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PART I - THE SCHEDULE

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

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

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

Proposals in Response to this solicitation are **due on July 17th, 2026, by 3:00PM EST**. The Price-Cost proposal shall be submitted separately from the technical proposal. Please provide searchable electronic copies only.

Interested parties are hereby notified that communications and submissions (e.g., proposals, solicitation questions, amendments, negotiation questions and responses, etc.) will be conducted via e-mail to Andrew Dinh, andrew.dinh@nih.gov and Melanie Suarez, melanie.suarez@nih.gov and via eCPS. See Attachment 1 for Proposal Submission instructions.

Proposal Intent

1. Contractors are asked to review this RFP and provide the below information via email to the Contracting Officer and Specialists/ emails (andrew.dinh@nih.gov and melanie.suarez@nih.gov) no later than close of business on June 22, 2026 . Choose one of the following options:

☐ Do intend to submit a proposal

☐ Do not intend to submit a proposal

If you do not intend to submit a proposal in response to this RFP, please state your reason(s) in your electronic response.

2. Include the following in your electronic response:
 - a. Solicitation Number and Title
 - b. Name of Contractor's Organization
 - c. Name (First, Middle Initial, Last) of Contractor's Representative
 - d. Title of Contractor's Representative

Your expression of intent is not binding but will greatly assist us in planning for evaluation.

Requests for Clarification

1. Requests for clarification shall be submitted electronically via e-mail no later than June 29th, 2026 by 12PM EST.
2. When submitting requests for clarification, contractors must cite the relevant section, paragraph, and page number. Questions should be written in a way that enables clear understanding of the contractors' issues or concerns. Statements expressing opinions, sentiments, or conjectures are not considered valid inquiries and will not be provided a response. Further, contractors are reminded that the Contracting Officer will not address hypothetical questions aimed at receiving a potential "evaluation decision."
3. Contractors may submit no more than ten (10) questions for clarification.
4. Written responses to questions will be provided to all contractors by July 6th, 2026, by 3:00PM EST. Responses will not disclose proprietary information of the contractors.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The goal of this acquisition is for a single vendor to negotiate, award, and administer subcontracts or agreements resulting from the RADx Innovation Funnel. These subcontracts or agreements will cover validation and risk review as directed by the Government. Responsibilities will cover negotiations, award execution, post-award management and payments, and ongoing IT and legal resource support. Expertise in reviewing and negotiating milestones, budgets, and timelines for biomedical research and development awards is required, along with establishing terms & conditions, and execution of awards. Resources for ongoing oversight and support for milestone-based award contracts are required, including financial management capabilities to process invoices and payment.

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

ARTICLE B.3. PRICES/COSTS

1. This is an Indefinite Quantity contract as contemplated by RFO 16.504. The Contractor shall be reimbursed by the Government in an amount not less than a total of \$200,000 (minimum) nor more than a total of \$149,935,000 (maximum) for successful performance of this contract.
2. The costs set forth in this ARTICLE will cover the contract period August 18, 2026 through August 17, 2031.
3. The Government will issue Task Orders based on the work described in SECTION C of this contract.

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

Invoice Processing Platform (IPP)

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

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

If this award is a parent indefinite delivery award or a Blanket Purchase Agreement Set-Up, then HHSAR 352.232-71 applies to all task/delivery orders or Blanket Purchase Agreement calls issued under this award.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. DESCRIPTION-SPECIFICATION- STATEMENT OF WORK

1. 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 2/25/2026, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports shall be submitted electronically to the Contracting Officer.

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

[All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post-consumer fiber paper, whenever practicable.

a. Technical Progress Reports

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

For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s) no hard copies of these reports will be required.

☒ Monthly

☐ Quarterly

☐ Semi-Annually

☒ Annually

☐ Annually (with a requirement for a Draft Annual Report)

☐ Final - Upon final completion of the contract

☒ Final - Upon final completion of the contract (with a requirement for a Draft Final Report)

b. Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of racial and/or ethnic minority groups and their subpopulations (when appropriate) for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Cumulative Inclusion Enrollment Report," which is set

forth in SECTION J of this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report. If the clinical study(s) involves US and non-US sites, the US sites and non-US sites should be reported on separate Cumulative Inclusion Enrollment Reports.

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

In addition, the “NIH Policy and Guidelines on the Inclusion of Women and Members of Racial and/or Ethnic Minority Groups as Subjects in Clinical Research”, Amended effective, October 2001 August 16, 2025 also applies. If this contract is for Phase III clinical trials, see Section B of these guidelines. The Guidelines may be found at the following website: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-131.html>

For NIH-defined Phase III Clinical Trials: Include a description of the plans for valid analysis in the study design and outcomes. This includes designing the study in a manner that potential differences, as appropriate, by sex and/or racial/ethnic groups in the clinical trial protocol could be conducted. Also, provide a description of any analyses by sex, racial, and/or ethnic groups, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex, racial and/or ethnic groups.

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:
National Institutes of Health
6705 Rockledge Drive
Bethesda, MD 20892-7902
- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

RFO Clause **52.246-2, Inspection of Supplies - Fixed Price** (August 1996).

RFO Clause **52.246-4, Inspection of Services - Fixed Price** (August 1996).

RFO Clause **52.246-16, Responsibility for Supplies** (April 1984).

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The period of performance of this contract shall be from August 18, 2026 through August 17, 2031.

ARTICLE F.2. DELIVERIES

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

ARTICLE F.3. NOTIFICATION OF COMPLETION OF REPORTING IN ELECTRONIC RESEARCH ADMINISTRATION (eRA) SYSTEM

The Contractor shall submit data relevant to Human Subjects and Clinical Trial Information, including any required Inclusion Enrollment Reporting, into the NIH Electronic Research Administration (eRA) system. These requirements are described further in SECTION H - REPORTING IN ELECTRONIC RESEARCH ADMINISTRATION (eRA) SYSTEM.

The Contractor shall submit the data within the NIH eRA system within fifteen (15) calendar days of receiving a prompt from the NIH to complete these activities, or sooner as instructed by the Contracting Officer (CO).

Following submission of data within the NIH eRA system as instructed, the Contractor shall send an e-mail notification verifying completion to the CO and the Contracting Officer's Representative (COR).

ARTICLE F.4. 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 ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

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

52.242-17, Government Delay of Work (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:

TBD at the time of award

The COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3)

performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The 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
TBD	

ARTICLE G.3. TASK ORDER PROCEDURE

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

a. General

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

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

b. Requesting Task Order Proposals

The Contracting Officer or a designated individual may solicit responses to requirements from Contractors within a technical area covered by a task order requirement in writing. A Task

Order Request for Proposals (TORFP) will be prepared and issued for each task order requirement.

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

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

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

Contractors are not required to propose on all TORFPs. Those eligible Contractors that decide not to submit a proposal shall advise the Contracting Officer, in writing, of their intention not to submit a proposal on or before the closing date and time established in the TORFP. An election not to propose on a given TORFP will not negatively affect or prohibit a Contractor from competing on future TORFPs. However, it may affect the Contractor's eligibility for continuations or extensions of the resultant Task Order.

c. Competitive Ordering Process

1. All Contractors within a technical area will receive e-mail notification advising of the availability of each proposed task order requirement. All proposed task orders will incorporate all terms of this contract unless otherwise specified in the proposed task order.
2. Contractors will be provided an adequate time to prepare and submit responses based on the Contracting Officer's consideration of the estimated dollar value and complexity of proposed task order. Responses will not be considered a proposal as defined in RFO Part 15. However, the Contractor shall provide information sufficient for consideration in accordance with RFO Part 16. Each TORFP will indicate the criteria for the evaluation of proposals. The responses shall demonstrate capability for each criterion to be evaluated. Generally, the Contractor will be asked to demonstrate the following as appropriate:
 - Understanding of the requirements;
 - Experience and capability on similar tasks;
 - Technical approach, methods and procedures for satisfying the requirements with a discussion of potential problems to be encountered and proposed solutions and/or risk mitigation strategies;
 - Procedures for assuring quality of work, products, and deliverables;
 - Plan for managing the task order, including meeting requirements and schedules, and performance measures (if applicable);

- Staffing plan with skill levels and level of effort for each individual proposed. Generally, resumes will be required for proposed personnel (if not previously submitted);
- References to evaluate past performance; and
- Cost/Price to perform the task order.

d. Evaluation and Award of Task Order Proposals

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

Upon completion of evaluations, the Contracting Officer will issue a task order to the Contractor whose proposal is most advantageous to the government.

The Contracting Officer will notify the Contractor(s) of the selection decision in writing.

e. Fair Opportunity

- a) In accordance with RFO 16.507-2 each awardee will be given a fair opportunity to be considered for each order issued exceeding the micro-purchase threshold issued under multiple delivery-order contracts or multiple task-order contracts, except:
 - i. The agency need for the supplies or services is so urgent that providing a fair opportunity would result in unacceptable delays.
 - ii. Only one awardee is capable of providing the supplies or services required at the level of quality required because the supplies or services ordered are unique or highly specialized.
 - iii. The order must be issued on a sole-source basis in the interest of economy and efficiency because it is a logical follow-on to an order already issued under the contract, provided that all awardees were given a fair opportunity to be considered for the original order.
 - iv. It is necessary to place an order to satisfy a minimum guarantee.
- b) All awardees will be given a fair opportunity to be considered in accordance with the RFO 16.507-2 as follows:
 - i. For orders exceeding the micro-purchase threshold up to the simplified acquisition threshold, in accordance with RFO 16.507-3;
 - ii. For orders exceeding the simplified acquisition threshold up to \$7.5 Million, in accordance with RFO 16.507-4; and,
 - iii. For orders exceeding \$7.5 Million, in accordance with RFO 16.507-5.

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

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- _____ Email Address- _____

Contracting Officer Representative

Name- _____ Email Address- _____

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.

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

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

2. In addition to the requirements specified in RFO 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:
 - a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is R&D and Professional Services - Division B, OALM, Office of the Director, National Institutes of Health
 - 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: Rapid Acceleration of Diagnostics Award Management
- g. Contract Line Items as follows:

Line Item #	Line Item Description
TBD	TBD

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

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

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

(2) The Contractor agrees to make such payments to its small business subcontractors without any further consideration from or fees charged to the subcontractor.
- (b) The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.
- (c) Include the substance of this clause, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial products or commercial services.

(End of clause).

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and Final evaluations of Contractor performance will be prepared on this contract in accordance with RFO Subpart 42.11. The Final performance evaluation will be prepared at the time of completion of work. In addition to the Final evaluation, Interim evaluation(s) will be prepared Annually as follows on the anniversary date of the contract.

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

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

b. Electronic Access to Contractor Performance Evaluations

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

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

- a) The Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR part 46, are available on the Office for Human Research Protections (OHRP) website at: <http://www.hhs.gov/ohrp/index.html>.
 - i. These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of human subjects participating in research activities supported or conducted by HHS.
- b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable public information through intervention or interaction with the individual, or identifiable private information. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. 45 CFR part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.
- c) Activities which involve human subjects in one or more of the categories set forth in 45 CFR 46.104(d)(1)-(8) are exempt from complying with 45 CFR part 46. See <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.
- d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal.

- e) In accordance with 45 CFR part 46, Offerors considered for award must file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that OHRP accepts or approves. The initial and continuing review of a research project by an institutional review board must ensure that: The risks to subjects are minimized; risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result; selection of subjects is equitable; and informed consent will be obtained and documented by methods that are adequate and appropriate. Depending on the nature of the research, additional requirements may apply; see <http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.111> for additional requirements regarding initial and continuing review. HHS regulations for the protection of human subjects (45 CFR part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information is available at the OHRP Web site (at <http://www.hhs.gov/ohrp/assurances/index.html>).
- f) Offerors may consult with OHRP only for general advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. ONLY the contracting officer may offer information concerning a solicitation.
- g) The Offeror must document in its proposal the approved or active FWA from OHRP, related to the designated Institutional Review Board (IRB) reviewing and overseeing the research.
 - i. If the Offeror does not have an approved FWA from OHRP, the Offeror must obtain an FWA before the deadline for proposal submission.
- h) When possible, the Offeror must also certify the IRB's review and approval of the research. If the Offeror cannot obtain this certification by the time of proposal submission, they must include an explanation in their proposal.
- i) Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.

(End of provision)

Alternate I (MAR 2026) (RFO DEVIATION).

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

(1) If the Offeror does not have an active FWA from OHRP, the Offeror must take all necessary steps to obtain an FWA prior to the proposal submission deadline. If the Offeror cannot obtain an FWA before the proposal submission deadline, the proposal must indicate the steps/actions the Offeror will take to obtain OHRP approval within (Contracting Officer insert a time period in which the FWA must be obtained). Upon obtaining FWA approval, submit the approval notice to the Contracting Officer.

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

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject

participants, the Contractor should access the NIH Guide for Grants and Contracts Announcement dated August 25, 2000 at the following website:

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

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

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

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.3. INCLUSION OF WOMEN AND MEMBERS OF RACIAL AND/OR ETHNIC MINORITY GROUPS IN CLINICAL RESEARCH

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

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

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

The NIH Inclusion Policy is complementary to requirements outlined in the Clinical Trial Registration and Results Information Submission regulation at 42 CFR Part 11 and the accompanying NIH Policy

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

ARTICLE H.4. INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

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

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

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

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

<https://www.era.nih.gov/sites/default/files/2020-05/ParticipantLevelData-Template.CSV>

ARTICLE H.5. POSTING CLINICAL TRIAL INFORMED CONSENT FORMS TO CLINICALTRIALS.GOV

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

Contracting Officer (CO) and/or Contracting Officer Representative (COR) may permit or require redactions as appropriate.

ARTICLE H.6. REPORTING IN ELECTRONIC RESEARCH ADMINISTRATION (eRA) SYSTEM

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

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

System Access

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

Please note that if your organization does not currently have an account in eRA Commons, you will first need to register your organization at

<https://public.era.nih.gov/commonsplus/public/registration/initRegistration.era>.

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

For information on how to create/manage accounts in the eRA system, please refer to:

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

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

ARTICLE H.7. PUBLIC HEALTH SURVEILLANCE EXCLUSION

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

Contractor shall provide a compelling justification as to why NIH-funded or -conducted activities should be considered public health surveillance activities deemed not to be research for the purposes of the revised Common Rule.

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

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

Notice of Approval or Disapproval of Request for Exclusion

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

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

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

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

ARTICLE H.9. 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.10. NEEDLE EXCHANGE, HHSAR 352.35-72 (Mar 2026)(RFO DEVIATION).

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

(End of clause).

ARTICLE H.11. 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.12. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.235-73 (Mar 2026)(RFO DEVIATION).

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

(End of clause).

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

ARTICLE H.13. 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.14. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.235-75 (Mar 2026)(RFO DEVIATION).

1. Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United States Department of Agriculture (USDA), the Contractor must register with the Secretary of Agriculture of the United States in

accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor must furnish evidence of the registration to the Contracting Officer.

2. The Contractor must acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1-2.11, or from a source that is exempt from licensing under those sections.
3. The Contractor agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract must conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard must govern.
4. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with Animal Welfare Assurances.
5. The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: ace@aphis.usda.gov; Web site: <https://www.aphis.usda.gov/awa/apply>).

(End of clause).

ARTICLE H.15. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: <https://olaw.nih.gov/policies-laws/phs-policy.htm> .

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

ARTICLE H.16. INTRODUCTION OF RODENTS AND RODENT PRODUCTS

No rodent or rodent product shall be delivered into the NIH, [] environment (NIH) directly, or through collaborative research or holding facilities under contract to [] except by permit. Direct shipments to NIH from a Division of Veterinary Resources (DVR), Office of Research Services (ORS) approved source will be considered exempt. Non-exempt sources must be approved by permit issued through the DVR, ORS. The permit must be obtained by the Contractor prior to the shipment to NIH of the rodents and/or rodent products. The Contractor must be sure that this permit exists and is current before transferring rodents or rodent products into the NIH, [] environment. Refusal or negligence to do so will be considered a material breach of contract and may be treated as any other such material breach. Applications for permits should be submitted by facsimile not less than 30 days prior (60 days in situations where quarantine is likely) to shipping date to: NIH Division of Veterinary Resources (DVR), Office of Research Services (ORS), Building 14G, Service Rd. South, Room 102, BETHESDA MD 20892-5210, (301)496-2527, FAX: (301) 402-0352.

ARTICLE H.17. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

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

ARTICLE H.18. OMB CLEARANCE

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

ARTICLE H.19. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

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

ARTICLE H.20. GUN CONTROL

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

ARTICLE H.21. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C

and F of the contract. Pursuant to [RFO Clause 52.217-6, Option for Increased Quantity/RFO Clause 52.217-7, Option for Increased Quantity-Separately Priced Line Item/RFO Clause Article H.51, Option to Extend Services/RFO Clause 52.217-9, Option to Extend the Term of the Contract] set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost [plus fixed fee] of the contract will be increased as set forth in the ESTIMATED COST Article in SECTION B of this contract.

ARTICLE H.22. SUBCONTRACTING PROVISIONS

1. Small Business Subcontracting Plan

- a. In accordance with RFO 19.704 and RFO Clause 52.219-9, the submission of a subcontracting plan by other than small business offeror(s) is a requirement as a part of the proposal submission process and is to be submitted separately from the technical and cost proposals. An offeror's subcontracting plan must be determined to be acceptable, by the Contracting Officer, prior to the contract award.
- b. The failure of any Contractor or subcontractor to comply in good faith with RFO Clause 52.219-8, entitled " Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under RFO Clause 52.219-16 entitled, "Liquidated Damages- Subcontracting Plan."

2. Subcontracting Plan Submission

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

e. Subcontracting Reports

i. Individual Subcontract Reports (ISR)

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

May 15th

November 14th

Expiration Date of Contract

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

November 14th

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

TBD

ARTICLE H.56.13. 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.

ARTICLE H.56.14. 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.57. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

" This project has been funded in whole or in part with Federal funds from the National Institutes of Health (NIH)/ National Institute of Biomedical Imaging and Bioengineering (NIBIB), under Contract No. TBD."

ARTICLE H.58. TASK ORDER/DELIVERY ORDER CONTRACT OMBUDSMAN

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

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

For R&D Contracts:	For Non-R&D Contracts:
Dr. Anna Taylor	Dr. Kathy Partin
NIH Advocate for Competition	NIH Advocate for Competition
1 Center Drive, Room 150	1 Center Drive, Room 154, MSC 0140
Bethesda, MD 20892-0140	Bethesda, MD 20892-0140
	Phone: (301) 451-7764
Email: Anna.Taylor@nih.gov	E-mail: Kathryn.Partin@nih.gov

ARTICLE H.59. 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.60. SHARING RESEARCH DATA

[The Data Management and Sharing Plan submitted by the Contractor is acceptable/The Contractor's Data Management and Sharing Plan, dated [TBD], is hereby incorporated by reference herein.] The Contractor agrees to adhere to its Data Management and Sharing Plan and shall request the prior written approval of the Contracting Officer for any changes in its Data Management and Sharing Plan.

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

- [NOT-OD-14-124 - NIH Genomic Data Sharing Policy;](#)
- [NOT-OD-21-013 - Final NIH Policy for Data Management and Sharing;](#)

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

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

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

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.

This solicitation incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically as follows: RFO Clauses at:

<https://www.acquisition.gov/far-overhaul> . HHSAR Clauses at: <https://www.hhs.gov/grants-contracts/contracts/contract-policies-regulations/hhsar/part-352-solicitation-provisions-contract-clauses/index.html> .

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

Alternate II (DEVIATION) (Feb 2026) of RFO Clause 52.219-9, Small Business Subcontracting Plan (DEVIATION) (Feb 2026) is added.

Alternate I (DEVIATION) (Aug 2025) of RFO Clause 52.243-1, Changes, Fixed Price (DEVIATION) (Jul 2025), is hereby deleted in its entirety and **Alternate II (DEVIATION) (Jul 2025) of RFO Clause 52.243-1, Changes, Fixed Price (DEVIATION) (Jul 2025)**, is substituted therefor.

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

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

a. REVOLUTIONARY FAR OVERHAUL CLAUSES

1. RFO Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (Nov 2021).
2. RFO Clause **52.203-14, Display of Hotline Poster(s)** (Nov 2021).

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

Poster(s)	Obtain From:
HHS Contractor Code of Ethics and Business Conduct Poster	https://core-docs.s3.amazonaws.com/documents/asset/uploaded_file/576385/OIG_Hotline_Poster_1_.pdf

3. RFO Clause **52.204-15, Service Contract Reporting Requirements for Indefinite-Delivery Contracts (DEVIATION) (Nov 2025).**
4. RFO Clause **52.240-93, Basic Safeguarding of Covered Contractor Information Systems (DEVIATION) (Nov 2025).**
5. RFO Clause **52.240-90, Security Prohibitions and Exclusions Representations and Certifications (DEVIATION) (Nov 2025).**
6. RFO Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters (Nov 2025).**
7. RFO Clause **52.210-1, Market Research (DEVIATION) (July 2025).**
8. RFO Clause **52.216-18, Ordering (Aug 2020).**
 - a. Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from August 18, 2026 through August 17, 2031.
 - b. All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.
 - c. If mailed, a delivery order or task order is considered "issued" when the Government deposits the order in the mail. Orders may be issued orally, by facsimile, or by electronic commerce methods only if authorized in the Schedule.

(End of clause).

9. RFO Clause **52.216-19, Order Limitations (Oct 1995).**
 - d. **Minimum Order.** When the Government requires supplies or services covered by this contract in an amount of less than \$200,000.00, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.
 - e. **Maximum Order.** The Contractor is not obligated to honor—
 1. Any order for a single item in excess of the contract maximum.
 2. Any order for a combination of items in excess of the contract maximum; or
 3. A series of orders from the same ordering office within 30 days that together call for quantities exceeding the limitation in subparagraph (1) or (2) above.
 - f. If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Revolutionary FAR Overhaul (RFO)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) above.
 - g. Notwithstanding paragraphs (b) and (c) above, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon

receiving this notice, the Government may acquire the supplies or services from another source.

(End of clause).

10. RFO Clause **52.216-22, Indefinite Quantity (DEVIATION) (Nov 2025).**

- a. This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.
- b. Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."
- c. Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.
- d. Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after August 17, 2031.

(End of clause).

Alternate I (DEVIATION) (Nov 2025). As prescribed in 16.505(e)(1), add a paragraph (e) substantially the same as the following to the basic clause:

- e. Either party may cancel this contract in whole or in part by providing written notice. The cancellation will take effect 30 calendar days after the other party receives the notice of cancellation. If either party makes such notification, no further orders may be issued against the contract, but orders already awarded will be completed unless a termination action is taken against the order. If the Contractor elects to cancel this contract, the Government will not reimburse the minimum guarantee.

Alternate II (DEVIATION) (Nov 2025). As prescribed in 16.505(e)(2), add paragraphs (e) and (f) substantially the same as the following to the basic clause:

- f. The Government may cancel this contract in whole or in part by providing written notice. The cancellation will take effect 30 calendar days after the contractor receives the notice of cancellation. No further orders may be issued against the contract, but orders already awarded will be completed unless a termination action is taken against the order.
- g. The Contractor may request to cancel this contract by submitting a written cancellation request to the contracting officer. The cancellation will take effect 30 calendar days after the Government receives the cancellation request, unless the contracting officer informs the contractor, before cancellation is effective, that cancellation is not approved. A contractor who requests cancellation is not eligible for the minimum

guarantee. If cancelled, no further orders may be issued against the contract, but orders already awarded will be completed unless a termination action is taken against the order.

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

"...The Contracting Officer may exercise the option by written notice to the Contractor within the period of performance"

12. RFO Clause **52.217-8, Option to Extend Services (Nov 1999).**

"..The Contracting Officer may exercise the option by written notice to the Contractor within the period of performance.

13. FAR Clause **52.217-9, Option to Extend the Term of the Contract (Mar 2000).**

- a. The Government may extend the term of this contract by written notice to the Contractor prior to the expiration date of the contract; provided that the Government gives the Contractor a preliminary written notice of its intent to extend 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 __TBD____.

(End of clause).

14. RFO Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (Oct 2022).**

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

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

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

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

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

- b) For purposes of the salary rate limitation, the terms “direct salary,” “salary,” and “institutional base salary,” have the same meaning and are collectively referred to as “direct salary,” in this clause. An individual's direct salary is the annual compensation that the Contractor pays for an individual's direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs). The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services [(HHS)] contract or order; it merely limits the portion of that salary that may be paid with contract funds.
- c) The salary rate limitation also applies to individuals under subcontracts.
- d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.
- e) See the salaries and wages pay tables on the Office of Personnel Management website for Federal Executive Schedule (EX) salary levels at www.opm.gov.
- f) The Contractor must insert the substance of this clause, including this paragraph (f), in all subcontracts.

(End of clause)

2. 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 in FAR 32.905(b) and the applicable payment clause included in this contract.

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

(End of clause)

NATIONAL INSTITUTES OF HEALTH (NIH) RESEARCH CONTRACTING (RC) CLAUSES:

The following clauses are attached and made a part of this contract:

THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.

RFO Clause **52.222-55, Minimum Wages Under Executive Order 14026 (DEVIATION) (Nov 2025).**

RFO Clause **52.222-62, Paid Sick Leave Under Executive Order 13706 (DEVIATION) (Nov 2025).**

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

Attachment Number	Title
1	Packaging and Delivery of Proposals for Use with the NIH electronic Contract Proposal Submission (eCPS) Website
2	Proposal Intent Response Sheet
3	Statement of Work (Parent and Task Order)
4	Section K - Representations, Certifications, and Other Statements of Offerors
5	PHS Human Subjects and Clinical Trials Information Form-H OMB Number: 0925-0001 - Inclusion Enrollment Report (Study Record Form)
6	Summary of Related Activities
7	Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310)
8	Worksheet for the Vertebrate Animals Section (VAS) under Contract Proposals
9	Proposal Summary and Data Record, NIH-2043
10	Small Business Subcontracting Plan – Outlined in the HHS Small Business Customer Experience (SBCX) Industry User Guide for Subcontracting Plan Reviews
11	Disclosure of Lobbying Activities, OMB Form SF-LLL Access here: https://www.gsa.gov/forms-library/disclosure-lobbying-activities.
12	Sample Work Assignment
13	Public Health Surveillance Exclusion Request
14	Electronic Invoicing Instructions for NIH Contractors/Vendors
15	Breakdown of Proposed Estimated Costs plus fee with Excel Spreadsheet

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

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

(End of clause).

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

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

- i. *Definitions.* As used in this provision-
In writing, writing, or written means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

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

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

Time, if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays.

However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

- ii. *Amendments to requests for proposals.* If this request for proposal (RFP) is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this RFP by the date and time specified in the amendment(s).
- iii. Submission, modification, revision, and withdrawal of proposals.
 - 1. Proposals and modifications to proposals shall be—
 - a. Submitted using the method and the format specified in the RFP;
 - b. Addressed to the office specified in the RFP; and
 - c. Showing the time and date specified for receipt, the RFP number, and the name and address of the offeror.
 - 2. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i)(B) and (C) of this provision.
- iv. The first page of the proposal must show—
 - 1. The RFP number;
 - 2. The name, address, and telephone number of the offeror (and electronic address if available);
 - 3. A statement specifying the extent of agreement with all terms, conditions, and provisions included in the RFP and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
 - 4. Names, titles, and telephone number (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this RFP; and
 - 5. 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.
- v. Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the RFP by the time specified in the RFP. If no time is specified in the RFP, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.
 - 1. Any proposal, modification, or revision received at the Government office designated in the RFP after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and-
 - a. If it was transmitted through an electronic commerce method authorized by the RFP, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
 - b. 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
- c. It is the only proposal received.
2. 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.
- vi. 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.
- vii. If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the RFP, and urgent Government requirements preclude amendment of the RFP, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the RFP on the first work day on which normal Government processes resume.
- viii. Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral RFPs may be withdrawn orally. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.
- ix. Unless otherwise specified in the RFP, the offeror may propose to provide any item or combination of items.
- x. Offerors shall submit proposals in response to this RFP in English, unless otherwise permitted by the RFP, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the RFP.
- xi. Offerors may submit modifications to their proposals at any time before the RFP closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
- xii. Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
- xiii. Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
- xiv. *Offer expiration date.* Proposals in response to this RFP will be valid for the number of days specified on the RFP cover sheet (unless a different period is proposed by the offeror).
- xv. *Restriction on disclosure and use of data.* Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall-
1. Mark the title page with the following legend:
Mark the title page with the following legend: This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed—in whole or in part—for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of, or in connection with, the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This

restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [insert numbers or other identification of sheets]; and

2. Mark each sheet of data it wishes to restrict with the following legend:
Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

xvi. Contract Award.

1. The Government intends to award a contract or contracts resulting from this RFP to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the RFP.
2. The Government may reject any or all proposals if such action is in the Government's interest.
3. The Government may waive informalities and minor irregularities in proposals received.
4. The Government intends to evaluate proposals and award a contract without negotiations with offerors (except clarifications as described in FAR 15.202(b)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct negotiations if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly evaluated proposals.
5. The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
6. The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
7. The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting

Officer determines that the lack of balance poses an unacceptable risk to the Government.

8. If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
9. A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
10. If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:
 - a. The agency's evaluation of the significant weaknesses or deficiencies in the debriefed offeror's offer.
 - b. The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.
 - c. The overall ranking of all offerors, when any ranking was developed by the agency during source selection.
 - d. A summary of the rationale for award.
 - e. For acquisitions of commercial products, the make and model of the product to be delivered by the successful offeror.
 - f. Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the RFP, applicable regulations, and other applicable authorities were followed by the agency.
 - g. For DoD contracts in excess of \$10 million but not in excess of \$100 million with a small business or nontraditional defense contractor (10 U.S.C. 3014), an option for the contractor to request disclosure of the agency's written source selection decision document, redacted to protect the confidential and proprietary information of other offerors for the contract award.
 - h. For award of a DoD contract in excess of \$100 million, disclosure of the agency's written source selection decision document, redacted to protect the confidential and proprietary information of other offerors for the contract award.

(End of provision).

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

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

NAICS CODE AND SIZE STANDARD

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

1. The North American Industry Classification System (NAICS) code for this acquisition is 541618.
2. The small business size standard is \$19 million.

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.

TYPE OF CONTRACT AND NUMBER OF AWARDS

1. It is anticipated that one award will be made from this solicitation and that the award(s) will be made on/about August 18, 2026.
2. It is anticipated that the award(s) from this solicitation will be a multiple-year Fixed-Price type Completion contract with a Period of Performance of August 18, 2026 through August 17, 2031, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).
3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a Contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

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.

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.

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.

PREPARATION COSTS

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

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:

Contracting Officer
Office of Acquisitions

_____ Room
_____ MSC
_____ -

- 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).

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 fixed price 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:

a. 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.

b. 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.

c. 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. Page and Formatting Limitations

The Technical Plan (objectives, approach, methods and procedures, and substudy proposal) of the technical proposal shall not exceed 30 single-sided pages or 15 double-sided pages. This page limitation does not include the cover sheet, abstract, table of contents, personnel, facilities, equipment and resources, other considerations, schedule, other support, cost information, and literature cited. The substudy proposal section of the Technical Plan (included within the 30 page limit) shall not exceed 8 single-sided or 4 double-sided pages. Appendices shall not exceed a total of 50 single-sided pages or 25 double-sided pages. Pages in excess of the limitation will be deleted and will be neither read nor evaluated. Each page of the technical proposal must be numbered sequentially. Offerors are encouraged to limit the overall size of the technical proposal, inclusive of appendices, attachments, etc. Although no page limit has been placed on the business proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.

Type density and size must be 10 to 12 points. If constant spacing is used, 15 cpi (characters per inch) or fewer shall be used, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be no less than ½ inch around, exclusive of headers and footers.

6. 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.

7. Evaluation of Proposals

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

8. 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.

9. 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.

10. Standards for Privacy of Individually Identifiable Health Information

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR).

DHHS provides information about health information privacy here:

<https://www.hhs.gov/hipaa/for-professionals/index.html>. Discussion of the definition of "covered entities" and "business associates" can be found here:

<https://www.hhs.gov/hipaa/for-professionals/covered-entities/index.html>. Decisions about the applicability and implementation of the Privacy Rule reside with the Contractor and his/her institution. Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

11. 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.

12. Selection of Offerors

1. 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.
2. The business portion of each contract proposal found to be technical acceptable will be subjected to a cost and price analysis, management analysis, etc.
3. 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.
4. If the Government intends to conduct discussions prior to awarding a contract –
 - a. 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.

- b. 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.

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.

- c. While it is OD's policy to conduct discussions with all offerors in the competitive range, OD 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.
- 5. 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.
 - 6. The OD 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 OD requirements. Synopses of awards exceeding \$25,000 will be published in Contract Opportunities at: <https://sam.gov/content/home>.

13. 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>

14. 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.

15. Certification Regarding Tax Matters, FAR 52.209-12 (Oct 2020).

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

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

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

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

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

(End of provision).

16. Past Performance Information

- a. Offerors shall submit the following information as part of their Business proposal.
- b. A list of the last 3 contracts completed during the past Three years and ALL CONTRACTS 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 \$700,000 or greater.
- c. 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.

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

17. Information and Communication Technology Accessibility Notice, HHSAR 352.239-78 (Feb 2024) (Deviation).

- a. Any offeror responding to this solicitation must comply with established HHS Information and Communication Technology (ICT) accessibility standards. Information about Section 508 is available at <https://www.hhs.gov/web/section-508/index.html>.
- b. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-79 Information and Communication Technology Accessibility. In order to facilitate the Government's determination whether proposed ICT supplies, products, platforms, information, and documentation meet applicable Section 508 accessibility standards, offerors must submit an appropriate HHS Section 508 Accessibility Conformance Checklist (see <https://www.hhs.gov/web/section-508/accessibility-checklists/index.html>) or an Accessibility Conformance Report (ACR) (based on the Voluntary Product Accessibility Template (VPAT) see <https://www.itic.org/policy/accessibility/vpat>), in accordance with the completion instructions. The purpose of the checklists and conformance reports are to assist HHS acquisition and program officials in determining whether proposed ICT supplies, products, platforms, information, and documentation conform to applicable Section 508 accessibility standards. Checklists and ACRs evaluate—in detail—whether the ICT conforms to specific Section 508 accessibility standards and identifies remediation efforts needed to address conformance issues.
- c. If an offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies, products, platforms, information, documentation, or services support delivered do not conform to the described accessibility standards, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.
- d. In order to facilitate the Government's determination whether proposed ICT supplies meet applicable Section 508 accessibility standards, offerors must submit an Accessibility Conformance Report, in accordance with its completion instructions and tailored to the requirements in the solicitation. The purpose of the Report is to assist

HHS acquisition and program officials in determining whether proposed ICT supplies conform to applicable Section 508 accessibility standards. The template allows offerors or developers to self-evaluate their supplies and document, in detail, whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available at <https://Section508.gov/>.

- e. In order to facilitate the Government's determination whether proposed ICT services meet applicable Section 508 accessibility standards, offerors must provide enough information to assist the Government in determining that the ICT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.
- f. Respondents to this solicitation must identify any inability to conform to Section 508 requirements. If an offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.
- g. Items delivered as electronic content must be accessible to HHS acceptance criteria. Checklist for various formats are available at <http://508.hhs.gov/>. Materials, other than items incidental to contract management, that are final items for delivery should be accompanied by the appropriate checklist, except upon approval of the Contracting Officer or Contracting Officer's Representative.

(End of provision).

18. Information and Communication Technology Accessibility, HHSAR 352.239-79 (Feb 2024) (Deviation).

- a. Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all information and communication technology (ICT) supplies, products, platforms, information, documentation, and services support developed, acquired, maintained or delivered under this contract or order must comply with the Revised 508 Standards, which are located at 36 C.F.R. 1194.1 and Appendices A, B, and C, and are available at <https://www.access-board.gov/ict/>. Information about Section 508 is available at <https://www.hhs.gov/web/section-508/index.html>.
- b. Additional Section 508 accessibility standards applicable to this contract or order may be identified in the specification, statement of work, or performance work statement. If it is determined by the Government that ICT supplies, products, platforms, information, documentation, and services support provided by the Contractor do not conform to the described accessibility standards in the contract, remediation of the supplies, products, platforms, information, documentation, or services support to the level of conformance specified in the contract will be the responsibility of the Contractor at its own expense.

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

(End of clause).

19. 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, RFO Provision 52.204-7 (Nov 2025).

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

- b. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (DEVIATION) (Nov 2025).

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.

c. 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.

d. Technical Evaluation

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

e. Human Subjects

IMPORTANT NOTE TO OFFERORS: The following subparagraphs shall be addressed, as applicable, in a SEPARATE FILE of the Technical Proposal entitled, "HUMAN SUBJECTS."

- a. **Notice to Offerors of Requirements, Protection of Human Subjects, HHSAR 352.235-70** (Mar 2026) (RFO DEVIATION).
 - (a) The Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR part 46, are available on the Office for Human Research Protections (OHRP) website at:
<http://www.hhs.gov/ohrp/index.html>.
 - I. These regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of human subjects participating in research activities supported or conducted by HHS.
 - (b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data or identifiable public information through intervention or interaction with the individual, or identifiable private information. In most cases, the regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. 45 CFR part 46 does not directly regulate the use of autopsy materials; instead, applicable state and local laws govern their use.
 - (c) Activities which involve human subjects in one or more of the categories set forth in 45 CFR 46.104(d)(1)-(8) are exempt from complying with 45 CFR part 46. See
<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html>.
 - (d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal.
 - (e) In accordance with 45 CFR part 46, Offerors considered for award must file an acceptable Federal-wide Assurance (FWA) of compliance with OHRP specifying review procedures and assigning responsibilities for the protection of human subjects. The FWA is the only type of assurance that

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

- (f) Offerors may consult with OHRP only for general advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. ONLY the contracting officer may offer information concerning a solicitation.
- (g) The Offeror must document in its proposal the approved or active FWA from OHRP, related to the designated Institutional Review Board (IRB) reviewing and overseeing the research.
 - I. If the Offeror does not have an approved FWA from OHRP, the Offeror must obtain an FWA before the deadline for proposal submission.
- (h) When possible, the Offeror must also certify the IRB's review and approval of the research. If the Offeror cannot obtain this certification by the time of proposal submission, they must include an explanation in their proposal.
- (i) Never conduct research covered by 45 CFR part 46 prior to receiving certification of the research's review and approval by the IRB.

(End of provision)

Alternate I (March 2026) (RFO DEVIATION).

If the Offeror does not have an active FWA from OHRP, the Offeror must take all necessary steps to obtain an FWA prior to the proposal submission deadline. If the Offeror cannot obtain an FWA before the proposal submission deadline, the proposal must indicate the steps/actions the Offeror will take to obtain OHRP approval within (Contracting Officer insert a time period in which the FWA must be obtained). Upon obtaining FWA approval, submit the approval notice to the Contracting Officer.

b. Instructions to Offerors Regarding Protection of Human Subjects

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

1. Risks to the subjects
 - a. Human Subjects Involvement, Characteristics, and Design:
 - i. Briefly describe the overall study design in response to the solicitation.
 - ii. Describe the subject population(s) to be included in the study; the procedures for assignment to a study group, if relevant; and the anticipated numbers of subjects for each study group.
 - iii. List any collaborating sites where human subjects research will be performed, and describe the role of those sites and collaborating investigators in performing the proposed research.
 - b. Study Procedures, Materials, and Potential Risks
 - i. Describe all planned research procedures (interventions and interactions) involving study subjects; how research material, including biospecimens, data, and/or records, will be obtained; and whether any private identifiable information will be collected in the proposed research project.
 - ii. For studies that will include the use of previously collected biospecimens, data or records, describe the source of these materials, whether these can be linked with living individuals, and who will be able to link the materials.
 - iii. Describe all the potential risks to subjects associated with each study intervention, procedure or interaction, including physical, psychological, social, cultural, financial, and legal risks; risks to privacy and/or confidentiality; or other risks. Discuss the risk level and the likely impact to subjects.
 - iv. Where appropriate, describe alternative treatments and procedures, including their risks and potential benefits. When alternative treatments or procedures are possible, make the rationale for the proposed approach clear.
2. Adequacy of Protection Against Risks
 - a. Recruitment and Informed Consent:
 - i. Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. When appropriate, describe how potential adult subjects' capacity

to consent will be determined and the plans for obtaining consent from a legally authorized representative for adult subjects not able to consent. The informed consent document for the Contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the Contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

1. For research involving children: If the proposed studies will include children, describe the process for meeting HHS regulatory requirements for parental permission and child assent (45 CFR 46.408). See the HHS page on Research with Children FAQs and the NIH page on Requirements for Child Assent and Parent/Guardian Permission.
 2. If a waiver of some or all of the elements of informed consent will be sought, provide justification for the waiver.
- b. **Protection Against Risk:**
- i. Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
 - ii. Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
 - iii. In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.
- c. **Vulnerable Subjects, if relevant to your study** - Explain the rationale for the involvement of special vulnerable populations, such as fetuses, neonates, pregnant women, children, prisoners, institutionalized individuals, or others who may be considered vulnerable populations. 'Prisoners' includes all subjects involuntarily incarcerated (for example, in detention centers).
- i. **Pregnant Women, Fetuses, and Neonates or Children** - If the study involves vulnerable subjects subject to additional protections under

Subparts B and D (pregnant women, fetuses, and neonates or children), provide a clear description of the risk level and additional protections necessary to meet the HHS regulatory requirements.

1. HHS' Subpart B - Additional Protections for Pregnant Women, Fetuses, and Neonates
 2. HHS' Subpart D - Additional Protections for Children
 3. OHRP Guidance on Subpart D Special Protections for Children as Research Subjects and the HHS 407 Review Process
- d. Potential Benefits of the Proposed Research to the Subjects and Others
- i. Discuss the potential benefits of the research to the subjects and others.
 - ii. Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
 - iii. Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

Note: Financial compensation of subjects should not be presented as a benefit of participation in research.

- e. Importance of the Knowledge to be Gained
- i. Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
 - ii. Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note : If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

c. Required Education in the Protection of Human Research Participants

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 and amended September 24, 2010, at the following website: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html> . Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH Office of Extramural Research (OER) on-line tutorial, entitled "Protecting Human Research Participants" at: <https://phrptraining.com/> . This course is also available in Spanish under the title "Protección de los participantes humanos de la investigación" at: <https://phrptraining.com/> . You may take the tutorials on-line or download the information in PDF form at no cost. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement.

If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

d. Inclusion of Women and Minorities in Research Involving Human Subjects

NIH-conducted and supported clinical research must conform to the NIH Policy and Guidelines on the Inclusion of Women and Members of Racial and/or Ethnic Minority Groups as Subjects in Clinical Research in accord with Public Health Service Act sec. 4928 U.S.C. sec 289a-2. The policy requires that women and members of racial and/or ethnic minority groups and their subpopulations must be included in all NIH-conducted or supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant NIH Institute/Center (IC) Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an IC Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Members of Racial and/or Ethnic Minority Groups as Subjects in Clinical Research, effective August 16, 2025," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-131.html>

Effective August 16, 2025, these guidelines contain a definition of clinical research, as: “

Research with human participants that is:

(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. It includes: (a) mechanisms of human disease, (b), therapeutic interventions, (c) clinical trials, or (d) development of new technologies; or

(2) Epidemiological and behavioral studies; or

(3) Outcomes research and health services research.”

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and members of racial and/or ethnic minority groups in

the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex and racial and/or ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex, or racial and/or ethnic group
- The proposed sample composition using the "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report" (see Section J, Attachments)
-

NOTE 1 : For all proposals, use the ethnic and racial categories and complete the "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report" in accordance with the Office of Management and Budget (OMB) for all Application Packages after January 25, 2018, which may be found at :
<https://grants.nih.gov/policy/clinical-trials/new-human-subject-clinical-trial-info-form.htm> .

NOTE 2 : If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in RFO 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.

Standards for Collecting Data . When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in Appendix A- Revisions to the Standards for the Classification of Federal Data on Race and Ethnicity at: https://nces.ed.gov/programs/handbook/data/pdf/Appendix_A.pdf . The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and

ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for NIH defined Phase III clinical trials * require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect ((see NIH Guide:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-131.html>, Definitions – D. Significant Difference).

*The definition of an " NIH-Defined Phase III clinical trial " can also be found at this website.) by sex, racial and/or ethnic minority groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex and racial and/or ethnic minority group differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex and/or racial and/or ethnic minority subgroups when prior studies strongly support these significant differences among subgroups,

OR

- Plans to include and analyze sex and/or racial and/or ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups,

OR

- Plans to conduct valid analyses of the intervention effect in sex and/or racial and/or ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form entitled, "PHS Human Subjects and Clinical Trials Information Form/Planned Enrollment Report," when preparing your response to the solicitation requirements for inclusion of women and members of racial and/or ethnic minority groups. (See Section J-List of Documents, Exhibits and Other Attachments of the RFP)

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex specific study or a single or limited number of racial and/or ethnic minority population groups. Therefore, the NIH believes that the inclusion of women and racial and/or minority groups is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the form entitled, "PHS Human Subjects and Clinical Trials Information Form/Cumulative Inclusion Enrollment Report," for reporting in the resultant contract.

e. Inclusion of Children in Research Involving Human Subjects

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are clear and compelling reasons not to include them. (See examples of Justifications for Exclusion of Children below). For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 18 years.

All Offerors proposing research involving human subjects should read the "Inclusion of Children in Clinical Research: Change in NIH Definition " which was published in the NIH guide notice on October 13, 2015 and is available at the following URL address:

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-010.html>

Offerors also may obtain copies from the contact person listed in the RFP.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the

inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- a. The objective of the solicitation is not relevant to children.
 - i. There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
 - ii. The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
 - iii. A separate, age-specific study in children is warranted and preferable. Examples include:
 1. The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
 2. The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
 3. Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
 4. Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
 5. Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
 6. Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 18 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an

individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 18) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

f. Research Involving Prisoners as Subjects

- a. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: <http://www.hhs.gov/ohrp/policy/prisoner.html>.
- b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:
 - a. To describe the prevalence or incidence of a disease by identifying all cases, or
 - b. to study potential risk factor associations for a disease, and
2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2 7) and determined and documented that:
 - a. The research presents no more than minimal risk, and
 - b. no more than inconvenience to the prisoner subjects, and

- c. prisoners are not a particular focus of the research.

For more information about this Waiver see
<http://www.gpo.gov/fdsys/pkg/FR-2003-06-20/html/03-15580.htm> .

g. Public Health Surveillance Exclusion

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

Requesting a Determination that NIH-Funded or -Conducted Activities be Considered Public Health Surveillance:

Offerors shall provide a compelling justification as to why NIH-funded or -conducted activities should be considered public health surveillance activities deemed not to be research for the purposes of the revised Common Rule. Refer to the attached template in Section J. All activities for which approval of the exclusion will be sought must be disclosed and described.

The justification shall include information that demonstrates **all three (3)** of the following:

- i. The proposed activity is strictly limited to only that necessary for NIH to identify, monitor, assess, or investigate:
 - (a) Potential public health signals; or
 - (b) Onsets of disease outbreaks; or
 - (c) Conditions of public health importance (including trends, signals, risk factors, or patterns in diseases).AND
- ii. The activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
AND
- iii. The activities will directly inform NIH public health decision-making or action.

Note: An Offeror shall submit its compelling justification for exclusion with its technical proposal as a separate attachment, so that the justification can be detached from and evaluated apart from the Offeror's technical proposal. The Government reserves the right to not consider any public health surveillance exclusion requests if the justification is not provided at the time of original proposal submission.

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

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

Notice of Approval or Disapproval of Request for Exclusion

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

The award budget may then be adjusted accordingly if approval of an exclusion is granted by NIH.

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

h. Human Stem Cell Research

On March 9, 2009, the President issued Executive Order (EO) 13505: Removing Barriers to Responsible Scientific Research Involving Human Stem Cells. The NIH has published Guidelines on Human Stem Cell Research at: <https://stemcells.nih.gov/research-policy/guidelines-for-human-stem-cell-research> . The Guidelines implement EO 13505

with regard to extramural NIH-funded human stem cell research, establish policy and procedure under which the NIH will fund such research, and help ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law.

To facilitate research using human embryonic stem cells, the NIH has established a Human Embryonic Stem Cell Registry ("the NIH Registry") that lists the human embryonic stem cells that are currently eligible for use in NIH-funded research. This registry is available at: https://grants.nih.gov/stem_cells/registry/current.htm . Proposed human embryonic stem cell line(s) must be on the NIH Registry at the time of proposal submission. Any possible changes to the proposed cell line must be discussed in the proposal. Offerors wishing to have Human Embryonic Stem Cell Lines added to the NIH Human Embryonic Stem Cell Registry must submit the request on Form NIH 2890 through the following website: https://hescregapp.od.nih.gov/NIH_Form_2890_Login.htm .

See Section H of this solicitation for more details.

i. PHS HUMAN SUBJECTS AND CLINICAL TRIALS INFORMATION FORM

Offerors shall submit the "PHS Human Subjects and Clinical Trials Information Form" with each technical proposal for work involving human subjects.

FORM SUBMISSION INSTRUCTIONS

- a. The PHS Human Subjects and Clinical Trials Information Form must be submitted with your technical proposal.
- b. Offerors must use the form and follow the associated instructions posted on the website at: <https://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files>.

j. INCLUSION OF INDIVIDUALS ACROSS THE LIFESPAN AS PARTICIPANTS IN RESEARCH INVOLVING HUMAN SUBJECTS

Section 2038 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions requiring NIH to address the consideration of age as an inclusion variable in research involving human subjects, to identify criteria for justification for any age-related exclusions in NIH research, and to provide data on the age of participants in clinical research studies. The NIH Policy and Guidelines on the Inclusion of Individuals Across the Lifespan as Participants in Research Involving Human Subjects applies to all NIH conducted or supported research involving human subjects, including research that is otherwise "exempt" in accordance with Sections 101(b) and 401(b) of 45 CFR 46 - Federal Policy for the Protection of Human Subjects.

Effective on all solicitations issued on or after January 25, 2019, individuals of all ages, including children (i.e. individuals under the age of 18) and older adults, must be included in all human subjects research, conducted or supported by the NIH, unless there are scientific or ethical reasons not to include them. The inclusion of individuals

across the lifespan as subjects in research must be in compliance with all applicable subparts of 45 CFR 46 as well as with other pertinent federal laws and regulations.

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

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

k. POSTING CLINICAL TRIAL INFORMED CONSENT FORMS TO CLINICALTRIALS.GOV

The Revised Common Rule sections 46.102(b) and 46.116(h) requires Contractors with to post one IRB-approved version of an Informed Consent Form that has been used to enroll participants on a public federal website designated for posting such Consent Forms. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database <https://clinicaltrials.gov/>. Note: ClinicalTrials.gov only accepts Informed Consent Forms written in English; non-English language forms must be submitted to <https://www.regulations.gov/>.

- a. Contractors shall post the Informed Consent Form to the National Institutes of Health's (NIH's) clinical trials registry and results database <https://clinicaltrials.gov/>
- b. The Informed Consent Form must be posted after recruitment closes, and no later than 60 days after the final study visit.
- c. The Contracting Officer (CO) and/or Contracting Officer's Representative (COR) may permit or require redactions as appropriate.
- d. Informed Consent Forms for the clinical trial(s) shall include a specific statement relating to posting of clinical trial information at <https://clinicaltrials.gov/>
- e. Informed Consent Forms must be compliant with the HHS Policy for the Protection of Human Research Subjects (45 CFR 46).

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

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before awarding a contract to an offeror, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC). In accordance with the PHS Policy, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6700B Rockledge Drive, Suite 2500, MSC 6910 Bethesda, MD 20892-6910 (Email: olaw@od.nih.gov ; Phone: 301-496-7163).

The PHS Policy is available on the internet at: <https://olaw.nih.gov/>.

(End of provision).

m. Research Involving Live Vertebrate Animals

It is intended that live vertebrate animals will be used during performance of this contract. The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (authority derived from the Health Research Extension Act of 1985) specifies that certain information is required from offerors in contract proposals submitted to the NIH that will use live vertebrate animals.

The following criteria must be addressed in a separate section of the Technical Proposal titled "Vertebrate Animal Section" (VAS):

- a. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
- b. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).

- c. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
- d. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

A concise (no more than 1-2 pages), complete description addressing these criteria must be provided. The description must be cohesive and include sufficient information to allow evaluation by reviewers and NIH staff. For more discussion regarding the VAS, see NIH Guide Notice NOT-OD-16-006 at: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-006.html>.

The Contract Proposal VAS Worksheet is provided as an Attachment in SECTION J of this solicitation to assist in the preparation of the VAS as part of the Technical Proposal. It can be accessed at: <https://grants.nih.gov/grants/olaw/vascontracts.pdf>.

n. 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>.

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:

- i. Solicitation, contract, and/or modification number;
- ii. Name and address of Offeror;
- iii. Name and telephone number of point of contact;
- iv. Name, address, and telephone number of Contract Administration Office, (if available);
- v. Name, address, and telephone number of Audit Office (if available);
- vi. Proposed cost and/or price; profit or fee (as applicable); and total;
- vii. 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.
- viii. Date of submission; and
- ix. Name, title and signature of authorized representative.

This cover sheet information is for use by offerors to submit information to the Government when certified cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not required to be certified in accordance with RFO 15.402.

3. 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.

4. Multi-year Contract

a. General

The Government intends to award any contract resulting from this solicitation under the terms and conditions of Revolutionary FAR Overhaul (RFO) Subpart 17.1, Multi-year Contracting. A multi-year contract may provide that performance under the contract during the second and subsequent years of the contract is contingent upon the appropriation of funds. It also may provide for a cancellation payment to be made to the Contractor if appropriations are not made.

Funding will be obligated to cover performance of the first program year plus cancellation liability, if any. Thereafter, performance will be funded as specified in Section B of the contract.

b. Proposal Preparation and Evaluation

In accordance with RFO 17.103-3(a)(4), contract award will not be made on less than the requirements of the first program year; therefore, the offeror's proposal shall specifically identify the costs for the first program year, each subsequent program year, and the total multi-year contract.

Proposals will be evaluated in accordance with the evaluation factors set forth in Section M of this solicitation. The evaluation will consider the offeror's price and ability to perform the first program year as well as the total multi-year requirement. Award will be made based on the best overall value to the government.

If the Government determines before award that only the first program year requirements are needed, the Government's evaluation of the price or estimated cost and fee, if applicable, shall consider only the first year.

5. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$9000,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," RFO Clause No. 52.219-9, incorporated herein by reference in the Solicitation. In accordance with RFO 19.206-2 and RFO Clause 52.219-9, the submission of a subcontracting plan by other than small business offeror(s) is a requirement as a part of the proposal submission process and is to be submitted separately from the technical and cost proposals. An offeror's subcontracting plan must be determined to be acceptable, by the Contracting Officer, prior to the contract award.

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

THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

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.

The offeror understands that:

- a. 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.

- b. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
- c. 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.
- d. 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.
- e. It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
- f. 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.

Each plan must contain the following:

- g. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
- h. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
- i. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
- j. A description of the method used to develop the subcontracting goals.
- k. A description of the method used to identify potential sources for solicitation purposes.
- l. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small,

Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

- m. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
- n. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
- o. 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.
- p. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) to the Government at <https://www.SAM.gov>
- q. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

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

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

32.35% for Small Business; 5.45% for Small Disadvantaged Business; 8.95% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

6. 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—
- 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' OSDDBU;
 - 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' OSDDBU; and
 - Mentor-Protege agreements--joint agreements, approved by HHS' OSDDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision).

7. HUBZone Small Business Concerns

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

8. Other Administrative Data

- a. Property
- 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:
 - State why the property is essential to contract performance and whether the property will be used exclusively for this contract.
 - Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.
 - Government Property
The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:
 - a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);

- b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;
- c. The amount of rent that would otherwise be charged in accordance with RFO 52.245-9, Use and Charges; and
- d. A description of the offeror's property management system, plan, and any customary commercial practices, voluntary consensus standards, or industry-leading practices and standards to be used in the offeror in managing Government property.

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

- Government-Furnished Property

No Government Furnished Property is offered for this acquisition

- The management and control of any Government property shall be in accordance with the HHS Publication entitled, "Appendix Q, HHS Contracting Guide for Contract of Government Property," which can be found at:
[https://oamp.od.nih.gov/sites/default/files/DGS/HHS Contracting Guide for Contract of Government Property-Appendix Q.pdf](https://oamp.od.nih.gov/sites/default/files/DGS/HHS%20Contracting%20Guide%20for%20Contract%20of%20Government%20Property-Appendix%20Q.pdf).
- **Submission of Electronic Funds Transfer Information with Offer, RFO Clause 52.232-38 (Jul 2013).**

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

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

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

(End of provision).

- **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.

- **Adequate Accounting System**

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

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

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

- i. Complies with Generally Accepted Accounting Principles (GAAP).
- ii. Provides for:
 - a. Proper segregation of direct costs from indirect costs.
 - b. Identification and accumulation of direct costs by contract.
 - c. A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
 - d. Accumulation of costs under general ledger control.
 - e. A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
 - f. A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
 - g. Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
 - h. Exclusion from costs charged to government contracts of amounts that are not allowable in terms of RFO 31, "Contract Cost Principles and Procedures," or other contract provisions.
 - i. Identification of costs by contract line item and by units (as if each unit or line item were a separate contract) if required by the proposed contract.
 - j. Segregation of preproduction costs from production costs, if applicable.

- iii. Accounting system provides financial information:
 - a. Required by contract clause concerning limitation of cost (RFO 52.232-20) or limitation on payments (RFO 52.216-16).
 - b. Required to support requests for progress payments.
- iv. 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.
- v. 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.

9. 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.

10. Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- a. Willingness to perform as a subcontractor for specific duties (list duties).
- b. What priority the work will be given and how it will relate to other work.
- c. The amount of time and facilities available to this project.
- d. Information on their cognizant field audit offices.
- e. How rights to publications and patents are to be handled.
- f. A complete cost proposal in the same format as the offeror's cost proposal.

11. Proposer's Annual Financial Report

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

12. Travel Costs/Travel Policy

a. Travel 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 significantly more important than cost/price. 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 RFO 15.404.

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

Cost Realism will be evaluated only on the offeror(s) inputs which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the offeror's proposal. Cost realism analysis will be conducted in accordance with RFO 15.404-3. The result of the cost realism analysis will be considered in the making the best value tradeoff decision.]

3. MULTI-YEAR CONTRACT

The evaluation will consider the offeror's price and ability to perform the first program year as well as the total multi-year requirement to assess whether the contractor's anticipated costs are unbalanced and to ensure that the proposed costs are consistent with the proposed effort across all program years. Within the context of RFO Subpart 17.1, "program year" has the same meaning as "contract year."

If the Government determines before award that only the first contract year requirements are needed, the Government's evaluation of the offeror's price and ability to perform shall consider only the first year.

The evaluated price will be determined by comparing the lowest priced proposal for the first program year to the lowest priced proposal for the entire multi-year period of performance. If the lowest priced proposal for the first program year is also the lowest priced proposal for the entire multiyear period of performance, then that proposal is the lowest priced proposal. If the lowest priced proposal for the first program year is not the same as the lowest priced proposal for the entire multiyear period, the lowest priced proposal will be determined by assessing the probability that the contract will continue for the entire multiyear period together with the magnitude of the price difference between the proposals. For example, if the Government determines that it is nearly certain that the contract will continue for the entire multiyear period, the proposal with the lowest price over the entire multiyear period will most probably be considered to be the low priced proposal.

4. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

a. Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

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

b. Women and Members of Racial and/or Ethnic Minority Groups

Women and members of racial and/or ethnic minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-

Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide Notice NOT-OD-25-131 at <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-131.html>, Definitions - Significant Difference) by sex, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups,
OR
- Plans to include and analyze sex and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged),
OR
- Plans to conduct valid analyses of the intervention effect in sex and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and members of racial and/or ethnic minority groups as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- Whether the plan proposed includes minorities and both sexes in adequate representation
- how the offeror addresses the inclusion of women and members of racial/ethnic minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for exclusion based on sex, the reviewers will examine the rationale to determine if it is because:
 - The purpose of the research constrains the offeror's selection of study participants by sex (e.g., uniquely valuable stored specimens or existing datasets are single sex; very small numbers of subjects are involved; or
 - overriding factors dictate selection of subjects); or
 - sex representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.
- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:

- Inclusion of those groups would be inappropriate with respect to their health; or
 - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and members of racial and/or ethnic minority groups is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed women/minority inclusion plans, or concerns are identified as to the sex or minority representation, or the proposal does not adequately address limited representation of one sex or minority groups; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

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

c. Children

Children (i.e. individuals under the age of 18) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful

analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance with NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

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

5. LIVE VERTEBRATE ANIMALS EVALUATION

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

- a. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the Request for Proposal (RFP) Statement of Work. Identify the species, strains, ages, sex and total number of animals by species to be used in the proposed work. If dogs or cats are proposed, provide the source of the animals.
- b. Justifications. Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).
- c. Minimization of Pain and Distress. Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain and injury.
- d. Euthanasia. State whether the method of euthanasia is consistent with the recommendations of the American Veterinary Medical Association (AVMA) Guidelines for the Euthanasia of Animals. If not, describe the method and provide a scientific justification.

As part of the overall technical evaluation of proposals, the reviewers will consider the acceptability of the offeror's description in the VAS of the technical proposal. The discussion of all criteria will be addressed and evaluated. Based on the evaluation of this Section, the VAS may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the description addressing each of the criteria, or no discussion can be found regarding the VAS), or "acceptable." If the reviewers find that this Section of the technical proposal is "unacceptable" they will provide a narrative supporting their findings.

If the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be

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

6. EVALUATION OF OPTIONS

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

In accordance with RFO Clause 52.217-5, Evaluation of Options, (Nov 2025), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with RFO 17.202 not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

7. TECHNICAL EVALUATION FACTORS

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

8. 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.

9. SUBCONTRACTING PROGRAM EVALUATION FACTORS

The offeror's proposed Small Business Subcontracting Plan will be evaluated to determine whether it represents the maximum practicable opportunity for subcontracting. Because the offeror's record of previous performance in carrying out the intent of the subcontracting program will be considered as a significant sub-factor, each offeror is encouraged to submit subcontracting plans and documentation that demonstrates their prior corporate support for small, small disadvantaged, women-owned small, HUBZone small, veteran-owned small, and service-disabled veteran-owned small business suppliers.

If offers are received from both large and small businesses, the small business offerors shall receive the maximum possible number of points for this factor.