SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

<table>
<tr><td colspan="3">1. Requisition or other Purchase Authority: 96-83</td></tr>
<tr><td>2. Request for Proposal Number:
75N93025R00011</td><td>3. Issue Date:
1/26/2026</td><td>4. Set Aside:
[X] No
[] Yes See Part IV Section L</td></tr>
<tr><td colspan="3">5. Title: Patient Safety Monitoring in International Laboratories (pSMILE)</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
Room 3D10
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 2/09/2026.</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 3/12/2026. 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 FAR 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: Patrick Finn
PHONE: 240-669-5401
e-MAIL: patrick.finn@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 February 9, 2026, so that we can provide timely responses before proposals are due.</td><td>Patrick Finn
Contracting Officer
Office of Acquisitions
NIAID, NIH, DHHS</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 Contractor shall provide a comprehensive and uniform approach to support and evaluate initial and on-going capability and readiness to carry out NIAID-funded and collaborative clinical trial protocols (Protocols) by (1) supporting and monitoring compliance with good clinical laboratory practice (GCLP) standards, (2) supporting and monitoring the quality and reliability of Protocol-specified laboratory test results, (3) providing Labs with various means of assistance, guidance and training to improve the quality of laboratory operations, and (4) hosting and maintaining the existing electronic data management system. Options to increase level of effort, to support unanticipated increases in demand related to oversight of additional Labs, are also within the scope of the contract.

ARTICLE B.2. ESTIMATED COST – OPTION

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

b. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount will be increased as follows:

	Estimated Cost ($)
Base Period	
Option Period(s)	
Total [Base Period and Option(s)]	

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.

The following Advanced Understandings will be included in any resultant contract:

a. Protection of Proprietary Data:

Materials, data and other information supplied by third-party providers or laboratories under this contract or the Contracting Officer's Representative (COR), including information concerning third party materials, shall be assumed to be confidential unless (a) specifically identified as not confidential in writing by the COR: (b) is within the public domain before its receipt by the Contractor or thereafter becomes within the public domain other than as a result of disclosure by the Contractor; (c) is in the possession of the Contractor before its receipt by the Contractor; (d) is acquired by the Contractor from a third party not under an obligation of confidentiality; (e) is hereafter independently developed by the Contractor, without reference to the supplied information; or (f) the COR or the third party expressly authorizes the Contractor to disclose. Materials supplied by third-party providers or laboratories under this Contract will not be further distributed to others without the COR's or the third party's written consent.

ISO 9001:2015 certification for pSMILE contract operations is recommended to support the establishment, maintenance, and continual improvement of contract quality management systems.

b. 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.

c. Invoices – Cost and Personnel Reporting, and Variances from the Negotiated Budget

1. The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

    a. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort, and amount claimed.

    b. Fringe Benefits - Cite rate and amount.

    c. Overhead - Cite rate and amount.

    d. Materials & Supplies - Include detailed breakdown when total amount is over $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

    e. Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.

    f. Consultant Fees - Identify individuals and amounts.

    g. Subcontracts - Attach subcontractor invoice(s).

    h. Equipment - Cite authorization and amount.

    i. G&A - Cite rate and amount.

    j. Total Cost

    Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

2. The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) of unexpended balance (greater than 10 percent) of the

amount allotted to the contract, and the reasons for the variance. Also refer to the requirement of the Limitation of Cost clauses in contract.

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated March 31, 2025, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

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."

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*.]

These reports shall include a cover page prepared in accordance with the following format:

- Contract Number and Project Title
- Period of Performance Being Reported
- Contractor's Name and Address
- Author(s)
- Date of Submission

1. Tri-annual 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 four months of performance including any fractional part of the initial month and shall be due on the 30th of the month following the reporting period. Thereafter, the reporting period shall consist of four full calendar months.

The Contractor shall submit the following required information within the Tri-annual Progress Report:

a. Summary and highlights of activities related to review and resolution of laboratory GCLP audit findings
b. Summary and highlights of activities related to review of method validation reports received from Labs and support provided to Labs
c. Summary and highlights of activities related to acquisition of PT panels, review of Labs performance and assistance to Labs
d. Summary of training activities, including visits to Labs
e. Description of activities related to web enhancement and maintenance
f. Summary of subcontract activities, if applicable
g. Summary of consultant activities, if applicable
h. Summary of meetings, teleconferences and discussions with the COR, Lab personnel, PT panels providers and others regarding issues relevant to the conduct of the contracted work
i. Summary of facilities/equipment issues
j. Personnel report, which shall include the name, title, percent effort and responsibility of each individual working on the contract and a summary of personnel changes occurring during the reporting interval

A Tri-annual Progress Report shall not be submitted when the Final Report is due.

2. Final Report

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 Tri-annual Progress Report will not be required for the period when the Final Report is due.

3. Summary of Salient results

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

b. Other Reports/Deliverables

1. Reporting of Financial Conflict of Interest (FCOI)

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

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

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

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. Source Code and Object Code

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

4. Other Reports and Deliverables Required by the Contract and Statement of Work

Item	Deliverables	Contract/SOW Reference	Recipient	Delivery Schedule
1.	Initial Transition Plan	SOW Section 3.G.1	Submitted via eRDS to COR and CO	Within 10 business days of the effective date of the contract
2.	Annual Utilization Report	Section C, ARTICLE C.3	Submitted via eRDS to COR and CO	Due on/before the 30th of the month following each anniversary date of the contract.

Item	Deliverables	Contract/SOW Reference	Recipient	Delivery Schedule
3.	Lab-specific post audit Action Plan	SOW Section 3.A.2	1 electronic copy to COR and to Others specified by the COR	Within 10 business days of receipt of audit report.
4.	Lab-specific PT evaluation, review and summary	SOW Section 3.B.5.b	1 electronic copy to COR, to each Lab and to Others specified by the COR	Within 5 business days of obtaining performance grading from PT provider.
5.	Summary report of performance failures	SOW Section 3.B.5.e	1 electronic copy to COR and to Others specified by the COR	Monthly.
6.	Lab visit reports	SOW Section 3.C.5	1 electronic copy to COR, to visited Lab and to Others specified by the COR	Within 10 business days of visit completion.
7.	Presentations and training materials	SOW Section 3.C.6	1 electronic copy to COR and to Others specified by the COR	At least 3 business days prior to presentation.
8.	Draft Final Transition Plan	SOW Section G.2.a	Submitted via eRDS to COR and CO	6 months prior to the expiration date of the contract.
9.	Final Transition Plan	SOW Section G.2.b	Submitted via eRDS to COR and CO	3 months prior to the expiration date of the contract.
10.	Section 508 Compliance Report	Section C, ARTICLE C.2	Submitted via eRDS to COR and CO	Annually on the anniversary date of the contract.

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 first annual utilization report shall be due on or before February 14, 2028. Thereafter, reports shall be due on or before the 30th calendar day following the reporting period. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
Office of Acquisitions
Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
National Institutes of Health
Department of Health and Human Services
5601 Fishers Lane, Room 3C19
Bethesda, Maryland 20892-9821

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, the Contracting Officer's Representative is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:

Laboratory and Clinical Sciences Branch
Therapeutics Research Program
Division of AIDS
National Institute of Allergy and Infectious Diseases, NIH
Department of Health and Human Services
5601 Fishers Lane
Bethesda, MD 20892

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

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

FAR Clause **52.246-8, Inspection of Research and Development - Cost-Reimbursement** (May 2001).

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

SECTION F – DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

a. The period of performance of this contract shall be from February 15, 2027 through February 14, 2028.

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

Option	Option Period
Option 1 (Contract Year 2)	February 15, 2028 through February 14, 2029
Option 2 (Contract Year 3)	February 15, 2029 through February 14, 2030
Option 3 (Contract Year 4)	February 15, 2030 through February 14, 2031
Option 4 (Contract Year 5)	February 15, 2031 through February 14, 2032
Option 5 (Contract Year 6)	February 15, 2032 through February 14, 2033
Option 6 (Contract Year 7)	February 15, 2033 through February 14, 2034

ARTICLE F.2. LEVEL OF EFFORT

a. During the period of performance of this contract, the Contractor shall provide _____ direct labor hours. The labor hours include vacation, holiday, and sick leave. The labor hours include the effort of subcontractors, but do not include the effort of consultants. It is estimated that the labor hours are constituted as specified below and will be expended approximately as follows:

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Professional							

Other Professional							
Support							
Totals							

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

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

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

FEDERAL ACQUISITIONS REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989)

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

52.247-35, F.o.b. Destination Within Consignees Premises (April 1984).

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 prior to 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. KEY PERSONNEL, HHSAR 352.237-75 (December 2015).

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

(End of clause).

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

Name	Title
To be specified prior to award	

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

a. Invoice Submission/Contract Financing Request and Contract Financial Reporting, 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.

2. Until the Contract has transitioned to IPP as specified on the OALM IPP website, the Contractor must follow step-by-step instructions as stated in the NIH/OFM Electronic Invoicing Instructions for NIH Contractors/Vendors, which is included as an attachment in Section J of this contract. The invoice submitted to the NIH/OFM must be transmitted as an attachment via email to the address listed above in one of the following formats: Word, or Adobe Portable Document Format (PDF). The Contractor must submit only one invoice per email. Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your invoice unless specified elsewhere in the contract or requested by the Contracting Officer.

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

   Official: Contracting Officer

   Name – TBD Emal Address - TBD

   Contracting Officer Representative

   Name – TBD Email Address – TBD

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

4. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

    a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Institute of Allergies and Infectious Diseases (NIAID).

    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: “Patient Safety Monitoring in International Laboratories (pSMILE)”

    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.4. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 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.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

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

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

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

b. Electronic Access to Contractor Performance Evaluations

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

End of clause.

ARTICLE G.6. GOVERNMENT PROPERTY

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

SECTION H – SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

ARTICLE H.2. HUMAN MATERIALS

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.

ARTICLE H.3. 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.4. NIH POLICY ON ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

Contractors shall adhere to the NIH policy of enhancing reproducibility through rigor and transparency by addressing each of the four areas of the policy in performance of the Statement of Work and in

publications, as applicable: 1) Scientific Premise; 2) Scientific Rigor; 3) Consideration of Relevant Biological Variables, including Sex; and 4) Authentication of Key Biological and/or Chemical Resources. This policy applies to all NIH funded research and development, from basic through advanced clinical studies. See NIH Guide Notice, NOT-OD-15-103 , "Enhancing Reproducibility through Rigor and Transparency" and NOT-OD-15-102 , "Consideration of Sex as a Biological Variable in NIH-funded Research" for more information. In addition, publications are expected to follow the guidance at https://www.nih.gov/research-training/rigor-reproducibility/principles-guidelines-reporting-preclinical-research, whether preclinical or otherwise, as appropriate. More information is available at https://grants.nih.gov/policy/reproducibility/index.htm, including FAQs and a General Policy Overview.

ARTICLE H.5. 2024 NIH PUBLIC ACCESS POLICY

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) electronic versions of all Author Accepted Manuscripts arising from this contract in whole or in part, upon acceptance for publication. NIH defines the Author Accepted Manuscripts as the author's final version that has been accepted for journal publication and includes all revisions resulting from the peer review process, including all associated tables, graphics, and supplemental material. NIH-funded investigators shall notify their Contracting Officers and Contracting Officer Representatives upon the acceptance of an Author Accepted Manuscript resulting from the contract, even if co-authored with those not using contract funds. Through execution of this contract, contractor, and through implementation of this provision by contractor to each of contractor's investigators and subcontractor, and through implementation of this provision to each of subcontractor's investigators, conducting work under this contract or a subcontract, respectively, hereby grants to NIH a royalty-free, nonexclusive, and irrevocable right to reproduce, publish, or otherwise use for federal purposes and to authorize others to do so, all Author Accepted Manuscripts that result from this contract, which includes making Author Accepted Manuscripts publicly available in PubMed Central upon the Official Date of Publication, in accordance with the 2024 NIH Public Access Policy. Upon receipt of a PMCID, investigators should report the PMCID to their Contracting Officers and Contracting Officer Representatives to demonstrate compliance with this term of the contract. The PMC archive will permanently preserve and retain these manuscripts for use by the public, health care providers, educators, scientists, and NIH. NIH Policy directs electronic submissions to the NIH/NLM/PMC: https://www.ncbi.nlm.nih.gov/pmc/.
Additional information is available at: https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-047.html and https://grants.nih.gov/policy-and-compliance/policy-topics/public-access

ARTICLE H.6. 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.7. 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.8. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

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

ARTICLE H.9. GUN CONTROL

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

ARTICLE H.10. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item, FAR Clause 52.217-8, Option to Extend Services, and FAR Clause 52.217-9, Option to Extend the Term of the Contract set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost of the contract will be increased as set forth in the ESTIMATED COST Article in SECTION B of this contract.

ARTICLE H.11. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan**

1. In accordance with FAR 19.704 and FAR 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 FAR Clause 52.219-8, entitled " Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages- Subcontracting Plan."

b. **Subcontracting Reports**

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

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

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

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

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

5. Individual Subcontract Reports (ISR)

   The Contractor must submit the following Subcontracting reports electronically via the Subcontracting Reporting System (eSRS) at https://www.esrs.gov/.
   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

   April 30th
   October 30th
   Expiration Date of Contract

6. Summary Subcontract Report (SSR)
   Regardless of the effective date of this contract, the Summary Subcontract Report must be submitted annually on the following date for the entire life of this contract:

   October 30th

   For both the Individual and Summary Subcontract Reports, the [Contracting Officer/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.12. 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.13. INFORMATION AND COMMUNICATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-79 (FEB 2024) (DEVIATION).

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

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

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

(d) If this is an Indefinite-Delivery type contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include ICT supplies, products, platforms, information, documentation, or services support will define the specifications and accessibility standards for the order. In those cases, the Contractor shall be required to provide a completed HHS Section 508 Accessibility Conformance Checklist (see *https://www.hhs.gov/web/section-508/accessibility-checklists/index.html*) or an ACR (based on the VPAT see https://www.itic.org/policy/accessibility/vpat), and any other additional information necessary to assist the Government in determining that the ICT supplies, products, platforms, information, documentation, or services support conform to Section 508 accessibility standards. If it is determined by the Government that ICT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

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

(End of clause).

ARTICLE H.14. 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:
    a. Management of financial conflicts of interest.
    b. Prior to the Institution's expenditure of any funds under a NIH-funded research project, the designated official(s) of an Institution shall, consistent with § 94.4(f) : review all Investigator disclosures of significant financial interests; determine whether any significant financial interests relate to NIH-funded research; determine whether a financial conflict of interest exists; and, if so, develop and implement a management plan that shall specify the actions that have been, and shall be, taken to manage such financial conflict of interest. Examples of conditions or restrictions that might be imposed to manage a financial conflict of interest include, but are not limited to:
        i. Public disclosure of financial conflicts of interest (e.g., when presenting or publishing the research);
        ii. For research projects involving human subjects research, disclosure of financial conflicts of interest directly to participants;
        iii. Appointment of an independent monitor capable of taking measures to protect the design, conduct, and reporting of the research against bias, resulting from the financial conflict of interest;
        iv. Modification of the research plan;
        v. Change of personnel or personnel responsibilities, or disqualification of personnel from participation in all or a portion of the research;
        vi. Reduction or elimination of the financial interest (e.g., sale of an equity interest); or
        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.15. 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"

ARTICLE H.16. ADVANCED COPIES OF PRESS RELEASES

a. 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.17. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477).** All telephone calls will be handled confidentially. The website to file a complaint on-line is: https://oig.hhs.gov/fraud/report-fraud/ and the mailing address is:
US Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.18. 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.19. CONSTITUTION DAY

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

ARTICLE H.20. 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.

PART II – CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

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

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

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

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

b. FAR Clauses **52.215-15, Pension Adjustments and Asset Reversions** (Oct 2010); **52.215-18, Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions** (Jul 2005); and, **52.215-19** , **Notification of Ownership Changes** (Oct 1997), are deleted in their entirety.

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

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

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

f. FAR Clause **52.232-17, Interest** (May 2014) is deleted.

g. FAR Clauses **52.249-6, Termination (Cost-Reimbursement)** (May 2004) and **52.249-14, Excusable Delays** (Apr 1984), are deleted in their entirety and FAR Clause **52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)** (Aug 2016), is substituted therefore.

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES IN FULL TEXT

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

Clause Database	Clause Number	Clause Title
FAR	52.203-13	Contractor Code of Business Ethics and Conduct. (NOV 2021)
FAR	52.203-14	Display of Hotline Poster(s). (NOV 2021)
FAR	52.204-14	Service Contract Reporting Requirements (DEVIATION) (RFO AUG 2025)
FAR	52.209-10	Prohibition on Contracting with Inverted Domestic Corporations (DEVIATION) (RFO AUG 2025)
FAR	52.210-1	Market Research. (DEVIATION) (RFO May 2025)
FAR	52.216-15	Predetermined Indirect Cost Rates (APR 1998)
FAR	52.217-7	Option for Increased Quantity – Separately Priced Line Item (MAR 1989)
FAR	52.217-8	Option to Extend Services (NOV 1999)
FAR	52.219-4	Notice of Price Evaluation Preference for HUBZone Small Business Concerns (OCT 2022)
FAR	52.219-28	Post-Award Small Business Program Representation. (FEB 2024)
FAR	52.227-14	Rights in Data-General. (MAY 2014) - Alternate IV (DEC 2007)
FAR	52.227-14	Rights in Data-General. (MAY 2014) - Alternate V (DEC 2007)
FAR	52.227-16	Additional Data Requirements. (JUN 1987)
FAR	52.230-5	Cost Accounting Standards – Educational Institution (DEVIATION) (RFO AUG 2025)
FAR	52.230-6	Administration of Cost Accounting Standards (DEVIATION) (RFO AUG 2025)
FAR	52.237-3	Continuity of Services. (JAN 1991)
FAR	52.240-90	Security Prohibitions and Exclusions Representations and Certifications (DEVIATION) (RFO AUG 2025)
FAR	52.242-3	Penalties for Unallowable Costs (May 2014)
FAR	52.243-2	Changes—Cost Reimbursement (DEVIATION) (RFO JUN 2025), Alt. V (DEVIATION) (RFO JUN 2025)
FAR	52.246-23	Limitation of Liability (FEB 1997)
FAR	52.247-63	Preference for U.S.-Flag Air Carriers. (JUN 2003)
FAR	52.208-10	Government Supply Source (DEVIATION) (RFO AUG 2025)
HHSAR	352.208-70	Printing and Duplication. (DEC 2015)
HHSAR	352.211-3	Paperwork Reduction Act. (Deviation) (RFO NOV 2025)

Clause Database	Clause Number	Clause Title
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 (February 2, 2022)

ARTICLE I.4. ADDITIONAL FAR 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. ***FAR 52.209-9 Updates of Publicly Available Information Regarding Responsibility Matters. (Deviation)(RFO AUG 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. FAR **52.217-9 Option To Extend the Term of the Contract**. (MAR 2000)*

(a) The Government may extend the term of this contract by written notice to the Contractor within 15 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

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

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

(End of clause)

C. FAR Clause **52.240-93, Basic Safeguarding of Covered Contractor Information Systems** (RFO August 2025)

(a) Definitions. As used in this clause—

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

Federal contract information—

(1) Means information, not intended for public release, that is provided by or generated for the Government under a contract to develop or deliver a product or service to the Government; but

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

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

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

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

(b) *Safeguarding requirements*.

(1) Basic requirements. The Contractor shall safeguard its covered contractor information systems by implementing, at minimum, the following security controls:

(i) Limit information system access to authorized users, processes acting on behalf of authorized users, or devices (including other information systems).

(ii) Limit information system access to the types of transactions and functions that authorized users are permitted to execute.

(iii) Verify and control/limit connections to and use of external information systems.

(iv) Control information posted or processed on publicly accessible information systems.

(v) Identify information system users, processes acting on behalf of users, or devices.

(vi) Authenticate (or verify) the identities of those users, processes, or devices, as a prerequisite to allowing access to organizational information systems.

(vii) Sanitize or destroy information system media containing Federal Contract Information before disposal or release for reuse.

(viii) Limit physical access to organizational information systems, equipment, and the respective operating environments to authorized individuals.

(ix) Escort visitors and monitor visitor activity; maintain audit logs of physical access; and control and manage physical access devices.

(x) Monitor, control, and protect organizational communications (i.e., information transmitted or received by organizational information systems) at the external boundaries and key internal boundaries of the information systems.

(xi) Implement subnetworks for publicly accessible system components that are physically or logically separated from internal networks.

(xii) Identify, report, and correct information and information system flaws in a timely manner.

(xiii) Provide protection from malicious code at appropriate locations within organizational information systems.

(xiv) Update malicious code protection mechanisms when new releases are available.

(xv) Perform periodic scans of the information system and real-time scans of files from external sources as files are downloaded, opened, or executed.

(2) Other requirements. This clause does not relieve the Contractor of any other specific safeguarding requirements specified by Federal departments and agencies relating to covered contractor information systems generally or other Federal safeguarding requirements for controlled unclassified information (CUI) as established by Executive Order 13556.

(c) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (c), in subcontracts under this contract (including subcontracts for the acquisition of commercial products, other than commercially available off-the-shelf items, or commercial services), in which the subcontractor may have Federal contract information residing in or transiting through its information system.

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposals for Use with the NIH electronic Contract Proposal Submission (eCPS) Website	See Attachments at the end of this RFP.
Attachment 2:	Proposal Intent Response Sheet	See Attachments at the end of this RFP.
Attachment 3:	Statement of Work	See Attachments at the end of this RFP.
Attachment 4:	Additional Technical Proposal Instructions	See Attachments at the end of this RFP.
Attachment 5:	Additional Business Proposal Instructions	See Attachments at the end of this RFP.
Attachment 6:	Additional RFP-Specific Materials	See Attachments at the end of this RFP.
Attachment 7:	Section K - Representations, Certifications, and Other Statements of Offerors	https://oamp.od.nih.gov/nih-document- generation-system/dgs-workform- information/attachment-files-section-j

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 8:	Technical Proposal Cost Summary	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf
Attachment 9:	Summary of Related Activities	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf
Attachment 10:	Voluntary Product Accessibility Template (VPAT)	hhttps://www.section508.gov/sell/vpat

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 11:	Proposal Summary and Data Record, NIH-2043	https://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf
Attachment 12:	Small Business Subcontracting Plan	https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j
Attachment 13:	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 14:	Offeror's Points of Contact	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf
Attachment 15:	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 16:	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 17:	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 18:	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 19:	eRDS Quick Reference Guide	See Attachment Section at the end of this RFP.
Attachment 20:	Commitment to Protect Non-Public Information Contractor Agreement	https://oamp.od.nih.gov/nih-document-generation-system/dgs-workform-information/attachment-files-section-j

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

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

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

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

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

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

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

(End of clause).

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

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

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

1. GENERAL INFORMATION

a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION *FAR 52.215-1 (NOV 2021)*

(a) *Definitions* . As used in this provision-
Discussions are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

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

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

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

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

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

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

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

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

(i) The solicitation number;

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

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

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

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

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

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

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

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

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

(3) It is the only proposal received.

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

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) Contract award.

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

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

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

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

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

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

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

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

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

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

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

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

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

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

(iv) A summary of the rationale for award.

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

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

(End of provision).

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

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

b. NAICS CODE AND SIZE STANDARD

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

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

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

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

1. It is anticipated that one award will be made from this solicitation and that the award will be made on/about February 15, 2027.

2. It is anticipated that the award from this solicitation will be a multiple-year Cost-Reimbursement/Level of Effort type/term contract with a Base Period of one year and 6 one year options to extend the term for a total period of performance of 7 years (See Section L.2.c. Business Proposal Instructions).

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

d. LEVEL OF EFFORT

The Government's requirement for the work set forth in the Statement of Work of this solicitation is 13.70 Full Time Equivalents (FTEs) for the Base Period (Year 1). If Options to extend the term of the contract are exercised, the Contractor shall provide 13.70 FTEs per year for Options 1 through 6 (Years 2-7). Please note, while the delivery of the total number of FTEs is a requirement for satisfactory performance of the contract, the labor mix provided below is the Government's estimate and should not be considered restrictive. Offerors should propose the labor mix they consider most appropriate for satisfactory performance of the work.

Please note that the number of FTEs includes the effort of subcontractors, but does not include the effort of consultants. It is estimated that the FTEs are constituted as specified below and will be expended approximately as follows:

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Principal Investigator	0.20	0.20	0.20	0.20	0.20	0.20	0.20
Project Director/ Manager	1.00	1.00	1.00	1.00	1.00	1.00	1.00
Professional Support (IT)	1.50	1.50	1.50	1.50	1.50	1.50	1.50
QA/QC Coordinators	9.00	9.00	9.00	9.00	9.00	9.00	9.00
Administrative Support	2.00	2.00	2.00	2.00	2.00	2.00	2.00
Total	13.70	13.70	13.70	13.70	13.70	13.70	13.70

OPTIONS 1-6: EXTEND THE TERM OF THE CONTRACT: The Government may exercise Options to extend the term of the contract beyond the base period (Year 1), annually for a total contract period of up to 7 years. Assume that the scope and types of activities as outlined in the Statement of Work for the base requirement would be continued for each succeeding annual contract period. The requirement will be the delivery of 13.70 full time equivalents (FTEs) per year for the Base Period (Year 1) and 13.70 FTEs per year for Options 1-6 (Years 2-7).

OPTIONS FOR INCREASED LEVEL OF EFFORT – INCREASED LEVEL OF EFFORT FOR INCREASED SERVICES (OPTIONS 7-27):

During the course of the contract, it may be necessary to incorporate additional Labs to support new NIAID clinical trials. Such an increase would require an increase in the Contractor's activities to be activated, at the discretion of the Government, as an Option. Each Option of this type will implement work commensurate with the addition of 15 Labs and the Option will be maintained for the life of the contract. If the Government elects to exercise this Option, the Contractor shall provide an additional 1.70 Full Time Equivalent (FTE). One Option for adding new Labs may be exercised once per year during any year of the contract, beginning with year 2 of the contract, to a total of 21 options during the life of the contract, as follows: Year 2 (Option 7), Year 3 (Options 8 & 9), Year 4 (Options 10, 11, 12), Year 5 (Options 13, 14, 15, 16), Year 6 (Options 17, 18, 19, 20, 21), and Year 7 (Options 22, 23, 24, 25, 26, 27). The period of performance of an Option for Increased Level of Effort will not exceed the term of the Option year in which the Option is exercised. If an Option for additional Labs is exercised, it is estimated that 1.7 FTE will be needed initially. Since it is the Government's intent to provide continued support for Labs once they are initiated, Options will be exercised for additional support in the outyears. The Options for continued support will be for an additional 1.7 FTE.

The labor mix provided below is to be used as an example only for the level of effort for Options 7 through 27. The following tables provide a breakdown of Options per year and the anticipated level of effort for each:

Labor Category	Yr 2	Yr 3	Yr 4	Yr 5	Yr 6	Yr 7
QA/QC coordinator	1.5	1.5	1.5	1.5	1.5	1.5
Administrator	0.2	0.2	0.2	0.2	0.2	0.2
Total	1.7	1.7	1.7	1.7	1.7	1.7

While the total level of effort provided above is a requirement, the labor mix is the Government's estimate and should not be considered restrictive for proposal purposes. Offerors should propose the labor mix they consider most appropriate for satisfactory performance of the work.

The following is a helpful table, to visually convey how Options 7-27 are delineated per year:

Year 1	**Option 1 Year 2**	**Option 2 Year 3**	**Option 3 Year 4**	**Option 4 Year 5**	**Option 5 Year 6**	**Option 6 Year 7**
02/15/27-02/14/28	02/15/28-02/14/29	02/15/29-02/14/30	02/15/30-02/14/31	02/15/31-02/14/32	02/15/32-02/14/33	02/15/33-02/14/34
	Option 7	**Option 8**	**Option 10**	**Option 13**	**Option 17**	**Option 22**
	1.7 FTEs	1.7 FTEs	1.7 FTEs	1.7 FTEs	1.7 FTEs	1.7 FTEs
		Option 9	**Option 11**	**Option 14**	**Option 18**	**Option 23**
		1.7 FTEs	1.7 FTEs	1.7 FTEs	1.7 FTEs	1.7 FTEs
			Option 12	**Option 15**	**Option 19**	**Option 24**

			1.7 FTEs	1.7 FTEs	1.7 FTEs	1.7 FTEs
				Option 16	**Option 20**	**Option 25**
				1.7 FTEs	1.7 FTEs	1.7 FTEs
					Option 21	**Option 26**
					1.7 FTEs	1.7 FTEs
						Option 27
						1.7 FTEs

e. COMMITMENT OF PUBLIC FUNDS

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

f. PROMOTING EFFICIENT SPENDING

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

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

Any contract awarded as a result of this solicitation will:

- Specifically prohibit the use of contract funds for the provision of food for meals, light refreshments and beverages for any NIH funded meeting or conference; and
- Limit the procurement of meeting space, promotional items, printing and publications.

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. REFERENCE MATERIALS

Please see Attachment 6, Additional RFP-Specific Materials. Failure of offerors to examine the reference materials prior to proposal preparation and submission will be at the offeror's risk.

j. PREPARATION COSTS

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

k. SERVICE OF PROTEST FAR 52.233-2 (SEP 2006)

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

Patrick Finn
Contracting Officer
Office of Acquisitions, DEA
National Institute of Allergy and Infectious Diseases
National Institutes of Health, DHHS
5601 Fishers Lane, MSC 9821
Bethesda, MD 20892-9821

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

(End of provision).

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

1. **Contract Type and General Clauses**

   It is contemplated that a cost-reimbursement level of effort type contract will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the selected offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

2. **Authorized Official and Submission of Proposal**

   The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper, printed/copied double-sided, on at least 30 percent post-consumer fiber paper, as required by FAR 4.302(b), and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the SOLICITATION should be placed in the following order:

   I. COVER PAGE

      Include RFP title, number, name of organization, UEI No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

   II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

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

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

5. **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the terms and conditions of the solicitation, as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the solicitation to allow all offerors an opportunity to submit revised proposals based on the revised requirements.

6. **Evaluation of Proposals**

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

7. **Potential Award Without Discussions**

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

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

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

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

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

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

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

9. **Privacy Act – Treatment of Proposal Information**

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made

of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

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

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

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

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

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

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

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

10. **Selection of Offerors**

a. The acceptability of the [scientific and] technical portion of each [research] contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation factors of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b. The business portion of each contract proposal found to be technical acceptable will be subjected to a cost and price analysis, management analysis, etc.

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

d. If the Government intends to conduct discussions prior to awarding a contract -

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

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

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

       While it is 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.

11. **Institutional Responsibility Regarding Investigator Conflicts of Interest**

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any Investigator financial conflicts of interest. The Institution shall comply with all requirements of 45 CFR Part 94 at: https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94

12. **ROTC Access and Federal Military Recruiting on Campus**

Section 514 of the FY 1997 Appropriations Act prohibits NIH from providing contract funds to educational institutions that the Secretary of Defense determines have a policy or practice (regardless of when implemented) that either prohibits, or in effect prevents (1) the maintaining, establishing, or operation of a unit of the Senior Reserve Officer Training Corps at the covered education entity; or (2) a student at the covered educational entity from enrolling in a unit of the Senior Reserve Officer Training Corps at another institution of higher education.

Further, contract funds may not be provided to educational institutions that have a policy or practice that prohibits or prevents (1) entry to campuses, or access to students (who are 17 years of age or older) on campuses, for purposes of Federal military recruiting; or (2) access by military recruiters for purposes of Federal military recruiting to information pertaining to students (who are 17 years of age or older) enrolled at the covered educational entity.

13. **Certification Regarding Tax Matters, FAR 52.20912 (OCT 2020)**

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

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

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

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

(3) Has not [ ] , more than 90 days prior to certification, been notified of any unpaid Federal tax assessment for which the liability remains unsatisfied, unless the assessment is the subject of an installment agreement or offer in compromise that has been approved by the Internal Revenue Service and is not in default, or the assessment is the subject of a non- frivolous administrative or judicial proceeding.

(End of provision).

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

    a. *Definition.* As used in this provision-
    Internal confidentiality agreement or statement, subcontract, and subcontractor, are defined in the clause at 52.203-19 , Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements.

    b. In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use funds appropriated (or otherwise made available) for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

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

d. Representation. By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(End of provision).

15. **Past Performance Information**

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

A list of the last 5 contracts completed during the past three years and at least three contracts awarded currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as any subcontract exceeding $750,000 in total cost.

Include the following information for each contract or subcontract listed:

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

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

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

16. **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).

17. **Information and Communication Technology Accessibility,** HHSAR 352.239-79 (FEB 2024) (Deviation)

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

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

(c) In the event of a modification(s) to this contract or order, which adds new ICT supplies or services or revises the type of, or specifications for, supplies, products, platforms,

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

(d) If this is an Indefinite-Delivery type contract, a Blanket Purchase Agreement or a Basic Ordering Agreement, the task/delivery order requests that include ICT supplies, products, platforms, information, documentation, or services support will define the specifications and accessibility standards for the order. In those cases, the Contractor shall be required to provide a completed HHS Section 508 Accessibility Conformance Checklist (see *https://www.hhs.gov/web/section-508/accessibility-checklists/index.html*) or an ACR (based on the VPAT see https://www.itic.org/policy/accessibility/vpat), and any other additional information necessary to assist the Government in determining that the ICT supplies, products, platforms, information, documentation, or services support conform to Section 508 accessibility standards. If it is determined by the Government that ICT supplies and services provided by the Contractor do not conform to the described accessibility standards in the provided documentation, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

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

(End of clause).

18. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1** (FEB 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may

identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. System for Award Management, FAR Provision 52.204-7 (DEVIATION) (RFO Aug 2025).

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

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

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

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

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

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

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

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

1. Technical Discussions

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

a. **Statement of Work**

1. Objectives

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

2. Approach

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

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

3. Methods

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

4. Schedule

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

b. Personnel

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

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

1. Single Principal Investigator/Project Director

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

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. 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

   a. 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.

   b. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results.

   c. Explain how relevant biological variables, including sex, [if deemed necessary by the IC, additional variables may be included here] are factored into research designs and analyses for studies in vertebrate animals and humans. For example, strong justification from the scientific literature, preliminary data, or other relevant considerations, must be provided for proposals proposing to study only one sex. If your proposal involves human subjects, the sections on 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.

   d. 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.

5. Enhancing 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.

6. 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:

36 CFR 1194.21(a)-(l)

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.

a. **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.

b. **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.).

c. **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 $900,000, 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.

d. **Raw Materials**

Consists of material in a form or state that requires further processing. Provide priced quantities of items required for the proposal.

e. **Purchased Parts**

Includes material items not covered above. Provide priced quantities of items required for the proposal.

f. **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.

g. **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.

h. **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.

i. **Travel**

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

j. **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, FAR Clause 52.215-20 (Nov 2021).

(a) Exceptions from certified cost or pricing data.

(1) In lieu of submitting certified cost or pricing data, offerors may submit a written request for exception by submitting the information described in the following paragraphs. The Contracting Officer may require additional supporting information, but only to the extent necessary to determine whether an exception should be granted, and whether the price is fair and reasonable.

(i) *Identification* of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) *Commercial product and commercial service exception.* For a commercial product and commercial service exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include:

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

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

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

(1) The offeror shall prepare and submit certified cost or pricing data, data other than certified cost or pricing data, and supporting attachments in accordance with the instructions contained in Table 15-2 of FAR 15.408, which is incorporated by reference with the same force and effect as though it were inserted here in full text. The instructions in Table 15-2 are incorporated as a mandatory format to be used in this contract, unless the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision).

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 $900,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation. In accordance with

FAR 19.704 and FAR 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 FAR Clause 52.215-1, Instructions to Offeror-Competition Acquisition. Disposition of late submittals of a subcontracting plan by an offeror via the SBCX system is at the discretion of the Contracting Officer.

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

    a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.
    b. The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
    c. The offeror understands that:

i. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
ii. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, , 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, , and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
vi. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:

i. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, , 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, , 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, 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, 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, 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, , and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan.

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

23% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 5% 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--

2. 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;
3. 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
4. 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).

8. 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 .

9. Total Compensation Plan

a. Instructions

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as a part of their Business Proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. Evaluation

1. **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the

predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. **Cost (Professional Compensation)**

   Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

3. **Other (Labor Relations)**

   An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

4. **Federal Acquisition Regulation Clauses incorporated by Reference**

   FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees.

10. Other Administrative Data

a. **Property**

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

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

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

2. Government Property

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

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

b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;

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

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

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

3. Government-Furnished Property

No Government Furnished Property is offered for this acquisition

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "Appendix Q, HHS Contracting Guide for Contract of Government Property," which can be found at:

https://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, FAR Clause 52.232-38** (Jul 2013).

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

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

(End of provision).

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:
    c. Proper segregation of direct costs from indirect costs.
    d. Identification and accumulation of direct costs by contract.
    e. A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
    f. Accumulation of costs under general ledger control.
    g. A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
    h. A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
    i. Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
    j. 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.
    k. 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.
    l. 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.

11. Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this RFP, Performance History and Pertinent Contracts."

a. **General Experience**

General experience is defined as general background, experience and qualifications of the offeror. A discussion of proposed facilities which can be devoted to the project may be appropriate.

b. **Organizational Experience Related to the RFP**

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

c. **Performance History**

Performance history is defined as meeting contract objectives within **delivery** and **cost schedules** on efforts, either past or on-going, which is comparable or related to the effort required by this RFP.

d. **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. **Pertinent Grants**

List grants supported by the Government that involved similar or related work to that called for in this RFP. Include the grant number, involved agency, names of the grant specialist and the Science Administrator, identification of the work, and when performed.

You are cautioned that omission or an inadequate or inaccurate response to this very important RFP requirement could have a negative effect on the overall selection process. Experience and past performance are factors which are relevant to the ability of the offerors to perform and are considered in the source selection process.

12. 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.

13. Proposer’s Annual Financial Report

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

14. Travel Costs/Travel Policy

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

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are: technical, cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance and cost/price are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are more important than cost. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractors in relation to the needs of the project as set forth in the SOLICITATION. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the SOLICITATION. Offerors must submit information sufficient to evaluate their proposals based on the detailed factors listed below.

2. COST/PRICE EVALUATION

Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition, but may also be determined through cost and price analysis techniques as described in FAR 15.404.

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

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

3. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with 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).

4. TECHNICAL EVALUATION FACTORS

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

TECHNICAL EVALUATION CRITERIA	WEIGHT
CRITERION 1: TECHNICAL PLAN/APPROACH	**45**
Appropriateness, feasibility, and adequacy of the proposed technical plan/approach for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.	
CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL	**25**
Appropriateness and adequacy of the education, training, experience, expertise, and proposed levels of effort of the Principal Investigator and scientific and technical staff including subcontractors/consultants for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.	
CRITERION 3: PROJECT MANAGEMENT	**20**
Appropriateness and adequacy of the Project Management Plan in terms of staffing, organizational structure and lines of authority, management of subcontracts/consultants, tracking of project activities, monitoring progress and timelines, and communication with stakeholders.	
CRITERION 4: FACILITIES, EQUIPMENT AND OTHER RESOURCES	**10**
Appropriateness and adequacy of facilities, equipment, space and other resources including those of subcontractors/consultants for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.	

EVALUATION OF OPTIONS	10
Soundness, appropriateness, adequacy and feasibility of proposed plan for identifying personnel to be assigned with appropriate education, training, experience, qualifications, and effort, including any proposed subcontractors and/or consultants, and their roles and responsibilities for accomplishing the work associated with all Options. ***Please note that All Offerors are required to propose on all Options 1-27.***	
TOTAL POSSIBLE WEIGHT (with Options)	**110**

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

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

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

6. PAST PERFORMANCE FACTOR

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.

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

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

The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

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

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

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

I. PROPOSAL SUBMISSION

A. eCPS

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

B. Creating and Naming Files:

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

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

   The Business Proposal should be created in a PDF format that enables word searches to the maximum extent practicable. Forms and/or documents requiring signature(s) may be scanned, but must be merged into the Business Proposal PDF file. Additionally, the "Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet" (http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/spshexcl_dec2012.xlsx) must be included in the Business Proposal.

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

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

   Examples:
   Technical Proposal: *XYZ Company_NIHAI2012001_Technical.pdf*
   Business Proposal: *XYZ Company_NIHAI2012001_Business.pdf*
   Excel Workbook: *XYZ Company_NIHAI2012001_Business.xlsx*

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. Font size must be 10 to 12 points.
4. Spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
5. Margins must be at least one-inch on all sides.
6. **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 175 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
3. Each Curriculum Vitae (CV) shall not exceed 3 pages.
4. **Pages exceeding limitations will be removed from the proposal and will not be considered.**

PROPOSAL INTENT RESPONSE FORM

RFP No: 75N93025R00011

RFP Title: Patient Safety Monitoring in International Laboratories (pSMILE)

Please review the Request for Proposal (RFP). Furnish the information requested below and return this page to the Contracting Officer/Contract Specialist identified on **Section A-Solicitation/Contract Form** by the following date: February 26, 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: STATEMENT OF WORK
Patient Safety Monitoring in International Laboratories (pSMILE)
RFP #75N93025R00011

1) BACKGROUND and INTRODUCTION

The Division of AIDS (DAIDS) in the National Institute of Allergy and Infectious Diseases (NIAID) supports a global research portfolio to advance biological knowledge of human immunodeficiency virus (HIV)/acquired immunodeficiency syndrome (AIDS), its related co-infections, and its co-morbidities. With the ultimate goal of creating an "AIDS-Free Generation," DAIDS develops and supports the infrastructure and biomedical research needed to: 1) reduce HIV incidence through the development of an effective vaccine and biomedical prevention strategies that are safe and desirable; 2) develop novel approaches for the treatment and cure of HIV infection; 3) develop interventions to treat and/or prevent HIV co-infections and co-morbidities of greatest significance; and 4) foster partnerships with scientific and community stakeholders to develop and implement effective interventions. NIAID supports four HIV/AIDS clinical trial networks as part of its HIV clinical research enterprise. High quality test results support the safety of study participants and the reliability of study results. DAIDS employs a variety of Laboratory Quality Assurance oversight contractual resources to monitor and enhance the ability of laboratories to accurately and reliably perform trial-specified clinical laboratory testing (https://www.niaid.nih.gov/research/daids-clinical-research-policies-standard-procedures).

The purpose of this contract for Patient Safety Monitoring in International Laboratories (SMILE) is to enhance the ability of mostly non-U.S. laboratories participating in NIAID-funded and collaborative clinical trials to perform study-specified tests in accordance with good clinical laboratory practice standards and produce reliable test results. SMILE activities also support 1) comparability between multi-site trial data obtained in licensed U.S. laboratories and data obtained in non-U.S. ones, 2) sponsor accountability to regulatory organizations (e.g., FDA, EMA) for investigational new drug (IND)/registrational studies, and 3) harmonized approach in laboratory operations and sponsor oversight.

SMILE will continue to serve current and future NIAID-sponsored clinical trial networks and collaborating study groups (User Groups), as well as individual grantees conducting clinical research. The current contract supports approximately 150 laboratories in 18 countries.

The current contract has been held by Johns Hopkins University, Baltimore, Maryland since its inception in 2004. The current contract is held under contract number 75N93020C00001. The period of performance of the current contract is November 15, 2019 through November 14, 2026.

2) SCOPE

The Contractor shall work with mostly non-U.S. laboratories (Labs) to provide a comprehensive and uniform approach to support and evaluate initial and on-going capability and readiness to carry out NIAID-funded and collaborative clinical trial protocols (Protocols) by (1) supporting and monitoring compliance with good clinical laboratory practice (GCLP) standards, (2) supporting and monitoring the quality and reliability of Protocol-specified laboratory test results, (3) providing Labs with various means of assistance, guidance and training to improve the quality of laboratory

operations, and (4) hosting and maintaining the existing electronic data management system. Options to increase level of effort, to support unanticipated increases in demand related to oversight of additional Labs, are also within the scope of the contract.

3) TECHNICAL REQUIREMENTS:

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Work below. Specifically, the Contractor shall:

A. SUPPORT COMPLIANCE WITH GOOD CLINICAL LABORATORY PRACTICES

Labs participating in NIAID-funded and collaborative clinical trials are audited periodically by a separate NIAID contract and/or by other organizations (e.g., the College of American Pathologists – CAP, the International Organization for Standardization – ISO) to document the ability of Labs to conduct activities in accordance with GCLP standards. Audits utilize checklists that capture observations regarding organization and personnel, safety of laboratory personnel, quality management, instrument performance specifications, test and control articles, verification of reagents, equipment maintenance and facilities, laboratory information systems, and specimen management and transport. Using the reports compiled and received from these audits, the Contractor shall perform the following tasks:

1. Review audit reports and identify findings that indicate lack of compliance with GCLP.

2. Within ten (10) business days of receipt of an audit report, create an Action Plan that captures audit findings and provides recommendations for corrective and preventive action (CAPA). Distribute each Action Plan to NIAID staff designated by the Contracting Officer's Representative (COR) and to User Groups for review. NIAID staff will distribute Action Plans to Labs. As needed, and upon COR direction, SMILE will distribute Action Plans to Labs.

3. Review documents received from Labs in support of addressing audit findings.

4. Monitor and track each individual Lab's progress on corrective actions.

5. Work closely with each Lab to resolve audit findings (refer to Statement of Work, paragraph 3.C., Assist, Guide and Train Labs to Improve Laboratory Operations, for further information).

In addition, a component of GCLP is the expectation that Labs perform various levels of validation or verification, based on the regulatory approval status of a method, of all protocol-specified test methods. Such validation/verification takes place upon introduction of a method in the Lab, major equipment service, and moving equipment to another location. In support of these efforts, the Contractor shall:

6. Provide technical support and guidance to Labs for proper conduct of method validations or verifications, as needed, to ensure compliance with regulatory requirements.

7. Review validation/verification documents received from Labs and determine their

adequacy.

8. Indicate to Labs and User Groups the outcome of the review.

9. As needed, provide further guidance and assistance to Labs.

10. As needed, and with COR approval, provide Labs with materials, e.g., linearity panels for hematology, chemistry, or Tuberculosis (TB) methods, to assist Labs with conducting adequate validation/verification.

B. MONITOR ABILITY OF LABS TO PERFORM PROTOCOL-SPECIFIED TESTS

When Labs are chosen by User Groups and/or NIAID to participate in a clinical trial, it is critical to evaluate, both initially and on an on-going basis, the ability of Labs to perform Protocol-specified tests correctly and reliably. Proficiency is determined through evaluation of results obtained with panels of coded (unknown to Labs) samples provided by External Quality Assurance (EQA) and Proficiency Testing (PT) programs. PT panels are applied to Protocol-specified tests used for diagnosing infections, determining the safety and efficacy of an intervention, and for applying criteria for inclusion/exclusion of subjects in trials. Examples of the range of tests that may be used include tests to diagnose viral, fungal, bacterial, and parasitic infections, hematology and blood chemistry assays, liver function tests, and drug resistance assays. The Contractor shall perform the following tasks:

1. Identify providers of PT panels and assess the suitability of applying their panels for the monitoring of the ability of Labs to reliably perform Protocol-specified testing. Such assessment shall include the appropriateness of the materials used to compose the PT panel, frequency of panel shipments to Labs, performance grading scheme, and ease of obtaining Lab proficiency data from PT panel providers.

2. Receive and review laboratory testing plans (also called Protocol Analyte Lists – PALs) provided by User Groups for a clinical site that will participate in a certain study protocol. The plans may include elements such as the list of protocol-mandated testing, the Labs that are proposed to perform the various tests, and test methodologies.

3. Facilitate enrollment of Labs with PT providers (e.g., CAP). As directed by the COR, pay for PT panels and their shipments to Labs.

4. When PT panels for certain tests are not available, propose alternative approaches to evaluate Labs' ability to perform testing reliably.

5. Grade each Lab's performance. Specifically, the Contractor shall:

    a. On a monthly basis, receive and track performance grading information from PT providers for all monitored Labs. For each Lab, summarize performance results in a report that indicates the most current and past three (3) years of performance results for each graded test, need for an investigation, whether bias was noted, and the annual schedule for shipping PT panels.

    b. Within five (5) business days of obtaining performance grading information, send each Lab its evaluation (developed by the PT provider), and the

evaluation summary developed by the Contractor. Copy relevant User Group(s) and NIAID staff designated by the COR.

c. When performance failure is identified, send the Lab an Investigation Report Form to initiate an investigation of the root causes of the failure and to indicate steps instituted to prevent such failure from re-occurring.

d. Provide guidance, assistance and training to Labs in areas needing improvement (refer to the Statement of Work, paragraph 3.C., Assist, Guide and Train Labs to Improve Laboratory Operations, for further information).

e. On a monthly basis, create and send to the User Groups and NIAID staff designated by the COR a summary report of performance failures, including the name of the Lab, the graded test, performance grading for the last three (3) PT rounds, and whether an Investigation Report was submitted by the Lab.

C. ASSIST, GUIDE AND TRAIN LABS TO IMPROVE LABORATORY OPERATIONS

Assessing the ability of Labs to conduct tests reliably and in accordance with GCLP will reveal the need for improvements in laboratory operations and performance and associated needs for assistance, guidance, and training. Using various means of delivery, such as phone and email communications, webinar presentations, instructional videos and presentations at User Group meetings, the Contractor shall perform the following tasks:

1. Provide guidance and training on procedures and Standard Operating Procedures (SOPs) related to:

    a. Laboratory quality management
    b. Instruments and test validation/performance verification, including reference ranges
    c. Specimen management, including chain-of-custody and compliance with shipping regulations
    d. Laboratory data management
    e. Equipment and equipment maintenance, including calibration
    f. Personnel safety measures
    g. Specific tests, including quality control and quality assurance
    h. Establishment of the range of normal test values for the regional and/or patient population
    i. Changing location of a laboratory

2. Provide Labs with information on choices and availability of FDA-approved tests and reagents for implementation in registrational studies.

3. Subscribe to on-line laboratory training and competency assessment resources, such as the Medical Training Solutions (MTS) http://www.medtraining.org/corpsite/ which allow access of multiple users.

4. Recommend to the COR the planning and conduct of visits to Labs to provide training and guidance based on site-specific needs/performance. Upon COR approval to conduct a Lab visit, submit to the COR a written plan providing relevant information that includes purpose/goals of the visit, visit duration,

existing materials to be provided and/or new materials requiring preparation, the names of visiting contract staff, and budget estimate.

5. Within ten (10) business days of visit completion, prepare a report delineating observations, activities conducted, resolution of needs/problems and any recommended future plans for additional site-specific guidance/training. Distribute the report to the visited Lab, the COR and User Group as appropriate.

6. Obtain COR pre-approval of training materials at least three (3) business days prior to the date of presentation.

D. MAINTAIN AND HOST EXISTING COMPUTERIZED SOFTWARE SYSTEMS

The Contractor shall maintain and host the existing computerized data management system and a document library to track and make available documents in support of activities performed under the contract. The Contractor shall utilize the existing pSMILE computerized data management system and further enhance the system as necessary, pending the COR and CO approval. The Contractor shall perform the following tasks:

1. Maintain software to store, organize, track, retrieve documents and report on Lab-specific information and activities. The application used shall be web-based and easy to navigate by various characteristics/parameters (e.g., by country, city, name of lab and document type). The web-based application and other applicable internet and intranet information services provided at the web sites and web pages shall comply with Section 508 and meet the Section 508 accessibility standards.

2. Post Lab-specific documents, including for example:

    a. Laboratory audit/assessment visit reports and Action Plans
    b. Proficiency testing performance records
    c. Study-specific site laboratory plans (e.g., Protocol Analyte Lists – PALs)

3. Maintain the existing publicly available, searchable, web-based document library that includes Contractor presentations, and guidance and training materials/resources organized by topics/categories. The web sites and web pages shall comply with Section 508 and meet the Section 508 accessibility standards.

4. Post summary information such as list(s) of supported Labs that indicate name of lab, overseeing Contractor staff, Network affiliation and DAIDS oversight staff.

5. Post documents such as forms, templates, and shells.

6. Provide tracking information for stored documents that includes name/type of document, description, author/origin, date received, and date stored by the Contractor.

7. Provide for report capabilities to allow the compilation of Lab information that include Lab name, location, analyte tested, and participation in PT programs.

8. Provide for software-specific security measures for Lab-specific GCLP and PT data, accessible only to Lab staff and to individuals identified by the COR.

9. Maintain the computerized system security documentation as required by OMB Circular A-130, Appendix III and the Federal Information Security Management Act (FISMA). This shall include a comprehensive assessment of the management, operational, and technical security controls in the system to determine the extent to which the controls are implemented correctly, operating as intended, and producing the desired outcome with respect to meeting a specified set of security requirements for the system. These actions are referred to as System Assessment and Authorization (SA&A). The NIAID Information System Security Officer (ISSO) reviews the Contractor's System Security Plan (SSP), Security Assessment Report, and their Corrective Action Plan to support the Contractor's decision to authorize operation of an information system and to explicitly accept the risk to NIAID data based on the implementation of an agreed-upon set of security controls. The Contractor shall use the National Institute of Standards and Technology (NIST) Special Publication (SP) NIST SP-800-171 - Protecting Controlled Unclassified Information in Nonfederal Information Systems and Organizations; https://csrc.nist.gov/publications/detail/sp/800-171/rev-2/final.

   Upon COR approval the Contractor shall place in operation and maintain the system. COR and CO approval shall be required for updates to the system that include hardware and/or software.

   Although the Contractor may choose to use a different web-based database from the established database, this contract will not cover costs for developing a new database.

E. PROGRAM MANAGEMENT and COORDINATION

1. Program Coordination. The Contractor shall:

   a. Provide for the overall management, integration, and coordination of all contract activities.

   b. Ensure that all personnel, equipment, and facilities are compliant with applicable regulatory requirements in effect throughout the contract period of performance.

2. Meetings and Teleconferences. The Contractor shall be responsible for the following:

   a. Contract Initiation Meeting

   Within 30 business days after the effective date of the contract, participate in a one-day Contract Initiation Meeting with the COR, the Contracting Officer (CO) and other NIAID personnel designated by the COR, to be held virtually or at the Contractor's site. The purpose of the Contract Initiation Meeting shall be to orient the Contractor to NIAID contract procedures.

   b. Annual Site Visits with the Contractor

   Arrange virtual or in-person Annual Site Visits at the Contractor's site for NIAID contract and program staff, designated by the COR, to review and discuss the following: project progress and costs; challenges, obstacles, and approaches to

overcoming them; recommendations for modification of project timelines, objectives, and research approaches and methodologies based on outcomes to date; and future plans. These site visits shall be attended by the Principal Investigator, the Project Manager, other Contractor staff, and, as needed, the Contractor's business representative.

3. Teleconferences. The Contractor shall:

   a. Plan and conduct periodic teleconferences with key Contractor staff, the COR, and other COR-designated subject matter experts, or User Groups as needed.

   b. As needed, plan and conduct teleconferences with key Contractor personnel and specific Lab investigators (identified by meeting content and agenda topic) to review Lab-specific problems, resolutions, and progress towards achieving reliable performance.

F. AUDITS

NIAID may authorize, at any time during the contract period of performance, independent audits of the Contractor's performance with respect to the functions specified in the Statement of Work, including review of Contractor processes, procedures and operations at the Contractor's site. NIAID shall notify the Contractor of plans for independent audits at least five (5) business days in advance of the scheduled audit. For remote audits or those conducted at Contractor facilities, the Contractor shall ensure that appropriate staff and all necessary information and documentation are available. For-cause audits may be performed at any time and without advance notice to the Contractor in instances of suspected non-performance and/or non-compliance with Federal and/or country-specific regulatory requirements.

G. EXECUTE INITIAL AND FINAL TRANSITION

1. Initial Transition

   In the event of transition between contractors is required, the Contractor shall work with the COR and incumbent contractor to ensure an orderly, secure, and efficient transition of contract activities and contract-related data, documents, and other materials from the incumbent contractor or from the Government, as directed by the Contracting Officer, as follows:

   a. Within three (3) business days of the effective date of the contract, the COR will provide the Contractor with a copy of the incumbent contractor's Final Transition Plan specifying transition requirements and processes. The Initial Transition shall require the transfer of contract-related materials and data that include the following:

      1) communication and correspondence files, all computerized data files, and software systems (with source codes, documentation and specifications)
      2) labeled and inventoried paper files, quality assurance (QA) data, reports, and laboratory procedures/SOPs

   b. Within ten (10) business days of the effective date of the contract, the

Contractor shall submit to the COR and CO for approval, an Initial Transition Plan and timeline for the transition of activities and contract-related materials from the current contractor, and the activities required for having the Contractor's facility ready for providing support to Labs. The Plan shall include coordination with the Labs to ensure an orderly transition.

c. Upon COR and CO approval of the Initial Transition Plan, implement and complete the transition within 30 business days following the effective date of the contract.

2. Final Transition

In the event of transition between contractors is required, the Contractor shall provide a Final Transition Plan for and ensure the orderly, secure and efficient transition of contract-related materials, data, and activities to the successor contractor or the Government, as directed by the Contracting Officer. This Plan shall be subject to written approval by the COR and CO.

a. The Draft Final Transition Plan shall be submitted to the COR and CO six (6) months prior to the expiration date of the contract, for review and comment. Upon receipt of comments, the Contractor shall revise the Draft Final Transition Plan as necessary.

b. The Final Transition Plan shall be submitted for written approval to the COR and CO two (2) months prior to the expiration date of the contract. The Contractor shall implement and complete the Transition Plan by the expiration date of the contract. The Contractor shall maintain full operational capacity during the final transition period.

c. The transition process shall require the transfer of contract-related material to include:

1) Communication and correspondence files, all computerized data files and software systems (with user guide, Source code, architecture diagram, documentation and specifications)

2) Labeled and inventoried paper files, QA data, reports, and laboratory procedures/SOPs

H. OPTIONS

In addition to the services/quantities outlined above, to be provided for the base requirement, Options(s) for additional services/quantities under the contract may be exercised at the discretion of the Government and are defined as follows:

1. **Options 1 through 6 to Extend the Term of the Contract:** The Government may exercise options to extend the period of the contract beyond the base period (Year 1), annually, for a total contract period of up to 7 years. The scope and types of activities as outlined for Year 1 of the contract would be continued for each succeeding annual contract period up to 7 total years. The percentage of effort includes the effort of subcontracts but excludes the effort of consultants.

2. **Options 7 - 27 to Increased Level of Effort for Additional Labs**: The Government may exercise Options for an increased level of effort that may result from unanticipated increases in demand for the activities supported by the base requirements of this contract. During the period of the contract, it may be necessary to incorporate additional Labs to support NIAID clinical trials. Such an increase would require an increase in the Contractor's effort activities to be activated, at the discretion of the Government, as an Option. Each Option of this type will implement work commensurate with the addition of 15 Labs. If the Government elects to exercise this Option, the Contractor shall provide an additional 1.7 Full Time Equivalents (FTEs). One Option for adding new Labs may be exercised once per year during any year of the contract, beginning with year 2 of the contract, to a total of 21 options during the life of the contract, as follows: Year 2 (Option 7), Year 3 (Options 8 & 9), Year 4 (Options 10, 11, 12), Year 5 (Options 13, 14, 15, 16), Year 6 (Options 17, 18, 19, 20, 21), and Year 7 (Options 22, 23, 24, 25, 26, 27). The period of performance of an Option for Increased Level of Effort will not exceed the term of the Option year in which the Option is exercised.

ATTACHMENT 4 – ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS, FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS

PROJECT TITLE: "PATIENT SAFETY MONITORING IN INTERNATIONAL LABORATORIES (pSMILE)"
RFP No. 75N93025R00011

It is strongly recommended that offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

These additional Technical Proposal instructions reflect the requirements of the solicitation and provide specific instructions and formatting for the Technical Proposal. While Section L of the solicitation provides a generic set of Technical Proposal instructions applicable to all NIH R&D solicitations, these instructions are tailored to the specific requirements of the RFP. The information requested in these instructions should be used to format and prepare the Technical Proposal and should be used as a Table of Contents for your Technical Proposal. Offerors should follow the instructions in Section L of the solicitation, and include the information requested here.

Offerors are advised to give careful consideration to the Statement of Work, all reference materials, and attachments, the Technical Evaluation Criteria in Section M, and the solicitation as a whole in the development of their Technical Proposals.

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

Offerors must refer to the solicitation Attachment entitled "Packaging and Delivery of the Proposal," which details strict guidelines, including page limitations (175 pages), 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 RFP title and number, name of organization, UEI number, and identify if the proposal is an original or a copy. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall also include the legend regarding Restriction on Disclosure and Use of Data prescribed by FAR 52.215-1(e)]
2) TABLE OF CONTENTS

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested 3-page maximum)

Provide a brief overview of the Technical Proposal, including:

1) A brief description of the activities proposed by the offeror and all proposed subcontractors, including identification of all proposed subcontractors and a list of key personnel for the offeror and the proposed subcontractors with degrees, titles and role in the project.
2) By area of expertise, provide the total number of staff, the number available to be assigned to the contract for the offeror and all proposed subcontractors, and total number of additional staff to be hired and trained. Describe the administrative structure of the proposed project.
3) A brief description of the facilities and equipment to be made available by the offeror and all proposed subcontractors.

SECTION 3: TECHNICAL PLAN/APPROACH

1) LABORATORY COMPLIANCE WITH GOOD CLINICAL LABORATORY PRACTICES (GCLP)
Discuss your experience, approach, and plans for evaluating and tracking Labs' compliance with GCLP, as well as supporting Labs in achieving GCLP. Additionally, discuss your experience, approach, and plans for reviewing and assessing the adequacy of method validation/verification documents provided by Labs, as well as provision of relevant materials in support of method validation.

2) ABILITY OF LABS TO PERFORM PROTOCOL-SPECIFIED TESTS
Discuss your experience, approach, and plans for evaluating and improving the ability of Labs to perform Protocol-specified tests, including assessment of proficiency testing (PT) needs, evaluation of appropriate PT providers and panels, analysis and grading of PT results, assistance to Labs, as well as tracking and reporting. Protocol-specified tests may include diagnosis of infectious diseases (e.g., HIV, HCV, HBV, TB, syphilis), serum hCG; blood chemistry, coagulation, hematology, urinalysis, and CSF glucose/protein. See Attachment 6 Appendix 1 for location of laboratories.

3) GUIDANCE AND TRAINING
Discuss your experience, approach and plans for providing assistance, guidance and training to Labs to address GCLP and PT deficiencies and improve laboratory operations.

4) COMPUTERIZED SOFTWARE SYSTEMS AND DOCUMENT LIBRARY
Discuss your experience, approach, and plans for hosting, managing, tracking and making available documents that support contract activities. Describe system hardware and software, as well as features that ensure logical organization of documents, access to documents, security of Lab-specific performance documents, and capability to generate reports. See Attachment 6 Appendix 2 for System Architecture and Software Design Specifications for the SMILE computerized system. The current SMILE User Guide can be found at https://resources.psmile.org/resources/smile-resources

SECTION 4: SCIENTIFIC AND TECHNICAL PERSONNEL
Provide information relevant to document individual training, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Limit CVs to 2-3 pages.

1) **Principal Investigator (PI):** Describe the experience, training, expertise, and qualifications, and level of effort of the proposed Principal Investigator to plan, lead and direct the activities to be carried out under this contract. Address knowledge and

experience in clinical laboratory testing, principles of proficiency testing, and GCLP; and ability to hire or have access to staff for projects in a way that reflects flexibility and responsiveness to changing needs.

2) **Other Key Scientific and Technical Personnel:** Describe the experience, training, expertise, and qualifications, as well as the level of effort, for all proposed managerial, scientific and technical personnel, with respect to experience managing and coordinating multi-task projects, performance of clinical laboratory testing, knowledge of GCLP, provision of training, customer service and laboratory trouble shooting.

SECTION 5: FACILITIES, EQUIPMENT, AND OTHER RESOURCES

The Technical Proposal should document availability and adequacy of facilities, equipment, space and other resources necessary to carry out the Statement of Work, including:

1) Description of facilities, as applicable, list of equipment and resources dedicated to the project for the prime contractor and any proposed subcontractors (lease or ownership information should be provided).

2) Identification and description of all support resources (including Information Technology systems) that will be required to effectively complete the SOW.

SECTION 6: PROJECT MANAGEMENT

1) Provide a Project Management Plan for the overall organization that addresses the planning, initiation, implementation, conduct, monitoring and completion of tasks identified in the Statement of Work. If consultants and/or subcontractors are proposed, include a plan to manage, coordinate, and oversee the work performed by consultants and/or subcontractor(s).

2) Provide a Staffing Plan that describes roles, responsibilities, and level of effort for all scientific and technical personnel, including all proposed subcontractors and consultants. Provide an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel. Include a chart of the proposed organizational/management structure for the project.

3) Describe the project management systems that will be used to track activities and to keep multiple activities on time and budget. The plan must include a description of the quality control methods that will be used to ensure the effective and efficient initiation, implementation, management, and oversight of contract requirements.

4) Outline how the PI and Project Manager will communicate with the Contracting Officer's Representative (COR) and Contracting Officer and how the PI and Project Manager will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

5) Provide plans for conducting a contract initiation meeting, periodic teleconferences (with key personnel, the COR, and others), teleconferences with Lab investigators, and annual in-person or virtual site visits. Indicate personnel to be included in conference calls and personnel to be included in meetings with the COR.

SECTION 7: OPTIONS

Please note: All Offerors are required to propose on all Options 1-27.

1) **OPTIONS 1 through 6: Extend the Term of the Contract**
   Discuss plans and procedures for continuing and providing the same services indicated in the Statement of Work beyond the contract base period. To address this option, offerors should describe the methods and procedures to maintain the operations specified in the Statement of Work beyond the base period, including retaining or recruiting necessary staff, and maintaining and/or acquiring required equipment and facility space.

2) **OPTIONS 7 through 27 to Increase the Level of Effort:** Discuss the approach for adding, through the exercise of Options, Labs to be supported through the end of the contract. Discuss the ability of the PI and Project Manager to oversee and manage the expansion. Discuss plans to expand the required staff and other resources necessary to provide the services called for in the Statement of Work to additional Labs.

SECTION 8: TRANSITION

1) **Initial Transition**: Describe plans for the initial transition of the current program from the incumbent, including all government furnished property and all data and data systems. Include plans for coordinating with Labs the transition of the SMILE program. Provide timelines for all transition activities.

2) **Final Transition:** Describe general plans for transition of the program to a subsequent contractor at the end of the Contract.

SECTION 9: 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 Sections 1 through 8 above necessary to carry out the Statement of Work, including:

Information Technology (IT) Systems Security

Section L of the RFP specifies the minimum documentation requirements for IT Systems security. All related documentation should be included in the Technical Proposal in this clearly marked section. The Technical Proposal should include a plan for IT Systems security as required by this RFP.

1) 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.

ATTACHMENT 5 – ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS

"PATIENT SAFETY MONITORING IN INTERNATIONAL LABORATORIES (pSMILE)"
RFP No. 75N93025R00011

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

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as attachments, the Technical Evaluation Criteria, and the RFP as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your Business Proposal. Offerors should consider and include the information requested here, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL – TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVER SHEET (use form NIH 2043 identified in Section J of the solicitation)

SECTION 2 – COST OR PRICE SUPPORT

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in a clearly marked section of the proposal.

SECTION 3 – UNIFORM COST ASSUMPTIONS

1) **Technical Cost Assumptions**

   a. For costing activities related to review and monitoring of Labs' compliance with Good Clinical Laboratory Practice (GCLP), assume that current activities provided by SMILE will be continued throughout the duration of the new contract. Assume review of 150 laboratory audits and preparation of 150 Action Plans per year.

   b. For costing activities related to support of method validations at the Labs, assume the following on an annual basis:

      1. Review of 200 validation/verification documents from Labs.

      2. Purchase of commercially available one linearity panel for hematology and one linearity panel for chemistry both shipped to 20 Labs, as well as one linearity panel for the GeneXpert MTB/RIF Ultra, shipped to 20 Labs.

c. For costing activities related to monitoring the ability of Labs to perform Protocol-specified tests, assume current activities provided by SMILE will continue throughout the duration of the new contract. Assume the following on an annual basis:

1. Review of 200 Protocol Analyte Lists (PALs).
2. Purchase of commercially available (e.g., College of American Pathologists) Proficiency Testing (PT) panels shipped to 60 Labs to monitor the ability of each Lab to perform HIV diagnostic tests, complete blood cell count, complete metabolic panel, lipid panel, coagulation, serum hCG and urinalysis.
3. Purchase of commercially available PT panels shipped to 60 Labs to monitor the ability of each Lab to perform rapid HIV diagnosis, urine pregnancy test and syphilis serology.
4. Purchase of commercially available PT panels shipped by a priority shipper (e.g., World Courier) to 35 TB Labs to monitor the ability of each Lab to perform of AFB smears, qualitative cultures, identification, drug susceptibility/resistance tests (e.g., Xpert® MTB/RIF Ultra) and Interferon-Gamma Release Assays (IGRAS). Include priority shipping (e.g., World Courier) when applicable.
5. Purchase of commercially available PT panels to 20 Labs to monitor the ability of each Lab to perform bacterial identification, yeast culture and cryptococcal antigen.
6. Subscribing to the Medical Training Solution (MTS) - medtraining.org) that allows access of 800 active users.

d. Assume the costs associated with hosting, maintaining and enhancing when necessary, the computerized software system and document library, including costs associated with complying with Section 508 accessibility standards, performing information systems security audit that conforms to standards for federal information systems and as relevant to the design, complying with FISMA and/or FedRAMP requirements (see https://www.dhs.gov/fisma).

e. Assume the cost for advanced programmer capabilities, possibly by consultants, to create and maintain internal electronic systems to support direct PT data capture from PT providers, provision of PT data to User Groups, query capabilities, and automated contract workflow processes.

f. Assume the cost of maintaining ISO 9001:2015 certification.

2) **Meetings**

a. For costing purposes, assume administrative costs of one contract initiation meeting of one-day duration at the Contractor's site as well as one annual site visit at the Contractor's site of one-day duration by the COR and other NIAID personnel designated by the COR. The Contractor will not be responsible for travel support for the COR nor NIAID personnel.

b. Hosting 36 one-hour conference calls for 10 U.S. and non-U.S. participants.

3) **Travel**

a. For costing activities related to providing Labs with assistance, guidance, and training, assume the following activities on an annual basis:

1. Conducting 6 fourteen-day visits to Labs in Uganda, South America, India and/or Thailand, each requiring 2 Contractor staff.
2. Attending 3 two-day User Group meetings in Washington DC, each requiring the attendance of 3 Contractor staff.
3. Attending 2 five-day meetings in Europe and 1 five-day meeting in Brazil to meet with providers of PT panels, requiring the attendance of 2 Contractor staff.

5) **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 – TYPE OF CONTRACT AND ESTIMATE OF EFFORT

It is anticipated that a cost reimbursement, level of effort type contract will be awarded as a result of this solicitation. The period of performance will be for one year beginning approximately February 15, 2027 through February 14, 2034. The requirement will be the delivery of 13.7 full time equivalents (FTEs) per year for the base period (Year 1). If Options to extend the term of the contract are exercised, the contractor shall provide 13.7 FTEs per year for Options 1-6 (Years 2-7). ***PLEASE NOTE: The number of FTEs includes the effort of subcontractors, but does not include the effort of consultants.***

Labor Category	Years 1 – 7 (Base Period and Options 1-6)
Principal Investigator (PI)	0.20
Project Director/Manager	1.00
Professional Support (IT)	1.50
QA/QC Coordinators	9.00
Administrative Support	2.00
Total	13.70

While the total level of effort provided above is a requirement, the labor mix is the Government's estimate and should not be considered restrictive for proposal purposes. Offerors should propose the labor mix they consider most appropriate for satisfactory completion of the work.

Options 1-6: Extend the Term of the Contract: The Government may exercise Options to extend the term of the contract beyond the base period (Year 1), annually for a total contract period of up to 7 years. Assume that the scope and types of activities as outlined in the Statement of Work for the base requirement would be continued for each succeeding annual contract period.

Options for Increased Services (Options 7-27):

The Government may exercise options for an increased level of effort that may result from unanticipated increases in demand for the activities supported by the base requirements of this contract. Options for increased services may include the following:

1. **OPTIONS 7 through 27 to Increase the Level of Effort:** During the period of the contract, it may be necessary to incorporate additional Labs to support new NIAID clinical trials. Such an increase would require an increase in the Contractor's activities to be activated, at the discretion of the Government, as an Option. Each Option of this type will implement work commensurate with the addition of 15 Labs and the Option will be maintained for the life of the contract. If the Government elects to exercise this Option, the Contractor shall provide an additional 1.70 Full Time Equivalent (FTE). One Option

for adding new Labs may be exercised once per year during any year of the contract, beginning with year 2 of the contract, to a total of 21 options during the life of the contract, as follows: Year 2 (Option 7), Year 3 (Options 8 & 9), Year 4 (Options 10, 11, 12), Year 5 (Options 13, 14, 15, 16), Year 6 (Options 17, 18, 19, 20, 21), and Year 7 (Options 22, 23, 24, 25, 26, 27). The period of performance of an Option for Increased Level of Effort will not exceed the term of the Option year in which the Option is exercised. If an Option for additional Labs is exercised, it is estimated that 1.7 FTE will be needed initially. Since it is the Government's intent to provide continued support for Labs once they are initiated, Options will be exercised for additional support in the outyears. The Options for continued support will be for an additional 1.7 FTE.

The labor mix provided below is to be used as an example only for the level of effort for Options 7 through 27. The following tables provide a breakdown of Options per year and the anticipated level of effort for each:

Labor Category	**Yr 2**	**Yr 3**	**Yr 4**	**Yr 5**	**Yr 6**	**Yr 7**
QA/QC coordinator	1.5	1.5	1.5	1.5	1.5	1.5
Administrator	0.2	0.2	0.2	0.2	0.2	0.2
Total	1.7	1.7	1.7	1.7	1.7	1.7

While the total level of effort provided above is a requirement, the labor mix is the Government's estimate and should not be considered restrictive for proposal purposes. Offerors should propose the labor mix they consider most appropriate for satisfactory completion of the work.

Option 1 Year 2	Option 2 Year 3	Option 3 Year 4	Option 4 Year 5	Option 5 Year 6	Option 6 Year 7
09/15/27- 09/14/28	09/15/28- 09/14/29	09/15/29- 09/14/30	09/15/30- 09/14/31	09/15/31- 09/14/32	09/15/32- 09/14/33
Option 7	Option 8	Option 10	Option 13	Option 17	Option 22
1.7	1.7	1.7	1.7	1.7	1.7
	Option 9	Option 11	Option 14	Option 18	Option 23
	1.7	1.7	1.7	1.7	1.7
-		Option 12	Option 15	Option 19	Option 24
-		1.7	1.7	1.7	1.7
-			Option 16	Option 20	Option 25
-			1.7	1.7	1.7
-	-	-		Option 21	Option 26
-	-	-		1.7	1.7
-	-	-			Option 27
-	-	-			1.7

While the total level of effort provided above is a requirement, the labor mix is the Government's estimate and should not be considered restrictive for proposal purposes. Offerors should propose the labor mix they consider most appropriate for satisfactory completion of the work

For costing Options 7-27 for additional Labs, assume that each Option will include review and monitoring of Labs compliance with GCLP; review and support for method validations, provision of PT panels to monitor performance of HIV diagnostic tests, complete blood cell count, complete metabolic panel, lipid panel, coagulation and urinalysis; monitoring the ability of Labs to perform Protocol-specified tests; and assistance, guidance and training to improve laboratory operations. Assume the cost of annually conducting a total of 2 fourteen-day visits to Labs in India, each requiring 2 Contractor staff.

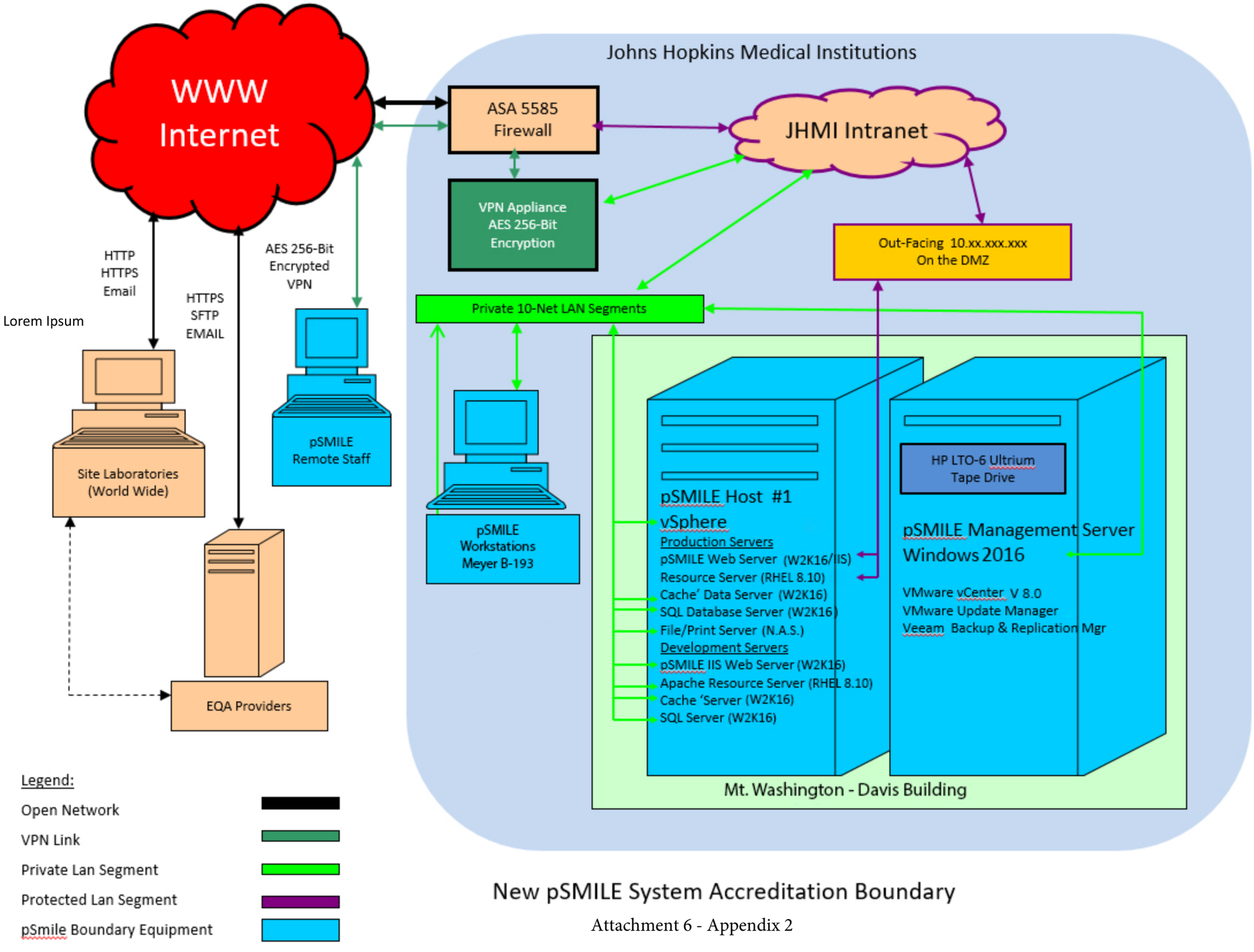
SECTION 5 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

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

Attachment 6 - Appendix 1

City	Country
Iquitos	Peru
Bangkok	Thailand
Eldoret	Kenya
Lima	Peru
Hanoi	Vietnam
Cape Town	South Africa
Johannesburg	South Africa
Westridge	South Africa
Kampala	Uganda
Gaborone	Botswana
Molepolole	Botswana
Pune	India
Hyderabad-Telangana	India
Lilongwe	Malawi
Durban	South Africa
Chiang Mai	Thailand
Vellore	India
Sao Paulo	Brazil
Cavite	Philippines
Harare	Zimbabwe
Rio de Janeiro	Brazil
Ribeirao Preto	Brazil
Manaus Amazonas	Brazil
Port-Au-Prince	Haiti
Nova Iguacu	Brazil
Mumbai	India
Buenos Aires	Argentina
Porto Alegre	Brazil
Salvador	Brazil
Mexico City	Mexico
Puducherry	India
Blantyre	Malawi
Pondicherry	India
Moshi	Tanzania

Kericho	Kenya
Kisumu	Kenya
Klerksdorp	South Africa
Ladysmith	South Africa
Sao Paulo	Brazil
Mbabane	Swaziland
Pretoria	South Africa
Mthatha	South Africa
Chennai	India
Chandigarh	India
Soweto	South Africa
Rustenburg	South Africa
Worcester	South Africa
Chitungwiza	Zimbabwe
Makati City	Philippines
Soshanguve	South Africa
Belo Horizonte	Brazil
Entebbe	Uganda
Khayelitsha	South Africa



New pSMILE System Accreditation Boundary

Invoice and Payment Provisions
(Vendor has Transitioned to IPP)

The following clause is applicable to all Purchase Orders, Task or Delivery Orders, and Blanket Purchase Agreement (BPA) Calls: ***Prompt Payment*** *(Jan 2017) FAR 52.232-25.* Highlights of this clause and NIH implementation requirements follow:

I. Invoice Requirements

A. An invoice is the Contractor's bill or written request for payment under the contract for supplies delivered or services performed. A proper invoice is an "Original" which must include the items listed in subdivisions 1 through 12, below, in addition to the requirements of FAR 32.9. If the invoice does not comply with these requirements, the Contractor will be notified of the defect within 7 days after the date the designated billing office received the invoice (3 days for meat, meat food products, or fish, and 5 days for perishable agricultural commodities, dairy products, edible fats, or oils) with a statement of the reasons why it is not a proper invoice. (See exceptions under II., below.) Untimely notification will be considered in the computation of any interest penalty owed the Contractor.

1. Vendor/Contractor: Name, Address, Point of Contact for the invoice (Name, title, telephone number, e-mail and mailing address of point of contact).
2. Remit-to address (Name and complete mailing address to send payment).
3. Remittance name must match exactly with name on original order/contract. If the Remittance name differs from the Legal Business Name, then both names must appear onthe invoice.
4. Invoice date.
5. Unique invoice #s for all invoices per vendor regardless of site.
6. NBS document number formats must be included for awards created in the NBS: ContractNumber; Purchase Order Number; Task or Delivery Order Number and Source Award Number (e.g., Indefinite Delivery Contract number; General Services Administration number); or, BPA Call Number and BPA Parent Award Number.
7. Unique Entity Identifier (UEI) which is in the System for Award Management (SAM) and replaces the Dun & Bradstreet Data Universal Numbering System (DUNS) number.
8. Federal Taxpayer Identification Number (TIN). In those rare cases where a Contractor does not have a UEI number or TIN, a Vendor Identification Number (VIN)must be referenced on the invoice. The VIN is the number that appears after the contractor’s name on the face page of the award document.
9. Identify that payment is to be made using a three-way match.
10. Description of supplies/services **that match** the description on the award, by line billed.*
11. Freight or delivery charge must be billed as shown on the award. If it is included in the itemprice do not bill it separately. If identified in the award as a separate line item, it must be billed separately.
12. Quantity, Unit of Measure, Unit Price, Extended Price of supplies delivered or servicesperformed, as applicable, and that **match** the line items specified in the award.*

NOTE: If your invoice must differ from the line items on the award, please contact the Contracting Officer before submitting the invoice. A modification to the order or contract may be needed before the invoice can be submitted and paid.

Shipping costs will be reimbursed only if authorized by the Contract/Purchase Order. If authorized, shipping costs must be itemized. Where shipping costs exceed $100, the invoice must be supported by a bill of lading or a paid carrier's receipt.

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

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

Approving Official: Contracting Officer
Name-_____Email Address-

Contracting Officer Representative
Name-_____Email Address-

II. Invoice Payment

A. Except as indicated in paragraph B., below, the due date for making invoice payments by the designated payment office shall be the later of the following two events:

1. The 30th day after the designated billing office has received a proper invoice.
2. The 30th day after Government acceptance of supplies delivered or services performed.

B. The due date for making invoice payments for meat and meat food products, perishable agricultural commodities, dairy products, and edible fats or oils, shall be in accordance with the Prompt Payment Act, as amended.

III. Interest Penalties

A. An interest penalty shall be paid automatically, if payment is not made by the due date and the conditions listed below are met, if applicable.

1. A proper invoice was received by the designated billing office.
2. A receiving report or other Government documentation authorizing payment wasprocessed and there was no disagreement over quantity, quality, or Contractor compliance with a term or condition.
3. In the case of a final invoice for any balance of funds due the Contractor for suppliesdelivered or services performed, the amount was not subject to further

settlement actions between the Government and the Contractor.

B. Determination of interest and penalties due will be made in accordance with the provisions of the Prompt Payment Act, as amended, the Contract Disputes Act, and regulations issued by the Office of Management and Budget.

IV. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (Mar 2023).

(a)

(1) In accordance with 31 U.S.C. 3903 https://www.govinfo.gov/link/uscode/31/3903 and 10 U.S.C. 3801 https://www.govinfo.gov/link/uscode/10/3801 , 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).

V. HHSAR 352.232-71 Electronic Submission of Payment Requests (February 2, 2022).

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

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

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

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

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

(End of clause).

Attachment 19

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

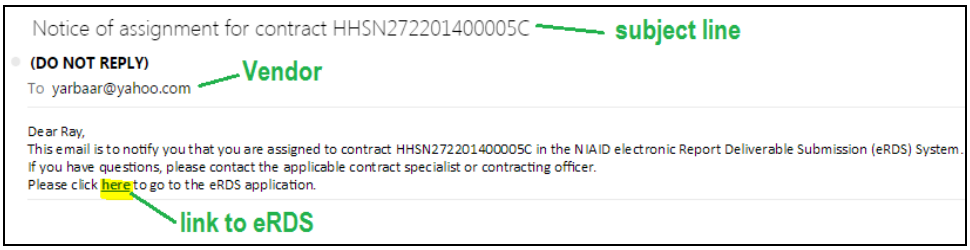
All Vendors must have an NIH EXT or eRA Commons account to access eRDS.

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.

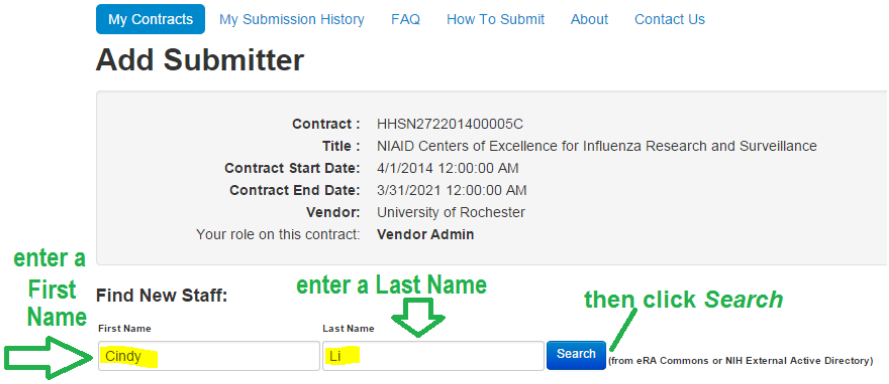


2. Vendors will land on the My Contracts page

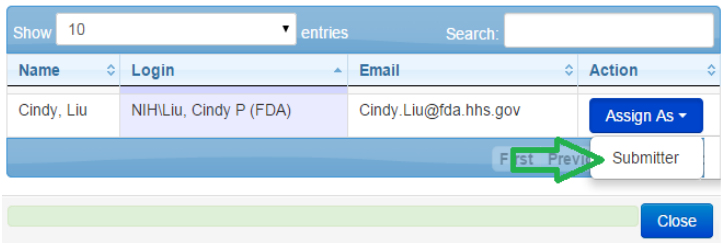
Add Submitter

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

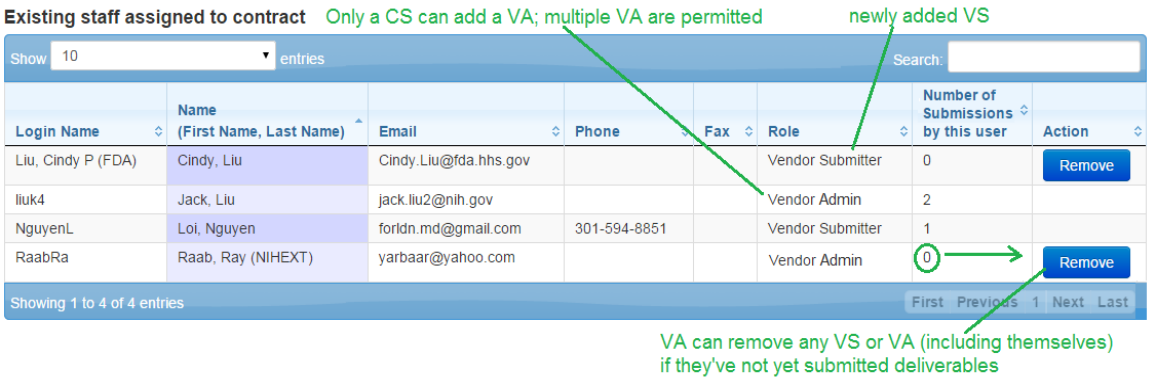
1. Select the Add Submitter (Add Submitter) button in the "Submitter Assignment" column
2. Enter First and Last Names in the "Find New Staff" fields and click Search (Search)



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).

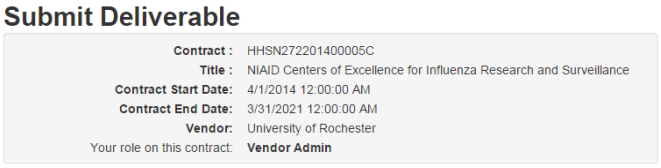


6. Select the Back (Back) button to return to My Contracts

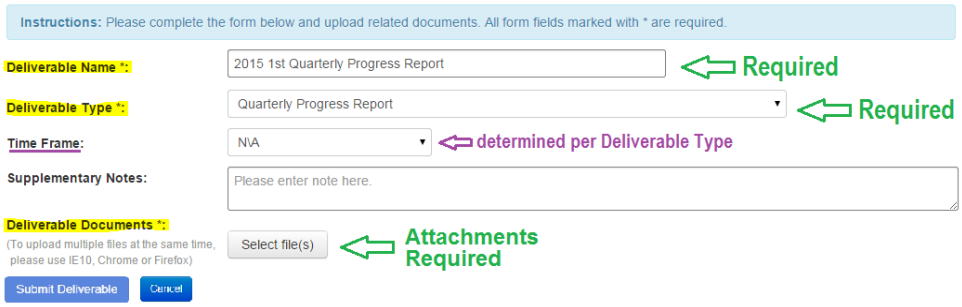
Submit New Deliverable

To Submit a New Contract Deliverable:

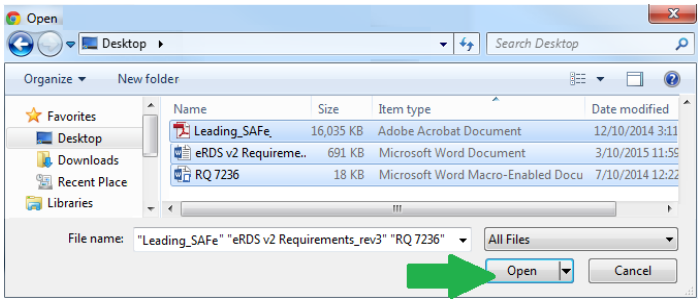
1. Select your contract's Submit New Deliverable (Submit New Deliverable) button in the "Action" column.



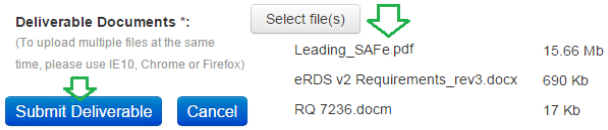
2. Enter the Deliverable's *Name*, *Type, Time Frame* (for recurring reports in the calendar year), and any *Supplementary Notes* as needed:



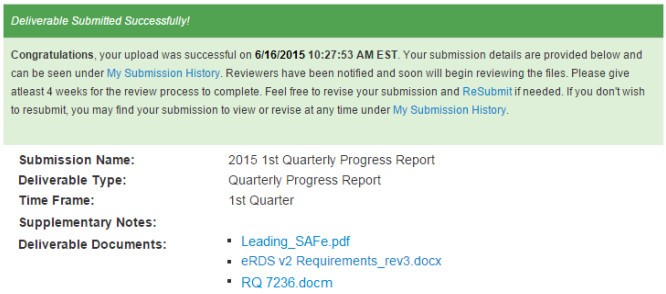
3. Choose Select file(s) (Select Files) to attach one or more documents. Using Internet Explorer 10, Google Chrome or Mozilla Firefox as web browsers will enable you to select multiple files at the same time. Microsoft Office files (word, excel) and Adobe PDF are accepted.



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

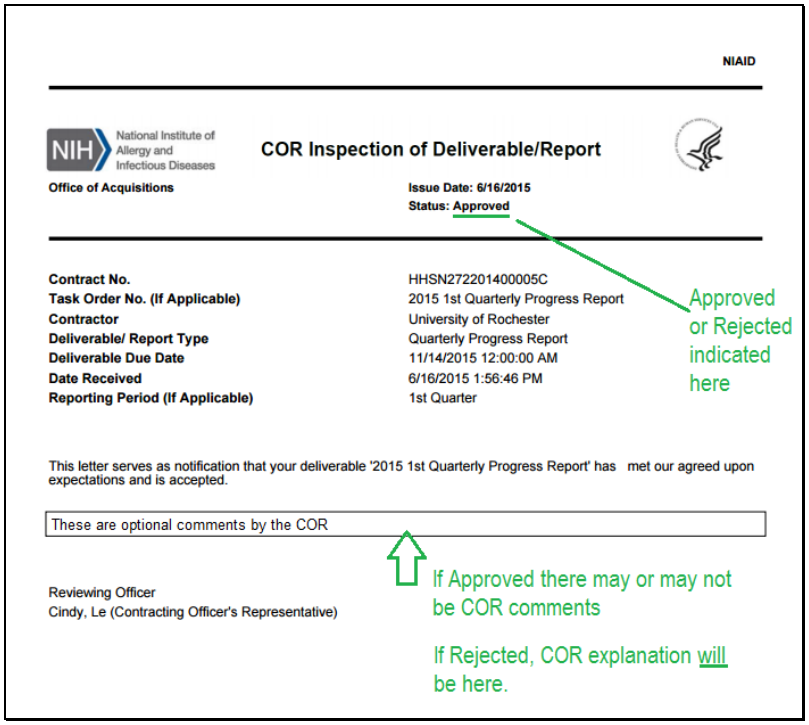
COR Inspection of Deliverable Report

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



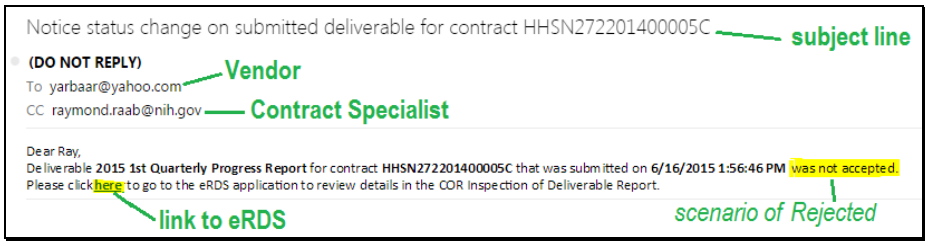
4. If the deliverable is auto-approved, the COR Inspection of Deliverable report won't be available.

Re-Submission & Alternate Submissions

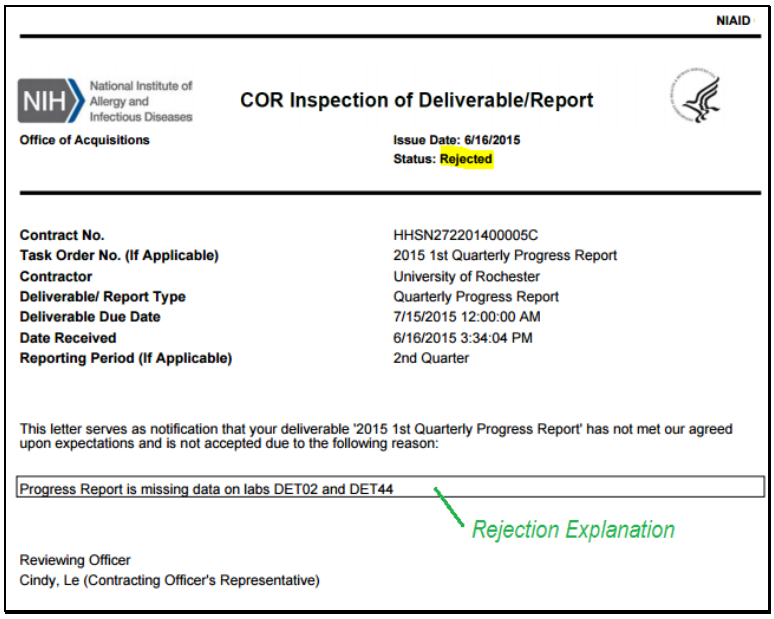
Re-Submit (Revise) a Deliverable

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

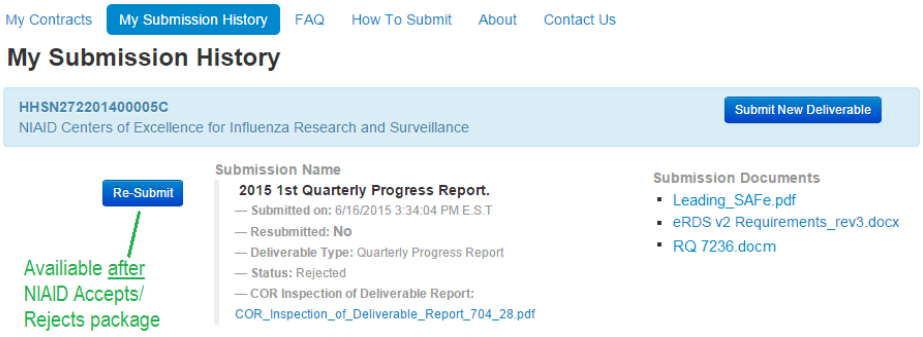
2. Once you receive the Notice of Status Change email notice from NIAID that your submission was *not accepted* (rejected), select the embedded link to go to My Submission History



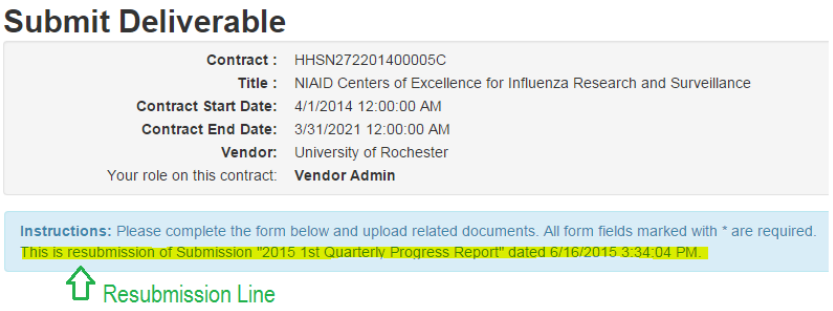
3. Under My Submission History, the COR Inspection of Deliverable Report PDF will provide an explanation for the rejection



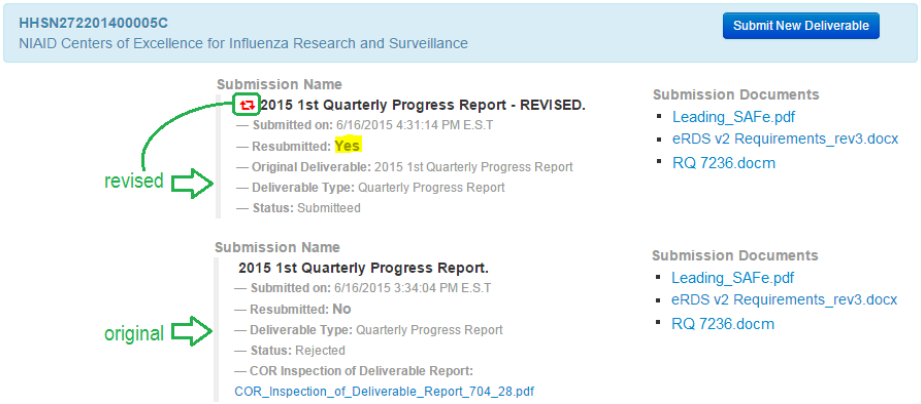
4. Select the Re-Submit (Re-Submit) button for revised deliverable resubmission. Click OK to get past the notification popup



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