Cap Cost of Money (Has) The prospective Contractor **has** specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

[ ] Fac Cap Cost of Money (Has Not) The prospective Contractor **has not** specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

9. **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this BAA, 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 BAA**

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 BAA. 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 BAA.

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 BAA.

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 BAA; 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 BAA. 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 BAA 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.

10. **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.

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

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

12. **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 BAA 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.

13. **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

ARTICLE M.1. GENERAL

Proposals will be evaluated against the following evaluation factors in the order of importance: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, cost/price, and past performance are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are more important than cost or price. The estimated cost of an offer must be reasonable for the tasks to be performed and will be subject to analysis by the Government.

The merit of each technical proposal will be evaluated by a peer review group. The Government reserves the right to convene multiple peer review groups to evaluate proposals. Offerors must demonstrate in their proposals that they have the necessary expertise and capabilities for conducting the proposed research. The evaluation will be based on the demonstrated capabilities of the offerors in relation to the needs of the project as set forth in the BAA. Each proposal must demonstrate the feasibility of its approach and its relevance to the Research and Technical Objectives of the BAA. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria.

Following the proposal evaluation, the Government will conduct negotiations with selected offerors to address identified weaknesses, questions, and areas for clarification, as well as to refine the proposed Statement of Work and deliverables. The selection of proposals for award is based upon the evaluation factors, importance to the agency programs, and fund availability.

ARTICLE M.2. COST/PRICE EVALUATION

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in 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 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value tradeoff decision.

ARTICLE M.3. 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.

ARTICLE M.4. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

a. **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.

b. **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.

ARTICLE M.5. LIVE VERTEBRATE ANIMALS EVALUATION

The offerors proposal must include, as a separate section of the Technical Proposal titled "Vertebrate Animal Section," (VAS) a complete, concise (no more than 1-2 pages) description addressing the following criteria. (See NIH Guide Notice NOT-OD-16-006 at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html):

a. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Broad Agency Announcement (BAA) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.

b. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).

c. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.

d. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

As part of the overall technical evaluation of proposals, the reviewers will consider the acceptability of the offeror's description in the VAS of the technical proposal. The discussion of all criteria will be addressed and evaluated. Based on the evaluation of this Section, the VAS may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the description addressing each of the criteria, or no discussion can be found

regarding the VAS), or "acceptable." If the reviewers find that this Section of the technical proposal is "unacceptable" they will provide a narrative supporting their findings.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed description under the VAS is still found to be unacceptable, then your proposal may not be considered further for award.

ARTICLE M.6. EVALUATION OF OPTIONS

It is anticipated that any contract awarded from this solicitation will contain option provisions and periods.

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

ARTICLE M.7. 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.

ARTICLE M.8. 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.

ARTICLE M.9. EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH

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

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

ARTICLE M.10. 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.

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	**70**

A. Relevance and merit of the proposed scientific approach to the research and technical objectives of the BAA.

B. Soundness of the supporting research used to justify the proposed work.

C. Documented ability of the offeror to successfully complete the proposed activities as demonstrated through the technical approach.

D. The potential of the research to: increase knowledge or understanding; the degree of innovation; and/or potential to advance the state-of-the-art.

E. Sufficiency of the proposed strategy to ensure a robust and unbiased approach, as appropriate for the work proposed. Adequacy of the proposed plan to address relevant biological variables, including sex, as applicable, for studies in vertebrate animals and/or human subjects.

CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL	**30**

Appropriateness and adequacy of the qualifications of the proposed Principal Investigator and scientific and technical personnel, including any proposed subcontractors and consultants, to perform the proposed Statement of Work.

CRITERION 3: PROJECT MANAGEMENT	**25**

Appropriateness and adequacy of the proposed Project Management Plan, Staffing Plan, project management systems, and timelines.

CRITERION 4: ORGANIZATIONAL FACILITIES, EQUIPMENT, AND OTHER	**25**

RESOURCES

Availability and adequacy of the necessary facilities, equipment, and other resources to implement the proposed research safely and successfully.

TOTAL POSSIBLE WEIGHT: 150

ARTICLE M.11. 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.

ARTICLE M.12. PAST PERFORMANCE FACTOR

Offerors' past performance information will be evaluated prior to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal is determined to be technically unacceptable.

ARTICLE M.13. EVALUATION OF FOREIGN CURRENCY OFFERS , RFO 52.225-17, (FEB 2000)

If the Government receives offers in more than one currency, the Government will evaluate offers by converting the foreign currency to United States currency using the U.S. Department of the Treasury’s Bureau of the Fiscal Service in effect as follows:

a. For acquisitions conducted using sealed bidding procedures, on the date of bid opening.
b. For acquisitions conducted using negotiation procedures
    1. On the date specified for receipt of offers, if award is based on initial offers; otherwise
    2. On the date specified for receipt of proposal revisions.

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 **200 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 **4 pages**.
4. **Pages exceeding limitations will be removed from the proposal and will not be considered.**

Attachment 2

PROPOSAL INTENT RESPONSE FORM

RFP No: NIAID-75N93026R00008

RFP Title: Immune Mechanisms of Protection Against Mycobacterium tuberculosis Center (IMPAc-TB)

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 July 9, 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: BROAD AGENCY ANNOUNCEMENT DESCRIPTION

Immune Mechanisms of Protection Against *Mycobacterium tuberculosis* Center (IMPAc-TB)
BAA 75N93026R00008

BROAD AGENCY ANNOUNCEMENT INFORMATION

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA). The BAA is authorized by Federal Acquisition Regulation (FAR) 6.102 and further described in FAR 35.016 as well as the NIH Policy Manual, Manual Chapter 6035, Broad Agency Announcements. A BAA may be used as a solicitation mechanism for basic and applied research directed toward advancing the state-of-the-art or increasing knowledge or understanding and that part of development not related to the development of a specific system or hardware procurement. BAAs are general in nature, identifying areas of research interest, and shall only be used when meaningful proposals with varying technical/scientific approaches can be reasonably anticipated.

Offers submitted in response to this BAA must present detailed technical and business proposals designed to meet the Research and Technical Objectives described. The Statement of Work, including the specific technical requirements and performance specifications, is developed and proposed by the offeror, not the Government.

Proposals are NOT evaluated against each other since they are not submitted in accordance with a common Statement of Work issued by the Government. Instead, Research and Technical Objectives are provided in the BAA that describe the research areas in which the Government is interested. Proposals received in response to the BAA are evaluated in accordance with Evaluation Factors for Award specified in Section M. NIAID will assess whether the work proposed should be redirected, removed, and/or whether schedule or budget adjustments should be made. As a result, during discussions with offerors, NIAID reserves the right to modify or delete proposed milestones, decision points, research plans, process, schedule, budget, or product. The selection of proposals for award is based upon the evaluation factors, importance to the agency programs (programmatic balance), and fund availability.

It is anticipated that two to three cost reimbursement, completion type contracts will be awarded with performance beginning about September 1, 2027. NIAID estimates that the average annual total cost (direct and indirect costs combined) for the entire program will be $10.5 million. However, it is anticipated that the total cost for each award may vary depending upon the scope of the project and the technical objectives and will be approximately $5 million total costs per year. The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research and should not exceed five years.

ATTACHMENT 4: BACKGROUND and INTRODUCTION

Immune Mechanisms of Protection Against *Mycobacterium tuberculosis* Center
(IMPAc-TB)
BAA 75N93026R00008

Research supported by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (DHHS), strives to understand, treat, and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives in the United States (U.S.). NIAID supports a robust program in basic immunology that includes detailed analyses of human immune responses to pathogenic infections and/or vaccines. NIAID also has a key role in basic, translational, and clinical studies to further the understanding of *Mycobacterium tuberculosis* (Mtb) infection and disease in people living with or without Human Immunodeficiency Virus (HIV). Furthermore, NIAID provides several resources to the scientific community including testing services of therapeutics, animal models, and reagents for research to support biomedical drugs, vaccines, and diagnostics research.

Tuberculosis (TB) caused by Mtb is the leading cause of death due to an infectious disease globally and remains a major public health concern with about a quarter of the world population estimated to have been infected. Although treatment for TB exists, infections with multidrug resistant Mtb are a major threat. According to the World Health Organization, in 2024 tuberculosis once again was identified as the world's leading cause of death by a single infectious agent with an estimated 10.7 million cases of TB and 1.23 million deaths globally in 2024. In the U.S., TB incidence rates have surged to their highest in over a decade, with 10,347 cases reported in 2024 — an 8% increase from 2023. An estimated 13 million Americans live with latent TB facing a lifelong risk of developing active TB disease. Recent outbreaks of TB (including drug-resistant TB) in the South, Midwest, and Pacific Northwest regions of the U.S. further underscore the critical need for sustained investments in TB research. Furthermore, the risk of developing TB once exposed to Mtb is increased in individuals with a weak immune system such as those with HIV, cancer, chronic diseases such as diabetes, or transplantation patients. Individuals diagnosed with TB require long-term treatment with several antibiotics and this can be further complicated by the emergence of multidrug-resistant bacteria that do not respond to first-line anti-bacterial drugs.

Despite widespread use of the Bacillus Calmette-Guérin (BCG) vaccine, global TB incidence remains high. While BCG provides good protection against severe forms of TB in children, it is ineffective against adult pulmonary TB, the form most responsible for ongoing transmission. In recent years, several candidate TB vaccines have advanced through clinical development and several show promising protection in mid-stage clinical trials. For example, the adjuvanted subunit vaccine M72/AS01E, which demonstrated approximately 50% efficacy in Phase 2b clinical trials, entered Phase 3 testing in 2024, representing the most advanced TB vaccine candidate in nearly a century. MTBVAC, a live attenuated Mtb strain, has shown stronger immunogenicity than BCG in both infants and adults and is now undergoing Phase 3 infant trials and early adult efficacy studies. However, some highly anticipated strategies have not succeeded: Phase 2b trials revealed that BCG revaccination

of adolescents failed to prevent sustained infection, and the H56:IC31 vaccine did not reduce TB recurrence.

These mixed outcomes underscore a critical challenge in TB vaccine development: improved vaccines require a better understanding of what constitutes protective immunity in humans. Studies indicate that effective immunity is not driven by a single mechanism, but rather by a combination of responses, including robust Th1 and Th17 type $CD4^+$ T cells, $CD8^+$ T cells, lung-resident memory T cells, non-classical T cell responses, innate immune training, and antibody-mediated mechanisms. Yet, recent clinical trial setbacks highlight that immunogenicity alone is not sufficient; the quality, location, and timing of immune responses are pivotal for protection.

A major barrier remains the lack of validated correlates of protection. Without clear markers of protective immunity, vaccine development continues to rely on empirical approaches, limiting our ability to rationally design and evaluate new candidates. Identifying robust correlates of protection is essential to improve efficacy and achieve greater success in TB vaccine development.

To gain a comprehensive understanding of the nature, location, and timing of protective immune responses required to prevent initial Mtb infection, development of latent infection, or transition to active disease, NIAID awarded three contracts in response to solicitation BAA-NIAID-NIH-AI201700104 (Seattle Children's Research Institute: 75N93021C00029 (2021) and 75N93019C00070 (2019); and Harvard T.H. Chan School of Public Health 75N93019C00071 (2019).

These contracts comprise the NIAID-sponsored IMPAc-TB program that has provided important insights into the host immune response to Mtb. Using state-of-the art technologies, the studies have revealed key components of immune protection. These include the unexpected protective role of cytotoxic T cells, non-IFNγ $CD4^+$ T-cells responses associated with protection, and the crosstalk between myeloid cells and antibodies that may modulate baseline immune status and responses. In addition, the IMPAc-TB program further supported the development of novel small animal models for evaluating immune responses against Mtb, such as the ultra-low dose (ULD) Mtb infection, non-tuberculous mycobacterial co-infection, and collaborative cross mouse models. Clinical samples from human cohorts (*e.g.,* household contacts studies) have helped identify transcriptional signatures associated with protection. Also, novel computational modeling and data integration methods were developed to identify correlates of protection across species. Overall, the current contracts are providing a better understanding of cross-species evaluations of infection as well as vaccine-induced immune responses and supported NIAID's first controlled human pulmonary infection model in a clinical trial for a TB vaccine candidate.

Despite these and other advances made by the IMPAc-TB program, many knowledge gaps remain. This BAA will continue NIAID support for a comprehensive understanding of protective immunity in people with and without HIV.

The objective of the IMPAc-TB program renewal is to address these knowledge gaps and accelerate TB vaccine development by supporting research that further characterizes both tissue-specific and systemic protective immune responses that prevent or contain Mtb

infection, and furthers the advancement of tools and resources that facilitate TB vaccine development (*e.g.*, biological models and *in vitro* systems, computational and modeling platforms). This program will continue to support the comprehensive understanding of protective immunity to Mtb and the impact of Human Immunodeficiency Virus/Simian Immunodeficiency Virus (HIV/SIV) infection on responses to Mtb infection and TB vaccine candidates.

This solicitation will require the use of human samples and/or clinical studies (*e.g.*, observational, household cohorts), at least one animal model, and computational data integration and modeling for cross-comparative analyses of the human and animal studies. These requirements are in alignment with NIH's initiative to prioritize human-based research and with NIAID's TB strategic plan to improve the fundamental knowledge of TB and accelerate TB vaccine development. Inclusion of animal models is essential to advance mechanistic insights into immune responses that currently cannot be conducted in New Approach Methodologies (NAMs) or in humans. Data generated from the animal studies can be used to further NAMs development and implementation. Proposed animal models must be scientifically valid and justified. Clinical trials are optional (Phase 1-2a) and, if included, should be designed to understand safety and immunogenicity of TB vaccines/candidates to inform protective immunity against Mtb.

In addition, investigators may consider using NAMs, such as organoid or other *ex vivo* systems, to assess human immunity to Mtb or TB vaccine candidates. This program will help identify signatures associated with risk or protection from disease/infection and identify and evaluate protective antigens/immune epitopes. The identification of immune epitopes within the IMPAc-TB program is complementary to the Division of Allergy Immunology and Transplantation's (DAIT) Immune Epitope Discovery programs, and ongoing support for both programs will help to foster cross-collaborative activities. In addition, the initiative will support translation of knowledge gained about tissue-specific immune responses to advance vaccine approaches (including mucosal vaccine approaches). The IMPAc-TB program will support the refinement of fit-for-purpose animal models for testing vaccine candidates targeting different stages of TB disease and emerging technologies such as tissue-based models, and computational modeling for cross-species analyses. Clinical research will also be supported through clinical cohorts or clinical trials using novel vaccine candidates and will enable back-translation to animal models. This program will advance research to support TB vaccine development and facilitate the identification of biomarkers for diagnostic approaches for treatment and prevention strategies.

ATTACHMENT 5: RESEARCH AND TECHNICAL OBJECTIVES

Immune Mechanisms of Protection Against *Mycobacterium tuberculosis* Center (IMPAc-TB)

BAA 75N93026R00008

RESEARCH and TECHNICAL OBJECTIVES

This section presents the research and technical objectives that the Government seeks to achieve through this BAA. Proposals should explain how the offeror will contribute to these overall objectives. Contracts awarded under this BAA will include the Statement of Work proposed by the offeror and negotiated and accepted by the Government.

I. SCOPE:

The objective of this solicitation is to accelerate tuberculosis (TB) vaccine development by supporting research that characterizes both tissue-specific and systemic protective immune responses that prevent or contain *Mycobacterium tuberculosis* (Mtb) infection, and the advancement of tools and resources that facilitate TB vaccine development (*e.g.*, biological models, new approach methodologies [NAMs] such as organoids and *in vitro* systems, computational and modeling platforms). This program will continue to support the comprehensive understanding of protective immunity to Mtb and the impact of Human Immunodeficiency Virus/Simian Immunodeficiency Virus (HIV/SIV) infection on responses to Mtb and TB vaccines. This solicitation also requires the use of human samples and/or clinical studies, at least one animal model, and computational data integration and modeling for cross-comparative analyses of the human and animal studies. In addition, investigators may consider using organoids or other *ex-vivo* systems to assess human immunity to Mtb or TB vaccines. These requirements are in alignment with NIH's initiative to prioritize human-based research.

Integration of data generated across all models (*e.g.*, human, animal, NAMs) is expected to allow cross-comparison, data analyses and mechanistic interpretation. Therefore, proposals from highly collaborative and well-integrated investigative teams across scientific disciplines will be expected to plan and conduct the required studies to achieve the goals of the BAA. These studies include the development of Standard Operating Procedures (SOPs) and assay harmonization to be implemented by the center's members, in-depth immunologic analyses of tissue-specific and systemic responses against Mtb/TB in human studies, as well as in relevant animal models, examining host responses to Bacillus Calmette-Guérin (BCG) or novel, promising vaccine candidates (pre-and post-exposure candidates). Investigators supported through this solicitation will be required to collaborate with each other and share novel research resources including both positive and negative study results, reagents and other resources within their contract, between contracts (as applicable), with other NIAID supported programs, and with the broader research community. This open exchange will facilitate the development of improved TB vaccines and help guide the research and development activities across the scientific community.

For the ***purpose of this BAA***, *pre-exposure vaccines* are defined as vaccines to prevent Mtb infection, *post-exposure vaccines* are defined as those given to Mtb exposed or

individuals with latent TB infection to prevent disease/reactivation, and *therapeutic vaccines* are defined as vaccines given to augment the treatment of active disease.

II. PROGRAM OBJECTIVES:

To achieve the IMPAc-TB program goals, Contractors will be responsible for the following required activities:

1. **Leadership Team:**
   Provide a Leadership Team that will oversee an integrated, multi-disciplinary team of highly collaborative investigators and be responsible for the management, planning, coordination, communication, and conduct of each IMPAc-TB contract's proposed activities including to:
   a. Finalize and implement the center's proposed Scientific Agenda and Strategic Plan;
   b. Develop laboratory SOPs to be used by all laboratories within each center and to be shared with other IMPAc-TB contracts as needed;
   c. Provide plans for data management and assay harmonization to be implemented by the center's members;
   d. Provide and execute the project management plan;
   e. ensure data deposition into NIAID ImmPort, NIAID Vaccine Adjuvant Compendium (VAC) and publicly available databases, as advised by NIAID;
   f. Coordinate distribution of reagents and other resources within an IMPAc-TB contract and across the IMPAc-TB program, to other NIAID-supported programs, and the broader research community to facilitate the development of improved TB vaccines;
   g. Establish procedures to support operations and scientific progress, including reallocating funds, forming working groups, engaging new collaborators and technologies, and – in coordination with NIAID Program - setting contract-wide guidelines for presenting and publishing collaborative project results;
   h. Facilitate collaborations with other IMPAc-TB contracts by organizing and establishing cross-contract collaborative studies and activities post-award, with the goal of maximizing results obtained by individual contracts to augment knowledge gained from the entire program. These activities will be performed in coordination with the other IMPAc-TB Contractors and will be evaluated by NIH Program staff, the PI(s) of each IMPAc-TB contract, and an External Scientific Advisory Group (ESAG) assembled post-award that will provide suggestions to NIAID on progress and scientific direction of the IMPAc-TB program;
   i. Coordinate and report on the status and outcomes of collaborative interactions/joint projects within and across the IMPAc-TB contracts;
   j. Coordinate with NIAID Program Staff to organize and participate in annual progress program meetings, bi-monthly webinars/calls with other IMPAc-TB Contractors to share research updates and foster collaborations, and monthly calls with NIAID Program Staff to provide updates on progress.

2. **Data and resource management**:

a. Provide for the storage, retrieval, and analysis of contract-generated data, as well as cataloging and reporting of all contract-generated reagents and research resources (*e.g.*, novel animal models, computational tools, novel reagents).
b. Make all study results (both positive and negative) available within the contract, to other NIAID-supported programs, and the broader research community in a timely manner through designated NIAID-supported programs (*e.g.* ImmPort, Vaccine Adjuvant Compendium) or other public portals designated by NIAID. Provide central data storage, data management, and information security services to all researchers within the contract.

3. Immunologic Analysis:

a. Conduct in-depth systemic and tissue-specific immunologic analyses to generate novel insights into the immune responses required to protect a host from initial Mtb infection across different stages of Mtb infection and TB disease using relevant animal models and samples from human based research;
b. Studies should seek to move beyond analysis of single arms of the immune system to elucidate how complex immune networks and interactions drive biological outcomes;
c. For murine studies, the use of strains that go beyond the commonly used laboratory strains and clinically relevant Mtb challenge strains are encouraged.

4. Human-Based Research (clinical trials are optional):

Each proposal must include human-based research, such as:

a. Immunologic studies to identify key immune responses needed for protection against Mtb and immunologic targets that can be used to improve TB vaccine strategies;
b. Studies to assess the immune response to Mtb infection or TB vaccines in the context of HIV infection;
c. Analyses of tissue-specific immune responses in a minimum of two stages of Mtb infection (*e.g.,* primary infection, various stages of TB disease) and/or in response to BCG or investigational TB vaccines;
d. Identification of immune correlates in blood or other easily accessible body fluids (*e.g.*, bronchioalveolar lavage, sputum, saliva);
e. Studies may also include the use and/or further development of relevant organoid/*ex vivo* models (NAMs).

Note:

- Proposals are encouraged to leverage ongoing clinical cohorts or vaccine trials to obtain human samples for analyses.
- Proposals may include a Discovery Medicine clinical trial to advance the identification of immune correlates against Mtb infection or TB disease and dissect/characterize the immune mechanisms triggered by a candidate vaccine(s) or antigens.

5. Animal Models:

Each proposal must include research using at least one relevant animal model that is scientifically valid and justified.

a. Extensive tissue immunologic analyses, coupled with analyses of systemic immune responses to Mtb infection or TB vaccines are required;
b. Comparative immunologic studies using animals and human approaches are required with two major goals being to: 1) identify protective immune responses and elucidate mechanisms of these protective responses identified in humans; and 2) improve the predictive value of the animal model(s) for evaluating Mtb vaccine efficacy (*i.e.*, development of rigorous, portable immunologic endpoints that can be measured in - and have biological relevance in - humans and animals);
c. Determination of the impact of HIV/SIV infection on immune responses to Mtb infection or TB vaccines (if applicable).

6. **Computational data integration and modeling approaches:**
Each proposal shall be responsible for providing the following support.
a. Bioinformatics expertise and data integration and analysis support, including computational modeling, for the discovery and validation of immune signatures involved in protection (and/or susceptibility) that could inform the design or development of more effective vaccines against TB;
b. Statistical support for contract researchers shall be included. It is required to conduct cross-comparative data analyses of human-based and animal data, to develop and validate overall immune signatures associated with disease outcomes or vaccine efficacy;
c. A data scientist, or designee, will represent the IMPAc-TB contract in post-award meetings with other IMPAc-TB Computational Data Integration and Modeling teams to promote cross-contract collaboration, refinement of data standards, harmonization of data analysis and integration methods, and for further development or validation of immune signatures or biomarkers associated with TB disease or TB vaccination outcomes.

I. INCLUSIONS

Research areas may include but are not limited to:

1. Studies aimed at comprehensive understanding of protective systemic and tissue-specific immunity against Mtb in people living with or without HIV;
2. Identification of signatures associated with protection against infection, induction of latency or with risk of developing tuberculosis;
3. Translation of knowledge gained about tissue-specific immune responses to advance mucosal vaccine approaches;
4. Refinement of fit-for-purpose animal models for testing vaccine candidates targeting different stages of TB disease;
5. Identification and evaluation of protective antigens/immune epitopes;
6. Impact of the host immune response to Mtb infection and TB vaccines in the context of HIV/SIV infection;
7. Clinical research studies/trials that integrate data from preclinical models to guide trial design and analyses of clinical outcomes;
8. Clinical trials are optional (Phase 1-2a) and, if included, should be designed to understand safety and immunogenicity of TB vaccines/candidates to inform protective immunity against Mtb.

III. EXCLUSIONS

Contracts awarded under this solicitation <u>will NOT support</u>:

1. Proposals focused solely on HIV/SIV;
2. Proposals that do not include computational data integration and modeling to compare human-based and animal model data;
3. Proposals that do not include human research studies (*e.g.*, *in vitro* use of primary human cells or tissues; cells or tissue samples from individuals exposed to Mtb);
4. Proposals focused solely on the impact of sex differences on TB protective immunity against Mtb infection;
5. Proposals focused solely on the impact of nutrition on TB protective immunity against Mtb infection;
6. GMP (Good Manufacturing Practices) manufacturing, formulation, and/or process development of TB vaccine candidates;
7. Large clinical trials of TB vaccine candidates (*e.g.*, Phase 2b, 3 etc), where the main objective is vaccine licensure; although immunologic analyses of samples collected from independently funded large vaccine candidate trials are acceptable;
8. Development of TB diagnostics;
9. Development of host-directed therapies or therapeutic vaccines;
10. Early stage (*i.e.*, animal) testing of novel vaccine candidates in the absence of detailed immunologic analyses to define protective mechanisms triggered by vaccine candidates; or
11. Studies of Mtb pathogenesis in the absence of detailed immunological analyses.

ATTACHMENT 6: REPORTING REQUIREMENTS AND DELIVERABLES

Immune Mechanisms of Protection Against *Mycobacterium tuberculosis* Center (IMPAc-TB)

BAA 75N93026R00008

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Reports

☐ (1) Monthly 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 month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

☐ (2) Quarterly Progress Report

(a) This report shall include a [☐ summation of the Monthly Progress Reports 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) A Monthly Progress Report will not be submitted for the final month of a quarter.

☒ (3) Semi-Annual Progress Report

(a) This report shall include ☒a description of the activities during the reporting period and the activities planned for the ensuing reporting period. Additionally, a one-page executive summary highlighting key points and major findings should be included. The initial report will be submitted for the first full six months of the contract performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of six full calendar months.

(b) Monthly and Quarterly Progress Reports will not be submitted the month the Semi-Annual Progress Report is due.

☒ (4) Annual Progress Report

This report includes a summation of the results of the entire contract work for the period covered and a one-page executive summary highlighting key points and major findings should also be included. An Annual Progress Report will not be required for the period when the Final Report is due. A Semi-Annual Progress Report shall not be submitted when an Annual Progress Report is due.

(5) Annual Technical Progress Report for Clinical Research Study Populations

☒ (6) Final Report

☒This report is to include a summation of the work performed and the results obtained for the entire contract period of performance. 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 the contract. An Annual Progress Report will not be required for the period when the Final Report is due.

☐This report shall consist of the work performed and results obtained for the entire contract period of performance as stated in SECTION F of this contract. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted on or before the last day of the contract performance period. A/An [☐ Annual ☐ Semi-Annual ☐ Quarterly ☐ Monthly] Progress Report will not be required for the period when the Final Report is due.

☒ *Use the below narrative if the Contracting Officer's Representative requests a draft final report.*

The Contractor shall provide the Contracting Officer's Representative and Contracting Officer with an electronic copy of the Final Report in **draft** form [☒ in accordance with the DELIVERIES Article in SECTION F of this contract *sixty (60)* calendar days prior to the completion date of this contract.] The Contracting Officer's Representative will review the draft report and provide the Contracting Officer with comments within *thirty (30)* calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

☒ (7) Summary of Salient Results

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

☒ (8) Report on Select Agents or Toxins and/or Highly Pathogenic Agents *– required when contract performance will involve possession, use, or transfer of select agents or toxins and/or highly pathogenic agents.*

REPORTS AND DELIVERABLES

☒ **Human Subjects IRB Annual Report** (Form OMB No. 0990-0263-formerly Optional Form 310)

☐ **Information Security and Physical Access Reporting Requirements -** *Use when the Information and Physical Access Security Article is required in Section H of the contract.*

☒ **Section 508 Annual Report -** *Use in multiple year solicitations and contracts over the simplified acquisition threshold which contain the Electronic and Information Technology Accessibility Article in Section H of the contract.*

☒ **Source Code and Object Code -** *Use when software is used, produced, modified, or enhanced.*

☒ **Invention Report Requirement -** *Use when Patent Rights clause (FAR 52.227-11 or 52.227-13) may be included in the contract.*

☐ **Dual Use Research of Concern -** *Use below in solicitations and contracts when contract performance may involve an agent or toxin that is listed in the United States government policy for institutional oversight of life sciences dual use research of concern (DURC)*

☐ **Report of USDA-Designated Biobased Products -** *Use below in solicitations and contracts involving the use of USDA designated biobased products*

b. Other Reports and Deliverables

1. Monthly calls with NIAID contract and program staff to provide contract and scientific updates. Provide electronic summary of the discussion during the monthly teleconferences to the Contracting Officer's Representative (COR).
2. Bi-monthly (every two months) calls with NIAID staff and other IMPAc-TB Contractors. The schedule and nature of the bi-monthly calls will be established post-award.
3. Annual data depositions of all data and associated metadata from studies into ImmPort and/or other appropriate publicly accessible data repositories as designated by NIAID.
   a. Awardees also are expected to deposit newly identified immune epitopes from Tb immunogens into Immune Epitope Database and Tools (https://www.iedb.org/)
4. Upon request by the COR:
   a. Provide reports, data, and documents for work generated under the BAA. These may include, but are not limited to, standard operating procedures (SOPs), documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments, audit reports, quality assurance reports, reports and documents related to human subject research, and inventory records of biological materials and samples collected;
   b. Deposition of products, tools and reagents generated under the contract for distribution across the IMPAc-TB program and/or into repositories designated by NIAID for distribution to external researchers;
   c. Study data and documentation associated with all products, tools and reagents generated under the contract;
   d. Software under a license certified by the Open-Source Initiative, to the extent possible, to guarantee the right to read, redistribute, modify, and freely use the software, for projects that include development or refinement of computational tools.

SECTION D - PACKAGING, MARKING, AND SHIPPING

If special instructions regarding packaging, marking, and shipping are required, these will be developed after receipt of proposals as a result of the finalization of the Statement of Work during negotiations. Special instructions, if applicable, will be provided to offerors in the Attachment entitled "Additional Technical Proposal Instructions."

SECTION F - DELIVERY SCHEDULE

Delivery of other reports and deliverables will be proposed by the offerors in their technical proposal. They will be developed further after receipt of proposals as a result of finalization

of the Statement of Work and other terms and conditions of any resultant contract during negotiations. Specific instructions, if applicable, will be provided to offerors in the Attachment entitled “Additional Technical Proposal Instructions.”

ATTACHMENT 7: ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS

Immune Mechanisms of Protection Against *Mycobacterium tuberculosis* Center (IMPAc-TB)

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It is strongly recommended that offerors use the following template as the format 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 BAA and provide specific instructions and formatting for the Technical Proposal. While Section L. of the BAA provides a generic set of Technical Proposal Instructions applicable to all NIH R&D solicitations, these Additional Technical Proposal Instructions are tailored to the specific requirements of the BAA. The information requested in these instructions should be used along with Section L of the BAA 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 BAA, and include the information requested here.

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Background and Introduction, Research and Technical Objectives, all reference materials and attachments, the Technical Evaluation Criteria in Section M, and the BAA as a whole in the development of their Technical Proposals.

Offerors proposing subcontracts and/or consultants to perform portions of the proposed Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors and/or consultants, as well as the method and level of integration/coordination between the prime Contractor and all proposed subcontractors and/or consultants, and the expected advantages of such an approach.

Offerors must refer to the BAA 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 web site addresses (URLs) to direct readers to alternate sources of information.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1:

1) PROPOSAL TITLE PAGE. Include BAA title and number, name of organization, UEI number, and identify if the proposal is an original or a copy. Offerors that include data in their proposals 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)] **The total maximum number of pages for the technical proposal shall be 200 pages or less.**

2) TABLE OF CONTENTS

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (4-page maximum)

Provide a brief description of the proposed project, including:

1) 1-2 sentence summary describing the concept the offeror is proposing.
2) A summary describing the scope of the activities proposed.
3) 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 role in the project.
4) 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.
5) A brief description of the facilities and other resources to be made available by the proposed prime Contractor (Offeror) and any proposed subcontractors.

SECTION 3: STATEMENT OF WORK FORMAT (maximum of *ten (10)* pages)

Offeror(s) are required to provide a Statement of Work in their proposal. The Statement of Work shall be developed by each offeror based on the information in the Attachment entitled "Research and Technical Objectives," and shall consist of two parts: (1) Scope, and (2) Technical Requirements. Provided below is an outline of the Statement of Work format that shall be used by all offeror(s) in the preparation of their Technical Proposals. The headers and subheaders may be adjusted to match the requirements as proposed in each offeror's individual technical proposal.

Contracts awarded as a result of this BAA will include the Statement of Work proposed by the offeror, as negotiated and accepted by the Government. Offeror(s) will be required to perform the activities and provide the resources appropriate to the scope of their specific negotiated Statement of Work.

The opening paragraph under the Technical Requirements section of the Statement of Work shall be followed by a description of all activities that the Contractor shall perform after the award of the contract. The Technical Requirements shall include all activities required to effectively implement the project and shall include a description of all items to be delivered to the Government during performance of the contract, such as progress reports, financial reports, end products, and other deliverables, along with a timetable for their delivery.

[NOTE TO OFFEROR: Each offeror shall provide detailed specifications of the requirement utilizing the following sample outline of tasks and subtasks. Any tasks or subtasks that are not applicable to your proposed effort should be deleted. Any tasks or subtasks specific to your proposed effort not addressed below shall be added.]

[See Statement of Work outline on next page]

SAMPLE STATEMENT OF WORK

1. SCOPE

Instruction to offerors: Provide a brief description (one to two paragraphs) of the overall project and objectives in broad terms that indicates the size and magnitude of the proposed effort.

2. TECHNICAL REQUIREMENTS

[NOTE TO OFFEROR: The Technical Requirements shall begin with the following introductory paragraph.]

Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below. Specifically, the Contractor shall describe their plans for:

A. LEADERSHIP STRUCTURE

1. Contract goals, governance and strategic plan finalization/implementation
2. Study oversight, evaluation and refinement
3. Contract milestones and timelines
4. Coordination with other IMPAc-TB Contractors

B. DATA AND RESOURCE MANAGEMENT

C. IMMUNOLOGIC ANALYSES

1. Human-Based Research
2. Animal Models

D. COMPUTATIONAL DATA INTEGRATION AND MODELING APPROACHES

SECTION 4: TECHNICAL DISCUSSIONS

In addition to the guidance in section l of the BAA, this section of your technical proposal should include documentation to demonstrate how you will accomplish the work detailed in your proposed Statement of Work. It is recommended that your proposal be organized in accordance with the order of your Statement of Work and the technical evaluation criteria provided in Section M.

Additionally, please ensure that your Technical Proposal addresses the following:

Organizational Experience:

In addition to the information requested under Section L, Part c. Business Proposal Instructions, paragraph 12, Qualifications of the Offeror, all offerors are requested to include in their technical proposals a description of at least two examples of similar projects performed by your organization that are of comparable size and scope and/or related to the effort proposed in response to this BAA. The projects may be either completed or ongoing.

Technical Approach:

In clearly defined sections of the Technical Proposal, describe the detailed scientific rationale; technical approaches; proposed methodologies and data analysis tools including computational, bioinformatic and statistical methods; proposed plans and procedures; scientific milestones and timelines for achieving the IMPAc-TB contract goals, outlined in this solicitation, and as listed below. In addition, describe potential problems and proposed solutions and alternatives for each section:

A. Leadership Structure
Include description of the following:

1. Draft Scientific Agenda and Strategic Plan, including a discussion of the fundamental problems and challenges with TB vaccines and how the proposed scientific leadership and team propose to address these problems.
2. Processes that will be used for the planning and conduct of the IMPAc-TB contract's activities to achieve scientific milestones and timelines. Plans that will be used to ensure data and resource sharing and scientific coordination amongst all IMPAc-TB Contractors, including coordinating of animal and human studies to maximize information obtained from each and inform the design/direction of subsequent studies, and ensuring that members of each contract have sufficient access to Animal Biosafety Level 3 and Biosafety Level (ABSL-3/BSL-3) facilities to conduct the proposed studies in a timely manner.
3. Development of a Gantt chart summarizing the scientific milestones and timelines. Milestones must be quantitative, reflect key criteria of success and tangible outcomes of each activity and sub-activity for each required element.
4. **NOTE:** Milestones and timelines may be revised during negotiations with NIAID.
5. Methods for collaborating with existing National Institute of Allergy and Infectious Diseases (NIAID)-supported and other large TB programs, including other IMPAc-TB Contractors, Human Immunology Project Consortium (HIPC), Tuberculosis Research Units Network (TBRU-N), RePORT, etc.); and distribute study results, reagents and other resources to other NIAID-supported programs and the broader research community to facilitate the development of improved TB vaccines.
6. Collaborative studies: Plans for organizing and establishing cross-contract collaborative studies and activities post-award in coordination with the other IMPAc-TB Contractors.

B. Data and Resource Management

Include descriptions of the following:

1. The data and resource management system(s) that will be used for the: cataloging and reporting of all contract-generated resources (reagents, human samples, animal models, NAMs, etc); and transmission, storage, retrieval and analyses of all contract-generated data amongst contract members, including:
    a. data entry and validation

b. documentation of data corrections
c. routine maintenance and backup
d. transmission of data
e. data reporting and exporting system
f. access control and confidentiality
g. data security, including protection of Personally Identifiable Information (PII) and Protected Health Information (PHI), and development/implementation of procedures to prevent or rectify data breeches including reporting breeches to relevant institutional authorities and NIAID.
h. data retrieval and disaster recovery
i. data analysis/integration methods

2. Plans and procedures to ensure that data and reagent/resource information can be transferred to the COR, or their designate, without corruption of data or figures.
3. Provision of statistical design and analyses of data resulting from the research undertaken.
4. Plans and procedures that will be used to ensure that data and research resources (*e.g.*, novel animal models) are made available to the broader research community in a timely manner through existing NIAID-supported programs (*e.g.* ImmPort or the NIAID Adjuvant Vaccine Compendium) or other public portals designated by NIAID.
5. Data Deposition and Sharing (Required): Ensure public access to the data and computational models and tools generated by the program by depositing them into appropriate publicly available databases, such as ImmPort or the Adjuvant Vaccine Compendium as appropriate. Proposals must provide a detailed description of the plans and procedures to ensure transfer and compatibility with public databases. Data deposition into ImmPort shall be made on an annual basis.

C. Immunologic Analyses:

1. Human-Based Research
   a. Description of how participants will be identified, screened and characterized for the studies proposed;
   b. Discussion of anticipated sample size of cohorts to be studied, with consideration for statistical power for proposed studies and timeline to achieve expected events;
   c. Description of why development of new cohort(s) is required (use of existing cohorts is encouraged);
   d. Detailed description of clinical outcomes that will be captured and the methodologies that will be used; including the types of analyses to be conducted, and any high-throughput analyses and/or other advanced technologies that will be used to achieve program goals;
   e. Methods that will be used for development of immune-based assays to further analysis of human immune responses to Mtb or TB vaccines, or to distinguish different stages of Mtb infection based on immune parameters, if applicable;
   f. Description of studies that will be used to assess the impact of HIV/SIV infection on immune response to Mtb infection or TB vaccines, if applicable;
   g. Description of processes and procedures for the development of clinical protocols, informed consent forms, manual of procedures, protocol specific case report forms, training of clinical personnel prior to protocol initiation (both certified Good Clinical Practice (cGCP) and protocol-specific training) and preparing Institutional Review Board (IRB) applications and other approval processes, for each mechanistic clinical study that the project will conduct;
   h. Include a table summarizing all of the clinical samples/cohorts to be used in the entire Project. The table should include:

i. A short description of each cohort;
ii. Criteria/justification for selecting the cohort;
iii. Number, age range, and sex composition (percentage) of subjects included in each cohort;
iv. Sample source: independently funded clinical trial or other study, recruited for an IMPAc-TB contract study;
v. Status of the sample/cohort: to be collected, completed, ongoing etc., and documentation of access to the cohort/clinical samples;
vi. Clinical Trials.gov registration number, if available and applicable;
vii. Letter(s) of collaboration from the Clinical Trial Principal Investigator, where applicable.

i. For proposals that include clinical trials supported by the IMPAc-TB program:
   i. Describe how participants will be identified, screened, and characterized for each trial proposed;
   ii. Describe the outcomes that will be captured and the methodologies that will be used;
   iii. Describe processes and procedures for the development of clinical protocols, informed consent forms, manual of procedures, protocol specific case report forms, training of clinical personnel prior to protocol initiation (both cGCP and protocol-specific training) and preparing IRB and/or Investigational New Drug (IND) applications and other approval processes, for each mechanistic clinical trial to be conducted;
   iv. Include the sample size calculations and statistical analysis plan to be used for the clinical trial(s) study design;
   v. Describe how adverse events related to any intervention or procedure will be captured and reported and how protocol deviations will be handled;

j. For proposals proposing to obtain samples from independently-funded clinical trials, include the following:
   i. Synopsis of the parent clinical trial protocol;
   ii. Informed consent forms for the proposed studies, if consent form for the parent clinical trial does not allow third party use;
   iii. Reference to the ClinicalTrials.gov citation, if applicable;
   iv. Table of events including the volume of blood, or amount of tissue, collected for the proposed studies;
   v. Memorandum of understanding from the clinical trial sponsor(s), IND holder(s), and Principal Investigator(s), which includes assurance of sample availability for the mechanistic studies proposed

2. Animal Models:

Include descriptions of the following:

a. Justification of the animal species chosen for analysis, including a discussion of the strengths and weaknesses of each proposed animal model, and any proposed improvements to animal model, if applicable;
b. Justification of the Mtb strain(s) chosen for study; if new Mtb strains will be developed, include an explanation as to why such strains are necessary;
c. Detailed description of the types of analyses to be conducted, including high-throughput analyses, and/or other advanced technologies that will be used to achieve program goals;
d. Explanation of how the proposed studies will improve the predictive value of the animal model(s) for evaluating Mtb vaccine efficacy;

e. Description of studies that will be used to assess the impact of SIV/HIV infection on immune responses to Mtb infection or TB vaccines, if applicable.

D. Computational Data and Integration Modeling Approaches

Include Descriptions of the following:

1. Plans and procedures to be used for analysis, integration and visualization of the data sets generated by the contract members, including computational modeling methods.
2. Methods and procedures that will be used to integrate results from the animal studies and human studies to advance understanding of both tissue-specific and systemic immune responses to Mtb infection or TB vaccines and improve correlation between human and animal study results.
3. Plans on how a data scientist, or designee, will represent the IMPAc-TB contract in post-award meetings with other IMPAc-TB Computational Data Integration and Modeling teams to promote cross-program collaboration, refinement of data standards, harmonization of data analysis and integration methods and for further development or validation of immune signatures o biomarkers associated with TB disease or TB vaccination outcomes.

SECTION 5: SCIENTIFIC AND TECHNICAL PERSONNEL

Provide information relevant to document individual training, experience, qualifications, and expertise necessary for the successful completion of the proposed Statement of Work. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the contract.

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 the proposed Statement of Work. Include a description of the PI's experience in leading a multi-disciplinary and multi-site program.

2) **Other Key Scientific and Technical Personnel:** Describe the experience, training, expertise, and qualifications, as well as the level of effort, for all proposed key scientific and technical personnel.

The scientific and technical personnel should include investigators with expertise in research, statistical support and management and administrative activities.

i. For the research positions, describe the team's experience and expertise in immunology (especially in analysis of tissue- specific immunity and immune regulation), tuberculosis, mycobacterial research, clinical research, and the use of animal models;
ii. For statistical support, describe the expertise and experience of the team with computational data integration and modeling, and bioinformatics; and as applicable: systems biology; genetics; HIV/SIV immunology and/or clinical trials;
iii. For management and administrative activities, describe the experience and expertise of a Project Manager who will have responsibility for monitoring and tracking day-to-day progress and timelines, coordinating communication, project activities, assuring compliance with regulatory requirements, and tracking costs incurred.

SECTION 6: PROJECT MANAGEMENT

1) Provide a Project Management Plan that includes methods for tracking and keeping multiple activities on time and budget, procedures to ensure effective communication with the Contracting Officer's Representative and Contracting Officer, as well as strategies that address the planning, initiation, implementation, conduct, monitoring, and completion of tasks identified in the proposed 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 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).

5) Provide a plan to coordinate bi-monthly (every 2 months) calls with other IMPAc-TB Contractors and NIAID staff.

6) Describe the plan to coordinate and establish cross-contract collaborative studies and activities post-award.

7) Describe the plan for soliciting, evaluating, negotiating, awarding, and managing subcontracts in accordance with FAR Clause 52.244-2 (if applicable).

8) Describe the procedures that will be used to address intellectual property issues regarding access to necessary reagents (*e.g.*, Material Transfer Agreement [MTA]).

SECTION 7: 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 proposed 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 proposed Statement of Work.
3) Depending on the proposed research and requirements in the Statement of Work provide appropriate documentation to determine/evaluate the adequacy of training, throughput capacity, computing and analytical services, and other resources required to implement the Statement of Work in compliance with all Federal and NIH regulations.
4) The care and housing of laboratory animals, including:
    a. Appropriate veterinary coverage;
    b. Availability of appropriate facilities and capacity for proposed animal studies; and
    c. Provisions for complying with NIH guidelines for the housing and humane care and use of laboratory animals as delineated by the Office of Laboratory Animal Welfare (OLAW; https://olaw.nih.gov/home.htm);
    d. Methods for obtaining and maintaining Institutional Animal Care and Use Committee (IACUC) approval for animal work, IRB approval for the use of human samples and authorization to work with select agents, if applicable for the prime Contractor and all subcontractors (if applicable). NOTE: These documents shall be provided to the COR before an award is made and any changes shall be documented in the progress reports.
    The Centers for Disease Control and Prevention (CDC) Select Agent program can be found at: https://www.selectagents.gov.
5) Documentation of biocontainment capabilities, where necessary, to support the proposed studies.
6) Information regarding ownership/lease of the facility(ies), including documentation of the availability of proposed facilities for the duration of the contract.
7) Procedures to ensure compliance with all safety guidelines and regulations, including training and monitoring of personnel.
8) Methods for obtaining, adding, or deleting facilities as necessary due to progress or performance issues that arise during the course of the contract.
9) Provisions for ensuring safe facilities and resources, including an accredited ABSL-3/BSL-3 facility with capability to conduct Mtb infection and TB vaccine studies in proposed animal models, and any proposed studies with human samples requiring BSL-3 facilities; and for conducting work in accordance with the Biosafety in Microbiological and Biomedical Laboratories guidelines, and the Administration for Strategic Preparedness and Response, (Biosafety Levels & Lab Safety Guidelines) as well as Department of Health and Human Services (DHHS) regulations regarding the transfer of select agents (42 CFR Part 73) Guidance Documents | Compliance | Federal Select Agent Program. Safety and Health HHSAR 352.223-70 clauses shall apply.
10) Provisions for ensuring safe facilities for the conduct of work in accordance with Recommendations for the Safe Handling of Cytotoxic Drugs, NIH Publication No. 92-2621 and the NIH Guidelines for the Laboratory use of Chemical Carcinogens..
11) Documentation of the availability of reagents that are not commercially available, such as vaccine(s) used for *in vivo* or *in vitro* studies.

SECTION 8: OTHER CONSIDERATIONS

Other than those detailed in the Government Furnished Property clause or otherwise publicly available, the offeror shall not propose government furnished resources, to include government employees, facilities, intellectual property, or biological materials. If you

propose government furnished resources, your proposal will not be considered further for award.

This section of the Technical Proposal should document other resources not covered in 1 through 8 above necessary to carry out the proposed Statement of Work.

SECTION 9: POST-AWARD ACTIVITIES

This section of the Technical Proposal should document how the offeror will ensure compliance with the post-award activities described below.

Collaborations across the IMPAc-TB contracts:

Describe the plans and procedures to organize and establish cross-contract collaborative studies and activities post-award in coordination with the other IMPAc-TB Contractors. For example, the types of activities may include small-scale studies by each Contractor that foster collaboration across the Contractors. Projects may also include high-risk, innovative concepts, such as targeted research studies of emerging ideas, development of novel methodologies, or investigations of understudied questions related to protective immune responses against Mtb. These cross-contract collaborative studies are a requirement of the Statement of Work.

Do not provide descriptions of the cross-contract collaborative studies in the proposal: cross-contract collaborative studies will be proposed starting in year two of the contract by each IMPAc-TB Contractor. The proposed cross-contract collaborative studies will be evaluated by NIH Program staff, the PI(s) of each IMPAc-TB contract, and the External Scientific Advisory Group (ESAG). The final selection of the cross-contract collaborative study will be made by NIH.

Kick-off and Annual Review Meetings:

Contractors are required to attend a contract initiation meeting approximately 90 calendar days after contract award and annual review meetings, thereafter, to be held near or in Rockville, Maryland.

Initiation Meeting/Kick-off meeting: The purpose of the oneday contract initiation meeting is to establish working relationships and begin development of the IMPAc-TB contract Scientific Agenda and Strategic Plan with all of the awarded investigators.

Annual Meetings: The purpose of the 2.5-day annual meetings is for the Contractors to discuss:

i. Results of activities undertaken or completed since the last review meeting;
ii. Milestones and timelines, including an updated Gantt chart;
iii. Problems encountered or anticipated; potential approaches to overcoming problems; and of activities to be undertaken in the coming year;
iv. Proposed/ongoing/completed collaborative projects.

The Contractor PI shall provide an electronic copy of any slide presentations to the COR not later than three days before the annual meeting. All Contractor PIs, Project Managers, and other key contract investigators including subcontractor personnel, shall attend these meetings, along with the NIAID COR, the Contracting Officer (CO), and other designated NIAID staff. The COR may invite other NIH extramural program staff to attend these meetings as well as investigators from other NIAID-funded programs. All participants shall

be subject to a confidentiality agreement prepared by NIAID. Meetings will be closed to the public and shall involve oral and electronic presentations by the Contractors, and NIAID staff, as necessary.

Site Visits

Within 90 calendar days of the effective date of the contract, the Contractor shall plan, conduct and be responsible for the logistical arrangements for annual site visit meeting at the Contractor's facility. The Principal Investigator, Project Manager, all key investigators, key subcontractor personnel, the COR, and other designated NIAID staff, shall attend this meeting. The purpose of this meeting shall be to review the Technical Plan and to coordinate activities and communication between the Contractor and the NIAID. The Contractor PI shall provide an electronic copy of any slide presentations to the COR not later than three days before the annual meeting. The CO or COR may request site visits at the Contractor site(s) annually or as needed.

Teleconferences

The Contractor shall plan and conduct monthly teleconference meetings with the COR, and other designated NIAID staff, during the first year of the contract period of performance, to discuss technical progress and financial invoices. A teleconference schedule for subsequent years will be established by the COR. One week prior to the teleconference, the Contractor shall submit an agenda to the COR. Within one week after the teleconference, the Contractor shall provide a meeting summary of the teleconference to the COR. The timing of the bi-monthly teleconference meetings may be altered or adjusted by the COR as needed to address progress on the contract.

Additional Contract Meetings/Teleconferences

Bi-monthly calls will be conducted with NIAID staff and other IMPAc-TB Contractors to facilitate collaboration across contracts. The call schedule and nature of the calls will be established post-award.

The PI, Project Manager, key investigators, and key subcontractor personnel shall attend additional meetings or teleconferences at the request of the COR. Such meetings will be requested, as necessary, to discuss contract specific issues and to review recommended changes or deviations from milestones and timelines in the Statement of Work.

External Scientific Advisory Group (ESAG)

After award, NIAID will convene an External Scientific Advisory Group (ESAG) to provide suggestions to NIAID on progress and scientific direction of the IMPAc-TB program. The PI of each contract will be asked to suggest three or more investigators, including community representatives, as potential ESAG members. NIAID will decide on the final ESAG composition. Do not name any potential ESAG members in the proposal or contact any potential members.

ATTACHMENT 8: ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

Immune Mechanisms of Protection Against *Mycobacterium tuberculosis* Center (IMPAc-TB)

BAA 75N93026R00008

In addition to the instructions and format requirements for the proposal that are contained in Section L of the BAA, the information presented in this attachment is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Background and Introduction, Research and Technical Objectives, all reference material provided as attachments, the technical evaluation criteria, and the BAA as a whole, in the development of your proposal. The information requested here should be used as further guidance for the development of your proposal. Offerors should consider and include the information provided below in the development of their Technical and Business 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 BAA specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in a clearly marked section of the proposal.

SECTION 3 – UNIFORM COST ASSUMPTIONS

1) Technical Cost Assumptions

Cross-Contract Collaborative Studies:
To facilitate cross-contract collaborative studies and activities, each Contractor will propose a line item in their individual budget of $300,000/year in total costs in years two through five of the contracts. Do not propose cross-contract collaborative studies/activities in the proposal. The cross-contract collaborative studies will be proposed starting in year two of the contract by each IMPAc-TB contractor.

2) Travel

A. *Contract Initiation Meeting*: Assume one meeting in Rockville, 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 Contractor's key

personnel. Budget for four travelers.

B. *Annual Program Progress Meetings*: Assume 2.5-day programmatic meeting to be held in the Rockville, Maryland area. Assume that this meeting will require a 3-night stay and shall be attended by all of the Contractor's and subcontractor(s) key personnel. Also budget for the travel of three IMPAc-TB program ESAG members to the annual progress meetings.

C. *Annual Site Visits:* Assume at least two one-day site visits for the life of the contract at the Contractor's facilities to be attended by the Principal Investigator, Project Manager, all key investigators, key subcontractor personnel, the COR, and other designated NIAID staff. Travel and per-diem costs for Government personnel **shall not** be provided by the contract.

D. *Scientific Meetings*: Include travel costs for up to three staff to attend one scientific meeting each per contract year.

3) Government Furnished Property

☐ 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 contract.

SECTION 4 – OPTIONS

It is anticipated that the award(s) from this BAA will be a Cost-Reimbursement type Completion contract with a one Base year and four Option Periods, for a total of five years. Each Option must be budgeted separately within the Business Proposal. Uniform cost assumptions associated with Options are described above.

SECTION 5 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE BAA

Refer to Section L of the BAA for documentation requirements. All relevant documentation should be included in a clearly marked section of the proposal.

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

This SECTION is made up of eight parts as follows:

1. **Offeror Identification, FAR Provision 52.204-90**
2. **Information Regarding Responsibility Matters, FAR 52.209-7 (Deviation) (RFO Aug 2025)**
3. **Cost Accounting Standards**
4. **Cost Proposal Disclosure-Cost Accounting Practice Changes**
5. **Certification Regarding Environmental Tobacco Smoke**
6. **Certification of Institutional on Financial Conflicts of Interest**
7. **Disaster or Emergency Area Representation**
8. **Alternate – Representation by Corporations Regarding an Unpaid Delinquent Tax Liability or a Felony Conviction Under Any Federal Law**

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

1. OFFEROR IDENTIFICATION, FAR Provision 52.204-90 (Deviation) (RFO Aug 2025)

If the Offeror will not have an active Federal Government contracts registration in the System for Award Management (https://www.sam.gov) when submitting its offer, it shall complete paragraphs (c) and (d) of this provision and include its responses with its offer.

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

Commercial and Government Entity (CAGE) code has the meaning provided in the clause at FAR 52.204-91, Contractor Identification, of this solicitation.

Common parent means that corporate entity that owns or controls an affiliated group of corporations that files its Federal income tax returns on a consolidated basis, and of which the offeror is a member.

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

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

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

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

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

Unique entity identifier (UEI) has the meaning provided in the clause at FAR 52.204-91, Contractor Identification, of this solicitation.

(b) *Unique entity identifier (UEI).*

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

(2) If the Offeror does not have a UEI, it shall go to https://www.sam.gov to obtain one. The Government will independently validate the existence and uniqueness of the Offeror before assigning a UEI.

(c) *Taxpayer identification*. The Offeror shall provide with its offer the following information that is necessary to comply with debt collection requirements of 31 U.S.C. 7701(c) and 3325(d); reporting requirements of 26 U.S.C. 6041, 6041A, and 6050M; and the implementing IRS regulations:

(1) Taxpayer identification number (TIN)

□ TIN: _____;

□ TIN has been applied for; or

□ TIN is not required because:

□ Offeror is a nonresident alien, foreign corporation, or foreign partnership that does not have income effectively connected with the conduct of a trade or business in the United States and does not have an office or place of business or a fiscal paying agent in the United States;

□ Offeror is an agency or instrumentality of a foreign government; or

□ Offeror is an agency or instrumentality of the Federal Government.

(2) *Type of organization.*

□ Sole proprietorship;

□ Partnership;

□ Corporate entity (not tax-exempt);

□ Corporate entity (tax-exempt);

□ Government entity (Federal, State, or local);

□ Foreign government;

□ International organization per 26 CFR 1.6049-4; or

□ Other.

(3) *Common parent.*

□ Offeror is not owned or controlled by a common parent as defined in paragraph (a) of this provision; or

□ Name and TIN of common parent:

Name: _____

TIN: _____

(4) The TIN provided in paragraph (c)(1) of this provision may be matched with IRS records to verify the accuracy of the Offeror's TIN. The Government may use the TIN to collect and report on any delinquent amounts arising out of the Offeror's relationship with the Government (31 U.S.C. 7701(c)(3)).

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

(1) The Offeror shall provide its CAGE code with its offer with its name and location address or otherwise include it prominently in its offer. The CAGE code shall be for that name and location address. Insert the word “CAGE” before the code. The Offeror may obtain a CAGE code as indicated in the following table.

If the Offeror is…	**Then…**

Located in the United States or its outlying areas	Submit a request to the DLA CAGE Branch via https://cage.dla.mil
Located outside the United States and its outlying areas and its country is a member of the North Atlantic Treaty Organization (NATO) or a sponsored nation	Contact the appropriate National Codification Bureau (https://www.nato.int/structur/ac/135/about/contacts)
Located outside the United States and its outlying areas and its country is not a member of NATO or a sponsored nation	Contact the NATO Support and Procurement Agency (NSPA) (https://eportal.nspa.nato.int/AC135Public/scage/CageList.aspx)

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

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

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

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

Owner Type	**CAGE Code**	**Legal Business Name**
Immediate owner		
Highest-level owner		
Predecessor*		

* Predecessor CAGE code may be marked "Unknown."

(3) If the Offeror has more than one immediate owner (such as a joint venture), give the information for each owner (or joint venture participant). If the Offeror has more than one predecessor, provide information for each predecessor in reverse chronological order.

(End of provision)

2. INFORMATION REGARDING RESPONSIBILITY MATTERS, FAR Provision 52.209-7 (DEVIATION) (RFO AUG 2025)

Note to Offeror: This provision is applicable when the resultant contract is expected to exceed $600,000.

(a) Definitions. As used in this provision—

Administrative proceeding means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (e.g., Securities and Exchange Commission Administrative Proceedings, Civilian Board of Contract Appeals Proceedings, and Armed Services Board of Contract Appeals Proceedings). This includes administrative proceedings at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include agency actions such as contract audits, site visits, corrective plans, or inspection of deliverables.

Federal contracts and grants with total value greater than $10,000,000 means—
(1) The total value of all current, active contracts and grants, including all priced options; and

(2) The total value of all current, active orders including all priced options under indefinite-delivery, indefinite-quantity, 8(a), or requirements contracts (including task and delivery and multiple-award Schedules).

Principal means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a division or business segment; and similar positions).

(b) The offeror □ has □ does not have current active Federal contracts and grants with total value greater than $10,000,000.

(c) If the offeror checked "has" in paragraph (b) of this provision, the offeror represents, by submission of this offer, that the information it has entered in the Federal Awardee Performance and Integrity Information System (FAPIIS) is current, accurate, and complete as of the date of submission of this offer with regard to the following information:

(1) Whether the offeror, and/or any of its principals, has or has not, within the last five years, in connection with the award to or performance by the offeror of a Federal contract or grant, been the subject of a proceeding, at the Federal or State level that resulted in any of the following dispositions:

(i) In a criminal proceeding, a conviction.

(ii) In a civil proceeding, a finding of fault and liability that results in the payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more.

(iii) In an administrative proceeding, a finding of fault and liability that results in–

(A) The payment of a monetary fine or penalty of $5,000 or more; or

(B) The payment of a reimbursement, restitution, or damages in excess of $100,000.

(iv) In a criminal, civil, or administrative proceeding, a disposition of the matter by consent or compromise with an acknowledgment of fault by the Contractor if the proceeding could have led to any of the outcomes specified in paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of this provision.

(2) If the offeror has been involved in the last five years in any of the occurrences listed in (c)(1) of this provision, whether the offeror has provided the requested information with regard to each occurrence.

(d) The offeror shall post the information in paragraphs (c)(1)(i) through (c)(1)(iv) of this provision in FAPIIS as required through maintaining an active registration in the System for Award Management, which can be accessed via https://www.sam.gov (see 52.204-7).

(End of provision).

3. COST ACCOUNTING STANDARDS NOTICES AND CERTIFICATION, FAR Provision 52.230-1 (Deviation) (RFO AUG 2025)

Note: This notice does not apply to small businesses or foreign governments. This notice is in three parts, identified by Roman numerals I through III.

Offerors shall examine each part and provide the requested information in order to determine Cost Accounting Standards (CAS) requirements applicable to any resultant contract.

If the offeror is an educational institution, part II does not apply unless the contemplated contract will be subject to full or modified CAS coverage pursuant to 48 CFR 9903.201-2(c)(5) or 9903.201-2(c)(6), respectively.

I. Disclosure Statement-Cost Accounting Practices and Certification

(a) Any contract in excess of the lower CAS threshold specified in Federal Acquisition Regulation (FAR) 30.205(b) resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR chapter 99), except for those contracts which are exempt as specified in 48 CFR 9903.201-1.

(b) Any offeror submitting a proposal which, if accepted, will result in a contract subject to the requirements of 48 CFR chapter 99 must, as a condition of contracting, submit a Disclosure Statement as required by 48 CFR 9903.202. When required, the Disclosure Statement must be submitted as a part of the offeror's proposal under this solicitation unless the offeror has already submitted a Disclosure Statement disclosing the practices used in connection with the pricing of this proposal. If an applicable Disclosure Statement has already been submitted, the offeror may satisfy the requirement for submission by providing the information requested in paragraph (c) of part I of this provision.

Caution: In the absence of specific regulations or agreement, a practice disclosed in a Disclosure Statement shall not, by virtue of such disclosure, be deemed to be a proper, approved, or agreed-to practice for pricing proposals or accumulating and reporting contract performance cost data.

(c) Check the appropriate box below:

(1) □ *Certificate of Concurrent Submission of Disclosure Statement*. The offeror hereby certifies that, as a part of the offer, copies of the Disclosure Statement have been submitted as follows:

(i) Original and one copy to the cognizant Administrative Contracting Officer (ACO) or cognizant Federal agency official authorized to act in that capacity (Federal official), as applicable; and

(ii) One copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable. Forms may be obtained from the cognizant ACO or Federal official.)

Date of Disclosure Statement: _____ Name and Address of Cognizant ACO or Federal Official Where Filed: _____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the Disclosure Statement.

(2) □ *Certificate of Previously Submitted Disclosure Statement*. The offeror hereby certifies that the required Disclosure Statement was filed as follows:

Date of Disclosure Statement: _____ Name and Address of Cognizant ACO or Federal Official Where Filed: _____

The offeror further certifies that the practices used in estimating costs in pricing this proposal are consistent with the cost accounting practices disclosed in the applicable Disclosure Statement.

(3) □ *Certificate of Monetary Exemption*. The offeror hereby certifies that the offeror, together with all divisions, subsidiaries, and affiliates under common control, did not receive net awards of negotiated prime contracts and subcontracts subject to CAS totaling $50 million or more in the cost accounting period immediately preceding the period in which this proposal was submitted. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

(4) □ *Certificate of Interim Exemption*. The offeror hereby certifies that (i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted and (ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under paragraph (c)(1) or (c)(2) of part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

Caution: Offerors currently required to disclose because they were awarded a CAS-covered prime contract or subcontract of $50 million or more in the current cost accounting period may not claim this exemption (4). Further, the exemption applies only in connection with proposals submitted before expiration of the 90-day period following the cost accounting period in which the monetary exemption was exceeded.

II. Cost Accounting Standards-Eligibility for Modified Contract Coverage

If the offeror is eligible to use the modified provisions of 48 CFR 9903.201-2(b) and elects to do so, the offeror shall indicate by checking the box below. Checking the box below shall mean that the resultant contract is subject to the Disclosure and Consistency of Cost Accounting Practices clause in lieu of the Cost Accounting Standards clause.

□ The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received

less than $50 million in awards of CAS-covered prime contracts and subcontracts. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

Caution: An offeror may not claim the above eligibility for modified contract coverage if this proposal is expected to result in the award of a CAS-covered contract of $50 million or more or if, during its current cost accounting period, the offeror has been awarded a single CAS-covered prime contract or subcontract of $50 million or more.

III. Additional Cost Accounting Standards Applicable to Existing Contracts

The offeror shall indicate below whether award of the contemplated contract would, in accordance with paragraph (a)(3) of the Cost Accounting Standards clause, require a change in established cost accounting practices affecting existing contracts and subcontracts

☐Yes ☐ No

4. COST PROPOSAL DISCLOSURE-COST ACCOUNTING PRACTICE CHANGES, (Apr 2005), FAR Provision 52.230-7

The offeror shall check "yes" below if the contract award will result in a required or unilateral change in cost accounting practice, including unilateral changes requested to be desirable changes.

☐ Yes ☐ No

If the offeror checked "Yes" above, the offeror shall-

(1) Prepare the price proposal in response to the solicitation using the changed practice for the period of performance for which the practice will be used; and

(2) Submit a description of the changed cost accounting practice to the Contracting Officer and the Cognizant Federal Agency Official as pricing support for the proposal.

(End of provision).

5. CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE (December 1994)

Public Law 103-227, also known as the Pro-Children Act of 1994 (Act), requires that smoking not be permitted in any portion of any indoor facility owned or leased or contracted for by an entity and used routinely or regularly for the provision of health, day care, early childhood development services, education or library services to children under the age of 18, if the services are funded by Federal programs either directly or through State or local governments, by Federal grant, contract, loan, or loan guarantee. The law also applies to children's services that are provided in indoor facilities that are constructed, operated, or maintained with such federal funds. The law does not apply to children's services provided in private residences; portions of facilities used for inpatient drug or alcohol treatment; service providers whose sole source of applicable federal funds is Medicare or Medicaid; or facilities where WIC coupons are redeemed. Failure to comply with the provisions of the law may result in the imposition of a civil monetary penalty of up to $1,000 for each violation and/or the imposition of an administrative compliance order on the responsible entity.

By submission of its signed offer, the offeror/contractor (for acquisitions) or applicant/grantee (for grants) certifies that the submitting organization will comply with the requirements of the Act and will not allow smoking within any portion of any indoor facility used for the provision of services for children as defined by the Act.

The submitting organization agrees that it will require that the language of this certification be included in any subawards which contain provisions for children's services and that all subrecipients shall certify accordingly.

6. CERTIFICATION OF INSTITUTIONAL POLICY ON FINANCIAL CONFLICTS OF INTEREST

Note: This certification is applicable to all Research and Development (R&D) Contracts except Phase I SBIR/STTR and Contracts with Federal Agencies.

By Submission of its signed offer, the offeror certifies that:

(1) there is in effect at the Institution (the term Institution includes any contractor, public or private, excluding a Federal agency) 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) the Institution shall promote and enforce Investigator compliance with this part's requirements including those pertaining to disclosure of significant financial interests;

(3) the Institution shall manage financial conflicts of interest and provide initial and ongoing FCOI reports to NIH consistent with this part;

(4) the Institution agrees to make information available, promptly upon request, to the Contracting Officer 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) the Institution shall fully comply with the requirements of 45 CFR Part 94.

7. DISASTER OR EMERGENCY AREA REPRESENTATION, (Nov 2007), FAR Provision 52.226-3

Note: This provision is applicable for acquisitions that are set-aside for a Disaster or Emergency Area under FAR Subpart 26.2. See Section L.1. of the Solicitation, paragraph entitled "Notice of Disaster or Emergency Area Set-Aside."

(a) Set-aside area. The area covered in this contract is: _____
[Contracting Officer to fill in with definite geographic boundaries.]

(b) Representations. The offeror represents that it .. does .. does not reside or primarily do business in the designated set-aside area.

(c) An offeror is considered to be residing or primarily doing business in the set-aside area if, during the last twelve months-

(1) The offeror had its main operating office in the area; and

(2) That office generated at least half of the offeror's gross revenues and employed at least half of the offeror's permanent employees.

(d) If the offeror does not meet the criteria in paragraph (c) of this provision, factors to be considered in determining whether an offeror resides or primarily does business in the set-aside area include-

(1) Physical location(s) of the offeror's permanent office(s) and date any office in the set-aside area(s) was established;

(2) Current state licenses;

(3) Record of past work in the set-aside area(s) (e.g., how much and for how long);

(4) Contractual history the offeror has had with subcontractors and/or suppliers in the set-aside area;

(5) Percentage of the offeror's gross revenues attributable to work performed in the set-aside area;

(6) Number of permanent employees the offeror employs in the set-aside area;

(7) Membership in local and state organizations in the set-aside area; and

(8) Other evidence that establishes the offeror resides or primarily does business in the set-aside area. For example, sole proprietorships may submit utility bills and bank statements.

(e) If the offeror represents it resides or primarily does business in the set-aside area, the offeror shall furnish documentation to support its representation if requested by the Contracting Officer. The solicitation may require the offeror to submit with its offer documentation to support the representation.

(End of provision).

8. ALTERNATE - REPRESENTATION BY CORPORATIONS REGARDING AN UNPAID DELINQUENT TAX LIABILITY OR A FELONY CONVICTION UNDER ANY FEDERAL LAW

The Consolidated and Further Appropriations Act, 2015 Pub. L 113-235, Division E, Sections 744 and 745 prohibit covered agencies from using funds to enter into contracts with corporations with unpaid federal tax delinquencies or certain felony convictions unless certain conditions are met.

The Offeror represents that:

(1) It is ☐ is not ☐ a corporation that was convicted of a felony criminal violation under federal or state law within the preceding 24 months.

(2) It is ☐ is not ☐ a corporation that has any unpaid federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability.

"

REGISTER OF WAGE DETERMINATIONS UNDER THE SERVICE CONTRACT ACT
By direction of the Secretary of Labor

Daniel W. Simms
Director

Division of Wage Determinations

U.S. DEPARTMENT OF LABOR
EMPLOYMENT STANDARDS ADMINISTRATION
WAGE AND HOUR DIVISION
WASHINGTON D.C. 20210

Wage Determination No.: 2015-4187
Revision No.: 35
Date Of Last Revision: 3/30/2026

State: New York

Area: New York Counties of Bronx, Kings, New York, Queens, Richmond, Rockland and Westchester

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Fringe Benefits Required Follow the Occupational Listing

OCCUPATION CODE - TITLE	FOOTNOTE	RATE
01000 - Administrative Support And Clerical Occupations		
01011 - Accounting Clerk I		22.66
01012 - Accounting Clerk II		25.43
01013 - Accounting Clerk III		28.45
01020 - Administrative Assistant		40.03
01035 - Court Reporter		52.27
01041 - Customer Service Representative I		19.19
01042 - Customer Service Representative II		20.94
01043 - Customer Service Representative III		23.50
01051 - Data Entry Operator I		19.66
01052 - Data Entry Operator II		21.45
01060 - Dispatcher, Motor Vehicle		28.37
01070 - Document Preparation Clerk		19.81
01090 - Duplicating Machine Operator		19.81
01111 - General Clerk I		18.55
01112 - General Clerk II		20.24
01113 - General Clerk III		22.72
01120 - Housing Referral Assistant		28.42
01141 - Messenger Courier		20.30
01191 - Order Clerk I		20.33
01192 - Order Clerk II		22.19
01261 - Personnel Assistant (Employment) I		21.74
01262 - Personnel Assistant (Employment) II		24.32
01263 - Personnel Assistant (Employment) III		27.11
01270 - Production Control Clerk		29.78
01290 - Rental Clerk		21.76
01300 - Scheduler, Maintenance		22.79
01311 - Secretary I		22.79
01312 - Secretary II		25.50
01313 - Secretary III		28.42
01320 - Service Order Dispatcher		24.37
01410 - Supply Technician		40.03
01420 - Survey Worker		25.70
01460 - Switchboard Operator/Receptionist		20.71
01531 - Travel Clerk I		21.86
01532 - Travel Clerk II		24.53

01533 - Travel Clerk III	27.44
01611 - Word Processor I	19.57
01612 - Word Processor II	21.97
01613 - Word Processor III	24.57
05000 - Automotive Service Occupations	
05005 - Automobile Body Repairer, Fiberglass	28.29
05010 - Automotive Electrician	28.50
05040 - Automotive Glass Installer	27.31
05070 - Automotive Worker	27.31
05110 - Mobile Equipment Servicer	24.42
05130 - Motor Equipment Metal Mechanic	30.31
05160 - Motor Equipment Metal Worker	27.31
05190 - Motor Vehicle Mechanic	29.68
05220 - Motor Vehicle Mechanic Helper	23.15
05250 - Motor Vehicle Upholstery Worker	26.12
05280 - Motor Vehicle Wrecker	27.31
05310 - Painter, Automotive	28.50
05340 - Radiator Repair Specialist	27.31
05370 - Tire Repairer	19.97
05400 - Transmission Repair Specialist	29.68
07000 - Food Preparation And Service Occupations	
07010 - Baker	19.55
07041 - Cook I	22.29
07042 - Cook II	24.88
07070 - Dishwasher	17.31
07130 - Food Service Worker	17.65
07210 - Meat Cutter	21.51
07260 - Waiter/Waitress	20.64
09000 - Furniture Maintenance And Repair Occupations	
09010 - Electrostatic Spray Painter	25.54
09040 - Furniture Handler	16.41
09080 - Furniture Refinisher	23.24
09090 - Furniture Refinisher Helper	18.79
09110 - Furniture Repairer, Minor	21.14
09130 - Upholsterer	23.95
11000 - General Services And Support Occupations	
11030 - Cleaner, Vehicles	19.29
11060 - Elevator Operator	19.40
11090 - Gardener	26.40
11122 - Housekeeping Aide	19.40
11150 - Janitor	19.40
11210 - Laborer, Grounds Maintenance	21.71
11240 - Maid or Houseman	20.72
11260 - Pruner	20.18
11270 - Tractor Operator	24.85
11330 - Trail Maintenance Worker	21.71
11360 - Window Cleaner	20.87
12000 - Health Occupations	
12010 - Ambulance Driver	24.99
12011 - Breath Alcohol Technician	31.40
12012 - Certified Occupational Therapist Assistant	35.79
12015 - Certified Physical Therapist Assistant	34.72
12020 - Dental Assistant	22.98
12025 - Dental Hygienist	49.83
12030 - EKG Technician	40.73
12035 - Electroneurodiagnostic Technologist	40.73
12040 - Emergency Medical Technician	24.99
12071 - Licensed Practical Nurse I	28.08
12072 - Licensed Practical Nurse II	31.40
12073 - Licensed Practical Nurse III	35.00
12100 - Medical Assistant	22.55
12130 - Medical Laboratory Technician	38.74
12160 - Medical Record Clerk	26.36
12190 - Medical Record Technician	29.49
12195 - Medical Transcriptionist	21.99
12210 - Nuclear Medicine Technologist	56.43
12221 - Nursing Assistant I	16.68
12222 - Nursing Assistant II	19.01
12223 - Nursing Assistant III	20.48

12224 - Nursing Assistant IV		22.99
12235 - Optical Dispenser		30.18
12236 - Optical Technician		20.31
12250 - Pharmacy Technician		20.90
12280 - Phlebotomist		23.48
12305 - Radiologic Technologist		47.04
12311 - Registered Nurse I		32.76
12312 - Registered Nurse II		38.41
12313 - Registered Nurse II, Specialist		38.41
12314 - Registered Nurse III		49.39
12315 - Registered Nurse III, Anesthetist		49.39
12316 - Registered Nurse IV		59.22
12317 - Scheduler (Drug and Alcohol Testing)		38.90
12320 - Substance Abuse Treatment Counselor		31.20
13000 - Information And Arts Occupations		
13011 - Exhibits Specialist I		30.00
13012 - Exhibits Specialist II		37.16
13013 - Exhibits Specialist III		45.45
13041 - Illustrator I		32.08
13042 - Illustrator II		39.22
13043 - Illustrator III		47.96
13047 - Librarian		38.29
13050 - Library Aide/Clerk		17.97
13054 - Library Information Technology Systems Administrator		34.57
13058 - Library Technician		25.62
13061 - Media Specialist I		24.95
13062 - Media Specialist II		27.91
13063 - Media Specialist III		31.11
13071 - Photographer I		22.76
13072 - Photographer II		25.46
13073 - Photographer III		32.88
13074 - Photographer IV		38.59
13075 - Photographer V		46.69
13090 - Technical Order Library Clerk		22.56
13110 - Video Teleconference Technician		33.70
14000 - Information Technology Occupations		
14041 - Computer Operator I		27.88
14042 - Computer Operator II		31.18
14043 - Computer Operator III		34.75
14044 - Computer Operator IV		38.62
14045 - Computer Operator V		42.78
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		27.88
14160 - Personal Computer Support Technician		38.62
14170 - System Support Specialist		42.78
15000 - Instructional Occupations		
15010 - Aircrew Training Devices Instructor (Non-Rated)		42.14
15020 - Aircrew Training Devices Instructor (Rated)		50.99
15030 - Air Crew Training Devices Instructor (Pilot)		61.13
15050 - Computer Based Training Specialist / Instructor		42.14
15060 - Educational Technologist		38.90
15070 - Flight Instructor (Pilot)		61.13
15080 - Graphic Artist		37.28
15085 - Maintenance Test Pilot, Fixed, Jet/Prop		61.13
15086 - Maintenance Test Pilot, Rotary Wing		61.13
15088 - Non-Maintenance Test/Co-Pilot		61.13
15090 - Technical Instructor		31.44
15095 - Technical Instructor/Course Developer		38.34
15110 - Test Proctor		25.30
15120 - Tutor		25.30

16000 - Laundry, Dry-Cleaning, Pressing And Related Occupations	
16010 - Assembler	20.00
16030 - Counter Attendant	20.00
16040 - Dry Cleaner	22.86
16070 - Finisher, Flatwork, Machine	20.00
16090 - Presser, Hand	20.00
16110 - Presser, Machine, Drycleaning	20.00
16130 - Presser, Machine, Shirts	20.00
16160 - Presser, Machine, Wearing Apparel, Laundry	20.00
16190 - Sewing Machine Operator	23.79
16220 - Tailor	24.75
16250 - Washer, Machine	20.95
19000 - Machine Tool Operation And Repair Occupations	
19010 - Machine-Tool Operator (Tool Room)	31.58
19040 - Tool And Die Maker	36.59
21000 - Materials Handling And Packing Occupations	
21020 - Forklift Operator	22.97
21030 - Material Coordinator	29.78
21040 - Material Expediter	29.78
21050 - Material Handling Laborer	19.84
21071 - Order Filler	18.37
21080 - Production Line Worker (Food Processing)	22.97
21110 - Shipping Packer	22.33
21130 - Shipping/Receiving Clerk	22.33
21140 - Store Worker I	20.32
21150 - Stock Clerk	25.47
21210 - Tools And Parts Attendant	22.97
21410 - Warehouse Specialist	22.97
23000 - Mechanics And Maintenance And Repair Occupations	
23010 - Aerospace Structural Welder	49.20
23019 - Aircraft Logs and Records Technician	41.47
23021 - Aircraft Mechanic I	47.36
23022 - Aircraft Mechanic II	49.20
23023 - Aircraft Mechanic III	51.04
23040 - Aircraft Mechanic Helper	36.86
23050 - Aircraft, Painter	45.58
23060 - Aircraft Servicer	41.47
23070 - Aircraft Survival Flight Equipment Technician	45.58
23080 - Aircraft Worker	43.70
23091 - Aircrew Life Support Equipment (ALSE) Mechanic I	43.70
23092 - Aircrew Life Support Equipment (ALSE) Mechanic II	47.36
23110 - Appliance Mechanic	29.67
23120 - Bicycle Repairer	23.36
23125 - Cable Splicer	57.58
23130 - Carpenter, Maintenance	33.50
23140 - Carpet Layer	28.96
23160 - Electrician, Maintenance	40.90
23181 - Electronics Technician Maintenance I	36.95
23182 - Electronics Technician Maintenance II	38.54
23183 - Electronics Technician Maintenance III	40.04
23260 - Fabric Worker	46.09
23290 - Fire Alarm System Mechanic	32.56
23310 - Fire Extinguisher Repairer	33.12
23311 - Fuel Distribution System Mechanic	50.25
23312 - Fuel Distribution System Operator	41.55
23370 - General Maintenance Worker	28.32
23380 - Ground Support Equipment Mechanic	47.36
23381 - Ground Support Equipment Servicer	41.47
23382 - Ground Support Equipment Worker	43.70
23391 - Gunsmith I	33.12
23392 - Gunsmith II	36.97
23393 - Gunsmith III	40.06
23410 - Heating, Ventilation And Air-Conditioning Mechanic	35.62
23411 - Heating, Ventilation And Air Contidioning Mechanic (Research Facility)	37.00
23430 - Heavy Equipment Mechanic	36.87
23440 - Heavy Equipment Operator	46.90

23460 - Instrument Mechanic	34.01
23465 - Laboratory/Shelter Mechanic	38.55
23470 - Laborer	19.84
23510 - Locksmith	28.79
23530 - Machinery Maintenance Mechanic	34.91
23550 - Machinist, Maintenance	29.96
23580 - Maintenance Trades Helper	22.26
23591 - Metrology Technician I	34.01
23592 - Metrology Technician II	35.33
23593 - Metrology Technician III	36.65
23640 - Millwright	41.36
23710 - Office Appliance Repairer	30.06
23760 - Painter, Maintenance	28.10
23790 - Pipefitter, Maintenance	38.18
23810 - Plumber, Maintenance	36.75
23820 - Pneudraulic Systems Mechanic	40.06
23850 - Rigger	47.48
23870 - Scale Mechanic	36.97
23890 - Sheet-Metal Worker, Maintenance	37.19
23910 - Small Engine Mechanic	26.38
23931 - Telecommunications Mechanic I	35.34
23932 - Telecommunications Mechanic II	36.72
23950 - Telephone Lineman	51.77
23960 - Welder, Combination, Maintenance	29.25
23965 - Well Driller	37.66
23970 - Woodcraft Worker	40.06
23980 - Woodworker	33.12
24000 - Personal Needs Occupations	
24550 - Case Manager	22.78
24570 - Child Care Attendant	17.57
24580 - Child Care Center Clerk	21.90
24610 - Chore Aide	18.27
24620 - Family Readiness And Support Services Coordinator	22.78
24630 - Homemaker	22.78
25000 - Plant And System Operations Occupations	
25010 - Boiler Tender	49.94
25040 - Sewage Plant Operator	39.82
25070 - Stationary Engineer	49.94
25190 - Ventilation Equipment Tender	38.87
25210 - Water Treatment Plant Operator	39.82
27000 - Protective Service Occupations	
27004 - Alarm Monitor	28.58
27007 - Baggage Inspector	20.21
27008 - Corrections Officer	42.48
27010 - Court Security Officer	43.70
27030 - Detection Dog Handler	22.61
27040 - Detention Officer	42.48
27070 - Firefighter	48.42
27101 - Guard I	20.21
27102 - Guard II	22.61
27131 - Police Officer I	45.76
27132 - Police Officer II	50.84
28000 - Recreation Occupations	
28041 - Carnival Equipment Operator	21.02
28042 - Carnival Equipment Repairer	22.33
28043 - Carnival Worker	17.07
28210 - Gate Attendant/Gate Tender	22.60
28310 - Lifeguard	17.61
28350 - Park Attendant (Aide)	25.28
28510 - Recreation Aide/Health Facility Attendant	18.95
28515 - Recreation Specialist	31.33
28630 - Sports Official	20.14
28690 - Swimming Pool Operator	24.92
29000 - Stevedoring/Longshoremen Occupational Services	
29010 - Blocker And Bracer	52.98
29020 - Hatch Tender	52.98
29030 - Line Handler	52.98
29041 - Stevedore I	46.44

29042 - Stevedore II		58.20
30000 - Technical Occupations		
30010 - Air Traffic Control Specialist, Center (HFO)	(see 2)	54.30
30011 - Air Traffic Control Specialist, Station (HFO)	(see 2)	37.44
30012 - Air Traffic Control Specialist, Terminal (HFO)	(see 2)	41.23
30021 - Archeological Technician I		23.42
30022 - Archeological Technician II		26.20
30023 - Archeological Technician III		32.45
30030 - Cartographic Technician		32.45
30040 - Civil Engineering Technician		32.63
30051 - Cryogenic Technician I		35.94
30052 - Cryogenic Technician II		39.68
30061 - Drafter/CAD Operator I		23.42
30062 - Drafter/CAD Operator II		26.20
30063 - Drafter/CAD Operator III		29.20
30064 - Drafter/CAD Operator IV		35.94
30081 - Engineering Technician I		21.37
30082 - Engineering Technician II		23.98
30083 - Engineering Technician III		26.83
30084 - Engineering Technician IV		33.23
30085 - Engineering Technician V		40.64
30086 - Engineering Technician VI		49.17
30090 - Environmental Technician		28.63
30095 - Evidence Control Specialist		32.45
30210 - Laboratory Technician		28.58
30221 - Latent Fingerprint Technician I		34.45
30222 - Latent Fingerprint Technician II		38.05
30240 - Mathematical Technician		39.86
30361 - Paralegal/Legal Assistant I		25.38
30362 - Paralegal/Legal Assistant II		31.45
30363 - Paralegal/Legal Assistant III		38.46
30364 - Paralegal/Legal Assistant IV		46.53
30375 - Petroleum Supply Specialist		39.68
30390 - Photo-Optics Technician		32.45
30395 - Radiation Control Technician		39.68
30461 - Technical Writer I		32.85
30462 - Technical Writer II		40.18
30463 - Technical Writer III		48.61
30491 - Unexploded Ordnance (UXO) Technician I		34.51
30492 - Unexploded Ordnance (UXO) Technician II		41.75
30493 - Unexploded Ordnance (UXO) Technician III		50.04
30494 - Unexploded (UXO) Safety Escort		34.51
30495 - Unexploded (UXO) Sweep Personnel		34.51
30501 - Weather Forecaster I		35.94
30502 - Weather Forecaster II		43.72
30620 - Weather Observer, Combined Upper Air Or Surface Programs	(see 2)	29.20
30621 - Weather Observer, Senior	(see 2)	32.45
31000 - Transportation/Mobile Equipment Operation Occupations		
31010 - Airplane Pilot		41.75
31020 - Bus Aide		29.58
31030 - Bus Driver		38.09
31043 - Driver Courier		21.21
31260 - Parking and Lot Attendant		17.08
31290 - Shuttle Bus Driver		21.44
31310 - Taxi Driver		18.40
31361 - Truckdriver, Light		22.53
31362 - Truckdriver, Medium		23.86
31363 - Truckdriver, Heavy		31.36
31364 - Truckdriver, Tractor-Trailer		31.36
99000 - Miscellaneous Occupations		
99020 - Cabin Safety Specialist		20.36
99030 - Cashier		17.04
99050 - Desk Clerk		20.11
99095 - Embalmer		39.23
99130 - Flight Follower		34.51
99251 - Laboratory Animal Caretaker I		21.53
99252 - Laboratory Animal Caretaker II		22.87

99260 - Marketing Analyst	46.81
99310 - Mortician	36.79
99410 - Pest Controller	23.29
99510 - Photofinishing Worker	27.69
99710 - Recycling Laborer	33.83
99711 - Recycling Specialist	38.72
99730 - Refuse Collector	31.43
99810 - Sales Clerk	17.96
99820 - School Crossing Guard	21.03
99830 - Survey Party Chief	35.00
99831 - Surveying Aide	22.87
99832 - Surveying Technician	30.18
99840 - Vending Machine Attendant	28.92
99841 - Vending Machine Repairer	34.29
99842 - Vending Machine Repairer Helper	28.92

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 $13.30 per hour (or the applicable wage rate listed on this wage determination, if it is higher) for all hours spent performing on the contract in 2025. The applicable Executive Order minimum wage rate will be adjusted annually. 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, 4 weeks after 10 years, and 5 weeks after 20 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 twelve paid holidays per year: New Year's Day, Martin Luther King Jr's Birthday, Washington's Birthday, Good Friday, 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) 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.

2) 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))."" "

Attachment 25

NIAID Office of Acquisitions electronic Report Deliverable Submission

National Institutes of Health
Turning Discovery Into Health

User Guide for Vendors

v1.1
June 2015

Contents

eRDS – Electronic Report Deliverable Submission

Vendor Guide

eRDS – Improving your contract deliverables submission process

The electronic Report Deliverable Submission (eRDS) application is a component of NIAID's integrated, secure system for the electronic submission, capture, tracking and review of NIAID contract deliverables. The **eRDS** application allows:

- **Vendors** to easily submit contract deliverables.
- **Program Technicians, Contracting Officers Representative, and Contract Specialists/Officer** to track and accept contract deliverables.

Vendor Roles

eRDS has two Vendor roles:

- **Vendor Admin (VA):** the 'lead' Vendor assigned to the contract by the NIAID Contract Specialist (CS). They can create and assign Vendor Submitters (VS) to their contracts, as well as submit deliverables themselves.
- **Vendor Submitter (VS):** created by the Vendor Admin to submit deliverables for their contracts The VA may add multiple Vendor Submitters to their contract as needed

Access eRDS

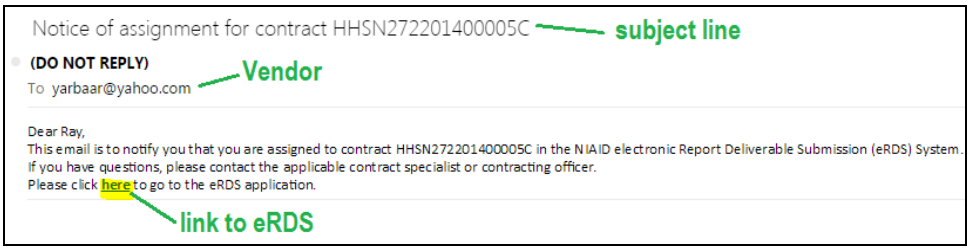
All Vendors must have an NIH EXT or eRA Commons account to access eRDS.

To Apply for an NIH EXT account:

- Go to the eRDS **NIH External Account Request** page, complete the application, and Submit https://erds.niaid.nih.gov/NIAID/NihExt/Create

Vendor login

1. Login using your NIH EXT account at https://erds.niaid.nih.gov (*Vendor Site*)
   a. A VA or VS can also log into the site by clicking on the eRDS embedded link in the Notice of Assignment email that is sent by the system when vendor is assigned to a contract.

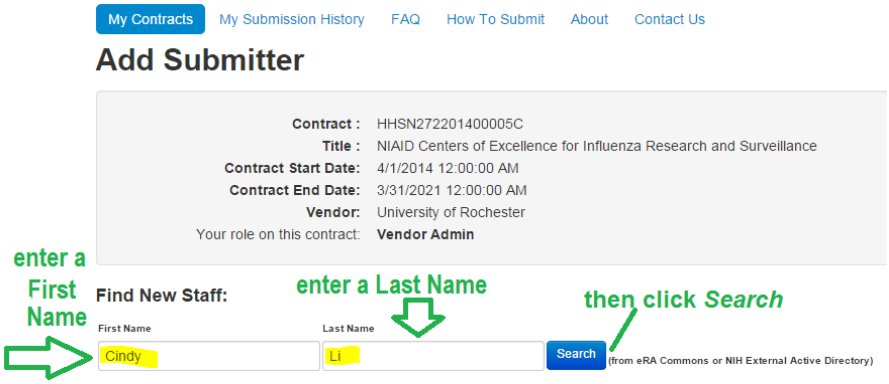


2. Vendors will land on the My Contracts page

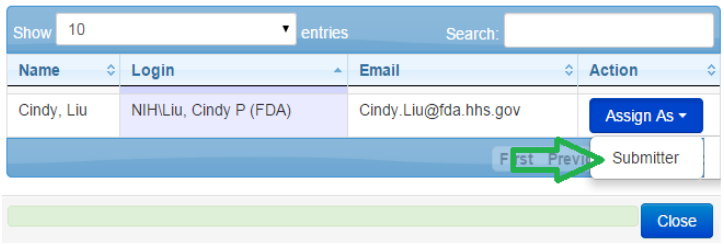
Add Submitter

To add a Vendor Submitter to a contract (Vendor Admin <u>ONLY</u>):

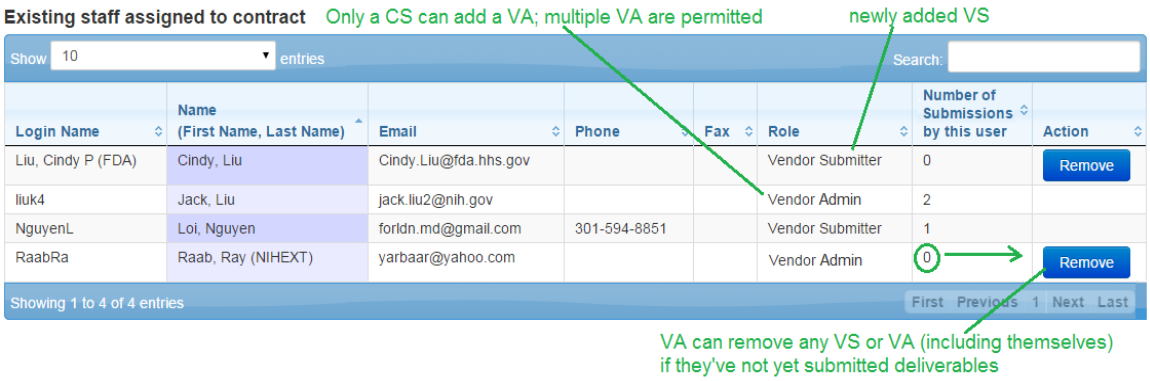
1. Select the Add Submitter (Add Submitter) button in the "Submitter Assignment" column
2. Enter First and Last Names in the "Find New Staff" fields and click Search (Search)



3. If the user has an account, it will display in a result popup window, where you can assign the user as Submitter, and Close:



4. If the user does not have an account, follow the '*Apply for an NIH EXT account'* instructions above on accessing eRDS.
5. Returning to Add Submitter, you'll see the name added to the list. The VA can remove vendor staff as well, so long as they haven't submitted anything yet (a *zero* under Number of Submissions by this user).

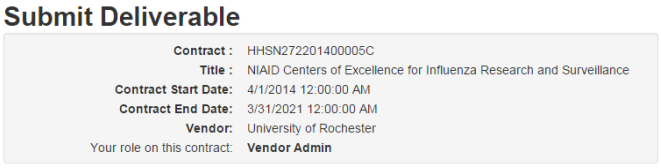


6. Select the Back (Back) button to return to My Contracts

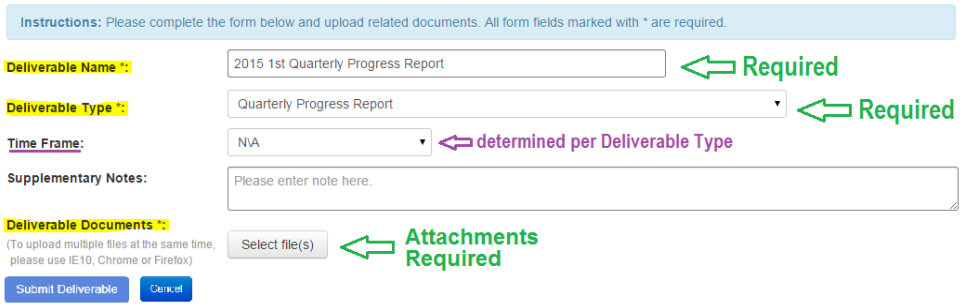
Submit New Deliverable

To Submit a New Contract Deliverable:

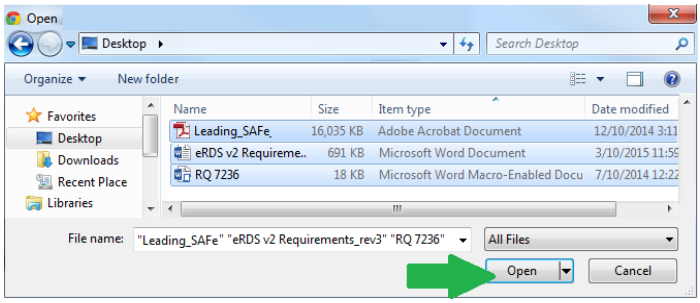
1. Select your contract's Submit New Deliverable (Submit New Deliverable) button in the "Action" column.



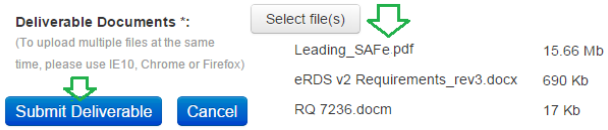
2. Enter the Deliverable's *Name*, *Type, Time Frame* (for recurring reports in the calendar year), and any *Supplementary Notes* as needed:



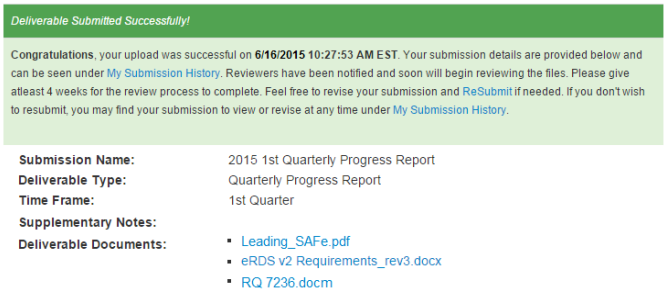
3. Choose Select file(s) (Select Files) to attach one or more documents. Using Internet Explorer 10, Google Chrome or Mozilla Firefox as web browsers will enable you to select multiple files at the same time. Microsoft Office files (word, excel) and Adobe PDF are accepted.



4. The attached files display next to Deliverable Documents. Select Submit Deliverable (Submit Deliverable) to complete the submission:



5. A green delivery confirmation screen with a summary of the delivered content is returned to the Vendor.



6. Upon submission of the deliverable you can view the data on My Submission History page

COR Inspection of Deliverable Report

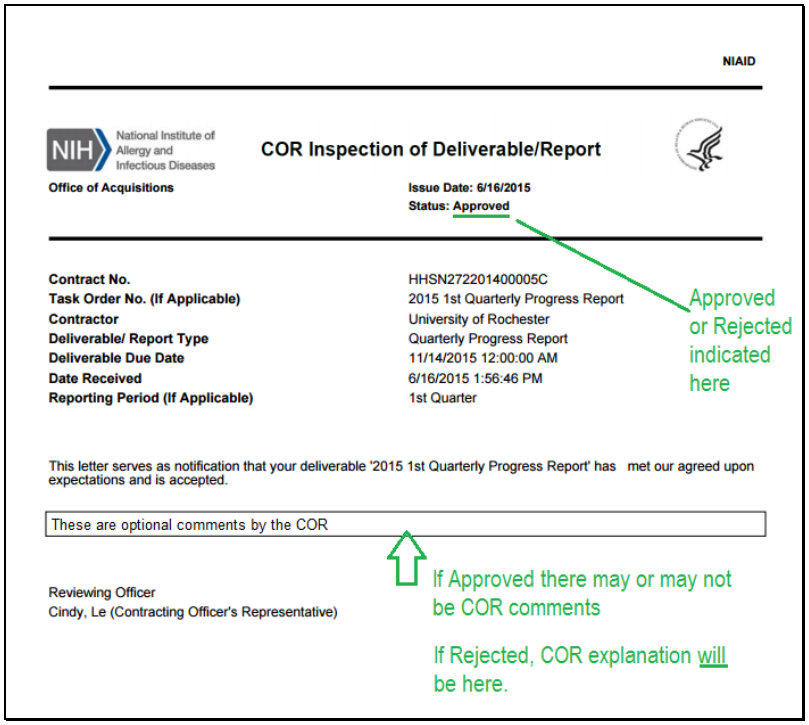
COR Inspection of Deliverable Report

1. Upon acceptance/rejection of the deliverable, you will receive a Notice of Status Change email with an embedded link to eRDS. After login, you'll land on My Submission History

   - *NOTE: The below screenshot is an example of acceptance scenario and if deliverables are rejected, a similar notice is sent*

2. On this page you'll see your contract's title and number, submission details, and document links. You will also see the COR Inspection of Deliverable Report PDF at the bottom of the details

3. To review, select the COR Inspection of Deliverable Report PDF to download the document through your web browser



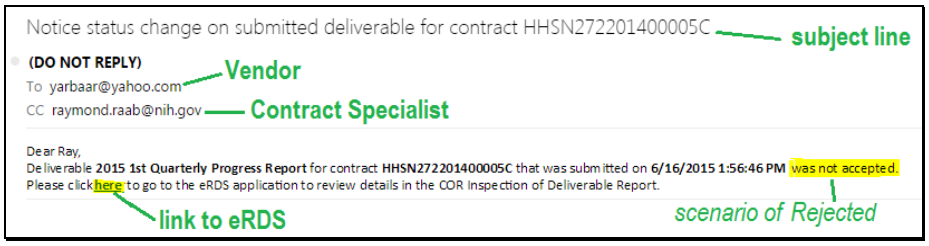
4. If the deliverable is auto-approved, the COR Inspection of Deliverable report won't be available.

Re-Submission & Alternate Submissions

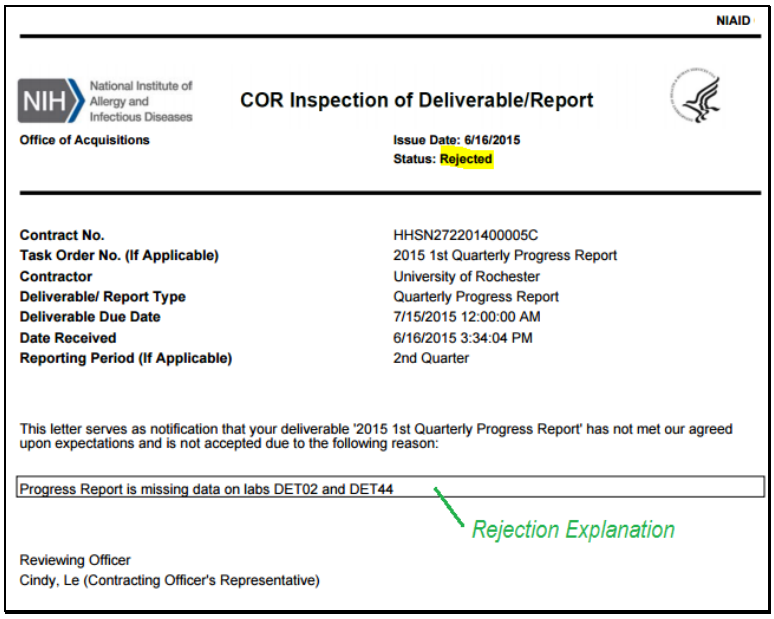
Re-Submit (Revise) a Deliverable

1. If you wish to revise a submitted deliverable, you may do so only after the acceptance/rejection of deliverable from NIAID OA Office.

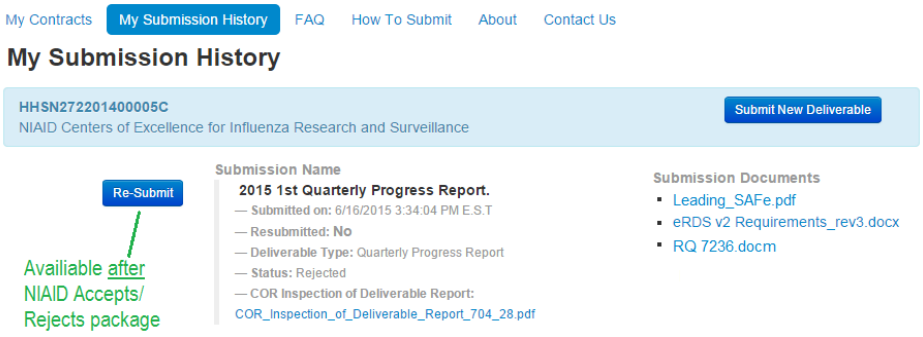
2. Once you receive the Notice of Status Change email notice from NIAID that your submission was *not accepted* (rejected), select the embedded link to go to My Submission History



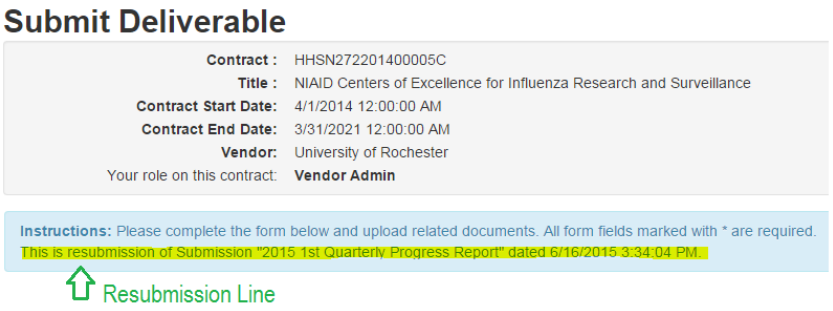
3. Under My Submission History, the COR Inspection of Deliverable Report PDF will provide an explanation for the rejection



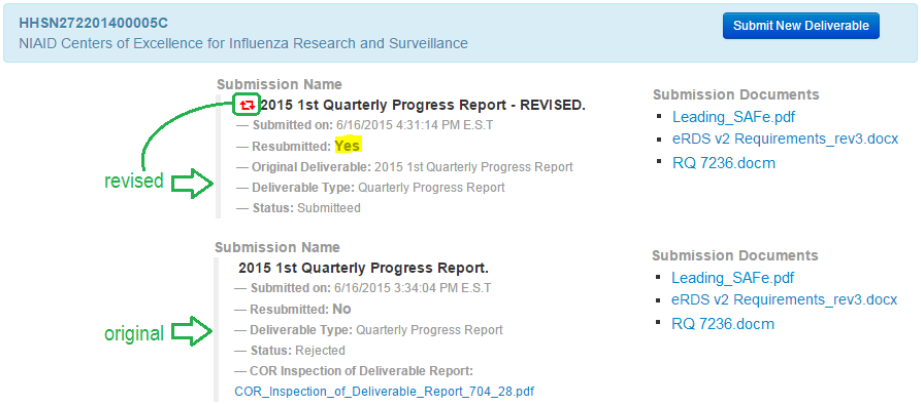
4. Select the Re-Submit (Re-Submit) button for revised deliverable resubmission. Click OK to get past the notification popup



5. The Submit Deliverable page is the same for re-submissions, with the exception of an additional instruction line indicating resubmission status. After submission, you'll receive the same confirmation messages and email notices



6. Under My Submission History, the submission details are updated with the revised submission. The original is also still visible



Submit an Alternate Deliverable

1. If your particular contract requires two different types of deliverables, eRDS allows the Vender to submit a second or 'alternate' deliverable. On the My Submission History page, there is a Submit New Deliverable (Submit New Deliverable) button for each contract. It is available even if the last submission for a given deliverable is still under review and is neither accepted nor rejected yet.

2. Selecting the button takes you to the Submit Deliverable page. After submission, the My Submission History page is updated with the new package