SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Requisition or other Purchase Authority: FAR 1.602-1		
2. **Request for Proposal (RFP) Number:** 75N93019R00027 including changes in Amendment 1	3. **Issue Date:** November 22, 2019	4. **Set Aside:** [X] No [ ] Yes See Part IV Section L

5. Title : Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases

6. ISSUED BY: Office of Acquisitions (OA) National Institute of Allergy and Infectious Diseases (NIAID) National Institutes of Health (NIH) 5601 Fishers Lane, Rm 3B54, MS 9821 Rockville, MD. 20892-9821	7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation. **NOTE:** This solicitation has a required total page limitation of not to exceed 175 pages for the technical proposal.

8. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 1:00 pm local time on February 7, 2020. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.

9. This solicitation requires delivery of proposals as stated in ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." If proposals are required to be delivered to two different locations, the OFFICIAL POINT OF RECEIPT for determining TIMELY DELIVERY is the address provided for the OFFICE OF ACQUISITIONS.

IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS/HER DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH subparagraph (c)(3) of FAR Clause 52.215-1, Instructions to Offerors--Competitive Acquisition," LOCATED IN SECTION L.1. OF THIS SOLICITATION.

10. Offeror must be registered in the System for Award Management (SAM) prior to award of a contract. Offerors must access the CCR through The System for Award Management (SAM) at http://www.sam.gov

11. FOR INFORMATION CONTACT: Chase Sullivan, Contract Specialist
Phone Number: 240-669-5141 e-MAIL: chase.sullivan@nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.

Deadline for receipt of offerors' questions pertaining to this RFP: Monday December 22, 2019.	Michael C. Finn Contracting Officer Office of Acquisitions, DEA NiAID, NIH, DHHS

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PART I - THE SCHEDULE

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

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The scope of activities to be performed by the Contractor shall encompass development and operational management of a Statistical and Data Coordinating Center.

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. ESTIMATED COST - OPTION

1. The estimated cost of the Base Period of this contract is $_____.
2. The fixed fee for the Base Period of this contract is $_____. [**For completion contracts:** The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer./ **For level of effort contracts:** The fixed fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended.] Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract.
3. The total estimated amount of the contract, represented by the sum of the estimated cost plus the fixed fee for the Base Period is $_____.
4. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total estimated contract amount represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost ($)	Fixed Fee ($)	Estimated Cost Plus Fixed Fee ($)
Base Period (12/31/2020 - 12/ 30/ 2021)			
Term Options			
Option 1 (12/ 31/ 2021 - 12/ 30/ 2022)			
Option 2 (12/31/2022 - 12/30/2023)			
Option 3 (12/31/2023 - 12/30/2024)			
Option 4 (12/31/2024 - 12/30/2025)			
Option 5 (12/31/2025 - 12/30/2026)			
Option 6 (12/31/2026 - 12/30/2027)			
Quantity Options (FAR 52.217-6)			
Option 7 (Add 5 full-time equivalents)			
Option 8 (Add 15 full-time equivalents)			
Non-Serverable Options (FAR 52.217-7)			
Option 9 (Initial Transition)			
Option 10 (Final Transition)			
Extension of Services (FAR 52.217-8)			
Option 11 (Add maximum of 6 months)			
Total [Base Period and Option(s)]			

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.5. 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.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently, and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated August 22, 2019, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at: http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

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, in accordance with FAR 4.302(b).

a. Technical Progress Reports

1. 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.*

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

2. Summary of Salient Results

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

b. Other Reports/Deliverables

1. Source Code and Object Code

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

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

All reports required herein shall be submitted in electronic format. All electronic contract deliverables shall be submitted via the NIAID electronic Report Deliverable Submission (eRDS) Site, available at the following website: https://erds.niaid.nih.gov/. All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional
information about testing documents for Section 508 compliance, including guidance and specific checklists, by application, can be found at http://www.hhs.gov/web/508/index.html under "Making Files Accessible."

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

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

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The first annual utilization report shall be due on or before December 30, 2021. Thereafter, reports shall be due on or before the last day of the month following the reporting period. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Office of Acquisition
3rd Floor
5601 Fishers Lane, Room 3B54
Bethesda, Maryland 20892- 9822

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

1. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
2. For the purpose of this SECTION, TBD is the authorized representative of the Contracting Officer.
3. Inspection and acceptance will be performed at:
   National Institute of Allergy and Infectious Diseases (NIAID)
   Divisoin of Microbiology and Infectious Diseases (DMID)
   Office of Clinical Research Affairs
   5601 Fishers Lane, Bethesda, 20892

   _____
   _____
   _____
   _____

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

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

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

1. The period of performance of this contract shall be from December 31, 2020 through December 30, 2021.
2. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased as listed below:

Option	Option Period
Term Option 1	12/31/2021 - 12/30/2022
Term Option 2	12/31/2022 - 12/30/2023
Term Option 3	12/31/2023 - 12/30/2024
Term Option 4	12/31/2024 - 12/30/2025
Term Option 5	12/31/2025 - 12/30/2026
Term Option 6	12/31/2026 - 12/30/2027
Non-Severable Option 10 Final Transition	TBD

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the items Attachment 18 - Reporting Requirements in accordance with the stated delivery schedule:

The items specified in Attachment 6 as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified in Attachment 18 - Reporting Requirements.

ARTICLE F.3. LEVEL OF EFFORT

a. During the period of performance of this contract, the Contractor shall provide 60 full-time equivalent (FTEs) per year. The labor hours should Include vacation, holiday, and sick leave. The Contractor shall include subcontractor labor hours. It is estimated that the number of FTEs are constituted as specified below and will be expended approximately as follows:

Labor [HOURS, MONTHS, YEARS]

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Principe Investigator	To be decided -->	---->	---->	---->	---->	---->	TBD
Other Professional	To be decided -->	---->	---->	---->	---->	---->	TBD

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Technical & Support	To be decided -->	---->	---->	---->	---->	---->	TBD
Totals	60	60	60	60	60	60	60

b. The Contractor shall have satisfied the requirement herein if not less than 90% nor more than 110% of the total FTEs specified herein are furnished. These terms and conditions do not supersede the requirements of either the "Limitation of Cost" or "Limitation of Funds" clause.

c. In the event fewer than the minimum specified FTEs in the total categories are used by the Contractor in accomplishing the prescribed work and the Government has not invoked its rights under FAR Clause 52.249-6, TERMINATION (Cost-Reimbursement) incorporated in this contract, these parties agree that the fee will be adjusted based solely upon the quantity of FTEs by which the number of FTE' furnished is less than the number of FTEs specified in this ARTICLE. The resulting adjustment shall be evidenced by a contract modification.

ARTICLE F.4. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 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.

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

To be specified prior to award.

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

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

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

The Government may unilaterally change its COR designation.

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

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

(End of Clause)

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

Name	
To be specified prior to award	

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

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

1. Payment requests shall be submitted to the offices identified below. **Do not submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless specified elsewhere in the contract or requested by the Contracting Officer.**

a. The original invoice shall be submitted to the following **designated billing office**:

National Institutes of Health
Office of Financial Management
Commercial Accounts
2115 East Jefferson Street, Room 4B-432, MSC 8500
Bethesda, MD 20892-8500

b. One copy of the invoice shall be submitted to the following **approving official**:

Contracting Officer
Office of Acquisitions
NIAID
_____Room ___
_____MSC ___
_____- ___

E-mail: NIAIDOAInvoices@niaid.nih.gov

The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number. ***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

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

1. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National institute of Allergy and Infectious Diseases .
2. 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, DUNS, or VIN, contact the Contracting Officer.
3. DUNS or DUNS+4 Number. The DUNS 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 DUNS 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, DUNS, or VIN, contact the Contracting Officer.

4. Invoice Matching Option. This contract requires a two-way match.

5. 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.

6. The Contract Title is:

Statistical Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases

g. Contract Line Items as follows:

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

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

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

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

ARTICLE G.4. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (December 2013)

a. Upon 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.

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, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of Clause)

ARTICLE G.5. INDIRECT COST RATES

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

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

These rates are hereby incorporated without further action of the Contracting Officer.

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

Contractor Performance Evaluations

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

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

Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address:

http://www.cpars.gov

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

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

ARTICLE H.2. NIH POLICY ON ENHANCING REPRODUCIBILITY THROUGH RIGOR AND TRANSPARENCY

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

ARTICLE H.3. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

NIH-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-071.html and http://publicaccess.nih.gov.

ARTICLE H.4. ACKNOWLEDGEMENT OF FEDERAL FUNDING

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

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

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

ARTICLE H.6. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

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

ARTICLE H.7. GUN CONTROL

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

ARTICLE H.8. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in SECTION I., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to FAR Clause 52.217-6, Option for Increased Quantity ; FAR Clause 52.217-7, Option for Increased Quantity - Separately Priced Line Item; FAR Clause 52.217-8, Option to Extend Services; and FAR Clause 52.217-9, Option to Extend the Term of the Contract, set forth in SECTION I. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee of the contract will be increased as set forth in the ESTIMATED COST - Option Article in SECTION B of this contract.

ARTICLE H.9. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

b. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

1. Individual Subcontract Reports (ISR)

   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:

   April 30th
   October 30th
   Expiration Date of Contract

2. Summary Subcontract Report (SSR)

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

   October 30th

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

chase.sullivan@nih.gov
Contract Specialist

ARTICLE H.10. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY NOTICE HHSAR 352.239-73 (December 2015)

1. a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

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

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

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

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

ARTICLE H.11. CONFIDENTIALITY OF INFORMATION

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

b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.

c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.

d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.

e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

The following information is covered by this article:

All data and other information pertaining to product supplied by Companies serving as industry collaborators ("the companies") for the clinical trials to be undertaken by the Contractor, or supplied by the Contracting Officer's Representative (COR), shall be assumed to be confidential unless specifically identified as not confidential in writing by the COR.

ARTICLE H.12. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under NIH contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: : http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45
As required by 45 CFR Part 94, the Institution shall, at a minimum:

1. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:

    1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds $5,000. Included are payments and equity interests;

    2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds $5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any equity interest; or

    3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

    Significant financial interests do not include the following:

1. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

2. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any NIH-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.

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

4. Require that each Investigator who is planning to participate in the NIH-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for NIH-funded research. Require that each Investigator who is participating in the NIH-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.

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

6. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).

7. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).

8. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

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

10. Complete the certification in Section K - Representations, Certifications, and Other Statements of Offerors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the NIH-funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the NIH-funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the NIH-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that NIH-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

ARTICLE H.13. PUBLICATION AND PUBLICITY

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

> "This project has been funded in whole or in part with Federal funds from the National Institute of Allery and Infectious Diseases (NIAID), National Institutes of Health, Department of Health and Human Services, under Contract No. TBD"

a. Advanced Copies of Press Releases

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

ARTICLE H.14. 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: http://oig.hhs.gov/fraud/hotline/ 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.15. SHARING RESEARCH DATA

[The data sharing plan submitted by the Contractor is acceptable/The Contractor's data sharing plan, dated _____is hereby incorporated by reference.] The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

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 the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

ARTICLE H.16. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

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

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

ARTICLE H.17. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

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

ARTICLE H.18. USE OF FUNDS FOR CONFERENCES, MEETINGS AND FOOD

The Contractor shall not use contract funds (direct or indirect) to conduct meetings or conferences in performance of this contract without prior written Contracting Officer approval.

In addition, the use of contract funds to purchase food for meals, light refreshments, or beverages is expressly prohibited.

The following conferences and/or meetings have been approved by the Contracting Officer and are hereby authorized under this contract:

Conference or Meeting Title	Conference or Meeting Location	Federal/NonFederal Space	Date of Conference	Not to Exceed Estimate Cost
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		
		[ ] Federal [ ] NonFederal		
		[ ] Federal		

		[ ] NonFederal		

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

The complete listing of these clauses may be accessed at:
https://oamp.od.nih.gov/DGS/reference-material-prospective-offerors-and-contractors

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

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:

a. *FAR Clause **52.215-23, Limitations on Pass-Through Charges** (October 2009), is added.*

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

c. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (November 2016) is added.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

1. FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (October 2015).

2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (October 2015).

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

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf

3. FAR Clause **52.204-14**, **Service Contract Reporting Requirements** (October 2016).

4. FAR Clause **52.204-18 Commercial and Government Entity Code Maintenance** (July 2016)

5. FAR Clause **52.209-10, Prohibition on Contracting With Inverted Domestic Corporations** (November 2015).

6. FAR Clause **52.217-6, Option for Increased Quantity** (March 1989).

   "...The Contracting Officer may exercise the option by written notice to the Contractor within 30 days prior to the exercise of the option(s). "

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

   "...The Contracting Officer may exercise the option by written notice to the Contractor within 30 days prior to the exercise of the option(s). "

8. FAR Clause **52.217-8, Option to Extend Services** (November 1999).

   ". The Contracting Officer may exercise the option by written notice to the Contractor within 30 days prior to the exercise of the option(s). "

9. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (October 2014).

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

10. FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (July 2013).

11. FAR Clause 52.222-26, **Equal Opportunity** (September 2016)

12. **Alternate V** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (May 2014).

Specific data items that are not subject to paragraph (j) include:

13. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).

14. FAR Clause **52.230-2, Cost Accounting Standards** (October 2015).

15. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (June 2010).

16. FAR Clause **52.237-3, Continuity of Services** (January 1991).

17. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).

18. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2014).

19. FAR Clause **52.246-23, Limitation of Liability** (February 1997).

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

1. HHSAR Clause **352.208-70, Printing and Duplication** (December 2015)

2. HHSAR Clause **352.231-70, Salary Rate Limitation** (December 2015)

   Note: *The Salary Rate Limitation is at the Executive Level II Rate.*

   See the following website for 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*.)

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

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

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

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

This contract incorporates the following clauses in full text.

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

1. *FAR Clause **52.209-9, Updates of Publicly Available Information Regarding Responsibility Matters** (July 2013)*

As prescribed in 9.104-7(c), insert the following clause:

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

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

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

i. *Government personnel and authorized users performing business on behalf of the Government; or*

ii. *The Contractor, when viewing data on itself; and*

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

i. *Past performance reviews required by subpart 42.15;*

ii. *Information that was entered prior to April 15, 2011; or*

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

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

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

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

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

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

(End of clause)

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

1. The Government may extend the term of this contract by written notice to the Contractor within the period of performance, provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 daysdays before the contract expires. The preliminary notice does not commit the Government to an extension.
2. If the Government exercises this option, the extended contract shall be considered to include this option clause.
3. The total duration of this contract, including the exercise of any options under this clause, shall not exceed seven-and-one-half (7 1/2) years.

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

c. THERE ARE NO APPLICABLE CLAUSES IN THIS SECTION.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:		Packaging and Delivery of Proposals for Use with the NIH electronic Contract Proposal Submission (eCPS) Website
Attachment 2:	Proposal Intent Response Sheet	
Attachment 3:	Statement of Work	
Attachment 4:	Section K - Representations, Certifications, and Other Statements of Offerors	
Attachment 5:	Definitions and Information	
Attachment 6:	Reporting Requirements	
Attachment 7:	Additional Technical Proposal Instructions, Format for Technical Proposal, and Table of Contents	
Attachment 8:	Additional Business Proposal Instructions and Uniform Cost Assumptions	
Attachment 9:	Advance Understandings	

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 10:	Technical Proposal Cost Summary	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/Tech-Prop-Cost-Summ.pdf
Attachment 11:	Summary of Related Activities	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/summary-related-activities.pdf
Attachment 12:	HHS Section 508 Product Assessment Template	http://www.hhs.gov/web/508/contracting/technology/vendors.html

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 13:	Proposal Summary and Data Record, NIH-2043	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/NIH2043.pdf
Attachment 14:	Small Business Subcontracting Plan	https://oamp.od.nih.gov/DGS/DGS-workform-information/attachment-files
Attachment 15:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee-and-labor-hours https://oamp.od.nih.gov/

sites/default/files/DFASDocs/		buscntrctprpslsprdsht08-2014_508.xlsx
Attachment 16:	Offeror's Points of Contact	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/point-of-contact.pdf
Attachment 17:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://www.gsa.gov/portal/forms/download/116430

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 18:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://oamp.od.nih.gov/sites/default/files/DGS/contracting-forms/rc4_508.pdf
Attachment 19:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://www.gsa.gov/portal/forms/download/116430
Attachment 20:	Commitment to Protect Non-Public Information Contractor Agreement	https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Nondisclosure.pdf
Attachment 21:	Roster of Employees Requiring Suitability Investigations	https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/SuitabilityRoster_10-15-12.xlsx
Attachment 22:	Employee Separation Checklist	https://ocio.nih.gov/aboutus/publicinfosecurity/acquisition/Documents/Emp-sep-checklist.pdf

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: http://www.sam.gov ; and

2. Complete, and **INCLUDE as part of your BUSINESS PROPOSAL:**
   SECTION K - REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS

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

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

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

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

(End of Clause)

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. ***INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION*** *[FAR Provision 52.215-1 (January 2017)]*

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

"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.
"In writing", "writing", or "written" means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.
"Proposal modification" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.
"Proposal revision" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.
"Time," if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

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

c. *Submission, modification, revision, and withdrawal of proposals.*

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

2. *The first page of the proposal must show--*

i. *The solicitation number;*

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

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

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

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

3. *Submission, modification, revision, and withdrawal of proposals.*

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

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

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

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

(3) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

(e) Restriction on disclosure and use of data.

(1) The proposal submitted in response to this request may contain data (trade secrets; business data (e.g., commercial information, financial information, cost and pricing data); and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:

"Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services (HHS), data contained in the portions of this proposal which the offeror has specifically identified by page number, paragraph, etc. as containing restricted information shall not be used or disclosed except for evaluation purposes.
The offeror acknowledges that HHS may not be able to withhold a record (e.g. data, document, etc.) nor deny access to a record requested pursuant to the Act and that the HHS's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if HHS has determined that disclosure is required by the Act.
If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification)."

(2) In addition, the offeror must mark each page of data it wishes to restrict with the following statement:

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

(3) Offerors are cautioned that proposals submitted with restrictive statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) Contract award.

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

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

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

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

limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

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

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

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

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

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

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

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

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

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

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

(iv) A summary of the rationale for award.

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

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

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

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

b. **NAICS CODE AND SIZE STANDARD**

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

1. The North American Industry Classification System (NAICS) code for this acquisition is 541714.
2. The small business size standard is 500.

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

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

1. It is anticipated that one award will be made from this solicitation and that the award(s) will be made on/ about December 31, 2020.
2. It is anticipated that the award(s) from this solicitation will be a multiple-year Cost-Reimbursement type Level of Effort contract with a Term of 7-year period of performance of one year Base period, and 6 one-year Option years.
3. FAR 16.301-3 limits use of any contract type, other than firm-fixed price, to a contractor whose accounting system is adequate for determining costs applicable to the contract. To be considered for an award under this solicitation, the Offeror is required to certify, in its Business Proposal, the adequacy of its accounting system. See the paragraph entitled, Adequate Accounting System in Section L.2. Business Proposal Instructions in this solicitation for additional information about this certification.

d. **LEVEL OF EFFORT**

The Government's requirement for the work set forth in the Statement of Work of this solicitation is 60 FTEs. It is estimated that the FTEs are constituted as specified below and will be expended approximately as follows:

Labor [HOURS, MONTHS, YEARS]

Labor Category	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Year 7
Principe Investigator	To be decided -->	---->	---->	---->	---->	---->	TBD
Other Professional	To be decided -->	---->	---->	---->	---->	---->	TBD
Technical & Support	To be decided -->	---->	---->	---->	---->	---->	TBD
Totals	60	60	60	60	60	60	60

e. **COMMITMENT OF PUBLIC FUNDS**

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

f. PROMOTING EFFICIENT SPENDING

On September 21, 2011, the Office of Management and Budget issued Memorandum M-11-35, entitled, "Eliminating Conference Spending and Promoting Efficiency in Government," emphasizing the President's priority to ensure that the Government operates with the utmost efficiency and eliminates unnecessary or wasteful spending. This was followed by the Executive Order on Delivering an Efficient, Effective, and Accountable Government (EO 13576) and the Executive Order on Promoting Efficient Spending (EO 13589). On January 3, 2012, the Department of Health and Human Services (DHHS) issued the memorandum "HHS Policy on Promoting Efficient Spending: Use of Appropriated Funds for Conferences and Meetings, Food, Promotional Items, and Printing, and Publications" (See http://www.hhs.gov/asfr/ogapa/acquisition/effspendpol_memo.html).

In support of these directives, the NIH issued a January 30, 2012, Memorandum, entitled, "NIH Guidance Related to the HHS Policies on Promoting Efficient Spending: Use of Appropriated Funds for Conferences, Conference Grants and Meetings, Food, Promotional Items, and Printing and Publications." (See http://oamp.od.nih.gov/)

Any contract awarded as a result of this solicitation will:

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

g. COMMUNICATIONS PRIOR TO CONTRACT AWARD

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

h. RELEASE OF INFORMATION

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

i. PREPARATION COSTS

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

j. **SERVICE OF PROTEST** (SEPTEMBER 2006) - FAR 52.233-2

(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:

Michael Finn, Contracting Officer
Office of Acquisitions
5601 Fishers Lane
Bethesda, Maryland 20892 Room 3B40
MSC 9822

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

(End of Provision)

2. **INSTRUCTIONS TO OFFERORS**

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

1. Contract Type and General Clauses

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

2. Authorized Official and Submission of Proposal

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

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

4. Separation of Technical and Business Proposals

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

5. Alternate Proposals

You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

6. Evaluation of Proposals

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

7. Potential Award Without Discussions

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

8. Use of the Metric System of Measurement

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

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

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

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

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

9. Privacy Act - Treatment of Proposal Information

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

be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

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

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

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

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

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

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

I. to the cognizant audit agency and the Government Accountability Office for auditing.

II. to the Department of Justice as required for litigation.

III. to respond to congressional inquiries.

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

10. 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 -

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

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

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

   While it is NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR Part 315.

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 NIAID reserves the right to make a single award, multiple awards, or no award at all to the SOLICITATION. In addition, the SOLICITATION may be amended or canceled as necessary to meet NIAID's requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

11. Institutional Responsibility Regarding Investigator Conflicts of Interest

45 CFR Part 94 promotes objectivity in research by establishing standards to ensure there is no reasonable expectation that the design, conduct, or reporting of research to be performed under NIH contracts will be biased by any Investigator financial conflicts of interest. The Institution shall comply with all requirements of 45 CFR Part 94 at: http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45.

12. Certification of Filing and Payment of Taxes

None of the funds appropriated or otherwise made available by the Consolidated Appropriations Act of FY 2014, may be used to enter into a contract in an amount greater than $5,000,000 unless the prospective contractor certifies in writing to the agency awarding the contract that, to the best of its knowledge and belief, the contractor has filed all Federal tax returns required during the 3 years preceding the certification, has not been convicted of a criminal offense under the Internal Revenue Code of 1986, and 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.

13. 52.203-98 Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements--Representation (DEVIATION)

a. In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Resolution Appropriations Act, 2015 (Pub. L. 113-235), Government agencies are not permitted to use funds appropriated (or otherwise made available) under that or any other Act for contracts with an entity that requires employees or subcontractors of such entity seeking to report fraud, waste, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting

such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

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

c. Representation. By submission of its offer, the Offeror represents that it does not require employees or subcontractors of such entity seeking to report fraud, waste or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information. (End of provision)

14. Past Performance Information

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

   A list of the last 3 contracts completed during the past Five years and all contracts that are currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as any subcontract over $650,000.

   Include the following information for each contract or subcontract listed:

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

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

2. 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.

15. Prohibition on Contractor Involvement with Terrorist Activities

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

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

a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

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

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

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

(End of provision)

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

17. **Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)**

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. System for Award Management, FAR Provision 52.204-7 (October 2016).

Alternate I (July 2013) is not applicable to this solicitation.

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

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

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

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

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

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

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

1. Technical Discussions

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

a. Statement of Work

1. Objectives

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

2. Approach

   The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

Proposals which merely restate the requirements of the Government's scope of work will not be eligible for award.

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

3. Methods

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

4. Schedule

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

b. Personnel

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

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

1. Single Principal Investigator/Project Director

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

2. Other Investigators

   List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the

estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

3. Additional Personnel

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

   - The specific items or expertise they will provide.
   - Their availability to the project and the amount of time anticipated.
   - Willingness to act as a consultant.
   - How rights to publications and patents will be handled.

4. Resumes

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

2. Other Considerations

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

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

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

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

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

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

3. Technical Evaluation

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

4. Enhancing Reproducibility through Rigor and Transparency

The offeror shall demonstrate compliance with the NIH Policy on enhancing Reproducibility through Rigor and Transparency as described in NIH Guide Notice NOT- OD-15-103. Specifically, the offeror shall describe in its technical proposal the information described below:

5. Obtaining and Disseminating Biomedical Research Resources

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a condition of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "SHARING BIOMEDICAL RESEARCH RESOURCES: Principles and Guidelines for Recipients of NIH Research Grants and Policy," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website:

http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf

a. Sharing Research Data

Note: This policy applies to **all** NIH contracts, regardless of dollar value, that are expected to generate research data.

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site:

http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

6. Section 508 accessibility standards for HHS Web Site Content and Communications Materials
Regardless of format, all Web content or communications materials specifically produced for publication on, or delivery via, HHS Web sites, including text, audio, or video, under this contract shall conform to applicable Section 508 accessibility standards. Remediation of any materials that do not comply with the applicable accessibility standards of 36 CFR Part 1194 as set forth herein shall be the responsibility of the Contractor.

The following Section 508 accessibility standards apply to the content or communications material identified in this Statement of Work Performance Work Statement:

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c. BUSINESS PROPOSAL INSTRUCTIONS

1. Basic Cost/Price Information

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

2. Proposal Cover Sheet

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

1. Solicitation, contract, and/or modification number;
2. Name and address of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the offeror, if selected for discussions, grants the contracting officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

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

3. Data Other than Certified Cost or Pricing Data

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

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

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

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

a. Direct Labor

Provide a time-phased (e.g., monthly, quarterly, etc.) breakdown of labor hours, rates, and cost by appropriate category. Key personnel will be separately estimated as above and identified. Give the basis for the estimates in each case.

b. Materials

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

c. Subcontracted Items

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $750,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

d. Raw Materials

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

e. Purchased Parts

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

f. Fringe Benefits

Show fringe benefits as a separate line item. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

g. Indirect Costs

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

h. Special Equipment

If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

i. Travel

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

j. Other Costs

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

4. Requirements for Certified Cost or Pricing Data and Data Other than Certified Cost or Pricing Data, FAR Clause 52.215-20 (October 2010)

(a) Exceptions from certified cost or pricing data.

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

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.
(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;
(B) For market priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;
(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

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

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

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

the Contracting Officer and the Contractor agree to a different format and change this clause to use Alternate I.
(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

5. Salary Rate Limitation

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

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

https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/
(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

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

6. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of $700,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this RFP for an example of such a plan.

a. THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

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

c. The offeror understands that:

1. 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.

2. 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.

3. 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.

4. 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.

5. 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.

6. The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.

d. Each plan must contain the following:

1. 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.

2. 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.

3. 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.

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

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

6. 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.

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

8. 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.

9. 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 $700,000 adopt a plan similar to the plan agreed upon by the offeror.

10. 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.

11. 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 FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

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

    33% for Small Business; 5% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

7. Mentor-Protégé Program, HHSAR 352.219-70 (December) 2015

a. Large business prime contractors serving as mentors in theHHS 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 www.esrs.gov. The mentor firm and protege firm shall submit to the Contracting Officer a signed joint statement agreeing on the dollar value of the developmental assistance the mentor firm provided. (For example, a mentor firm would report a $10,000 subcontract awarded to a protege firm and provision of $5,000 of developmental assistance as $15,000 of subcontracting plan credit.) The mentor firm may use this additional credit towards attaining its subcontracting plan participation goal under this contract.

b. The program consists of--

1. Mentor firms--large businesses that:
   (i) Demonstrate the interest, commitment, and capability toprovide developmental assistance to small business protégé firms; and
   (ii) Have a Mentor-Protege agreement approved by HHS' OSDBU;

2. Protege firms--firms that:
   (i) Seek developmental assistance;

(ii) Qualify as small businesses, veteran-owned small businesses, service-disabled veteran-owned small businesses, HUBZone small businesses, small disadvantaged businesses, or woman-owned small businesses; and
(iii) Have a Mentor-Protege agreement approved by HHS' OSDBU; and

3. Mentor-Protege agreements--joint agreements, approved by HHS' OSDBU, which detail the specific terms, conditions, and responsibilities of the mentor-protégé relationship.

(End of provision)

8. HUBZone Small Business Concerns

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

9. Total Compensation Plan

a. Instructions

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

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

3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. Evaluation

1. Total Compensation Plan (Professional Employees)

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered

compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. **Cost (Professional Compensation)**

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

3. **Other (Labor Relations)**

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

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

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

10. Other Administrative Data

a. Property

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

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

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

2. Government Property

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

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

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

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

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

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

3. Government-Furnished Property

   No Government Furnished Property is offered for this acquisition

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, "Appendix Q, HHS Contracting Guide for Contract of Government Property," which can be found at: https://web.archive.org/web/20111015044731/http:/www.hhs.gov/hhsmanuals/.

b. **Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38** (JULY 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)

c. 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.

d. Adequate Accounting System

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

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

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

- Complies with generally accepted accounting principles (GAAP).
- Provides for:
    - Proper segregation of direct costs from indirect costs.
    - Identification and accumulation of direct costs by contract.
    - A logical and consistent method for the allocation of indirect costs to intermediate and final cost objectives.
    - Accumulation of costs under general ledger control.
    - A timekeeping system that identifies employees' labor by intermediate or final cost objectives.
    - A labor distribution system that charges direct and indirect labor to the appropriate cost objectives.
    - Interim (at least monthly) determination of costs charged to a contract through routine posting of books of account.
    - Exclusion from costs charged to government contracts of amounts that are not allowable in terms of FAR 31, "Contract Cost Principles and Procedures," or other contract provisions.
    - 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.
    - Segregation of preproduction costs from production costs, if applicable.
- Accounting system provides financial information:
    - Required by contract clause concerning limitation of cost (FAR 52.232-20) or limitation on payments (FAR 52.216-16).
    - Required to support requests for progress payments.
- 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.

- 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.

e. **Facilities Capital Cost of Money**, FAR 52.215-16, (June 2003)

(This is applicable if you are a commercial organization.)

(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

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

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

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

11. Qualifications of the Offeror

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

a. General Experience

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

b. Organizational Experience Related to the RFP

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

c. Performance History

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

d. Pertinent Contracts

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting

agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e. Pertinent Grants

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

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

12. Subcontractors

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

a. Willingness to perform as a subcontractor for specific duties (list duties).

b. What priority the work will be given and how it will relate to other work.

c. The amount of time and facilities available to this project.

d. Information on their cognizant field audit offices.

e. How rights to publications and patents are to be handled.

f. A complete cost proposal in the same format as the offeror's cost proposal.

13. Proposer's Annual Financial Report

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

14. Travel Costs/Travel Policy

a. Travel Costs - Commercial
Costs for lodging, meals, and incidental expenses incurred by Contractor personnel shall be considered to be reasonable and allowable to the extent they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulations, General Services Administration (GSA). Therefore, if travel costs are applicable and proposed by offerors, please be advised that they shall be calculated using the per diem rate schedule as established by GSA. Reimbursement of travel costs under any contract awarded from this RFP shall be in accordance with FAR 31.205-46.

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

15. Certification of Visas for Non-U.S. Citizens

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

SECTION M - EVALUATION FACTORS FOR AWARD

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. The Government intends to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

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

2. COST/PRICE EVALUATION

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

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

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

3. EVALUATION OF OPTIONS

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

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

4. EVALUATION OF AUTHENTICATION OF KEY BIOLOGICAL AND/OR CHEMICAL RESOURCES

If the offeror has proposed the use of key biological and/or chemical resources, the offeror's plan for authentication will be reviewed adequacy.

Any concerns associated with key biological and/or chemical resource authentication raised during the review process will need to be resolved prior to award.

5. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

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

6. 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. Sub-factors are considered to be of equal importance.

CRITERIA & WEIGHT
CRITERION 1: TECHNICAL PLAN/APPROACH 55
Appropriateness, feasibility, and adequacy of the proposed technical plan/approach for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.
CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL 25
Appropriateness and adequacy of the education, training, experience, expertise, and proposed levels of effort of the Principal Investigator and scientific and technical staff including subcontractors/consultants for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.
CRITERION 3: PROJECT MANAGEMENT 10
Appropriateness and adequacy of the Project Management Plan in terms of staffing, organizational structure and lines of authority, management of subcontracts/consultants, tracking of project activities, monitoring progress and timelines, and communication with stakeholders.

CRITERION 4: FACILITIES, EQUIPMENT, AND OTHER RESOURCES 10

Appropriateness and adequacy of facilities, equipment, space and other resources including those of subcontractors/ consultants for accomplishing the tasks outlined in the Statement of Work and the overall objectives of the solicitation.

EVALUATION OF OPTIONS 10

Options 7-8: Increase in Level of Effort

Suitability of an implementation plan to increase the level of effort that may result from unanticipated increases in demand, with the services required under these options to be of the same scope provided during the base year.

TOTAL POSSIBLE WEIGHT (with Options): 110

7. PAST PERFORMANCE FACTOR

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

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

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

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

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

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

I. PROPOSAL SUBMISSION

A. eCPS

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

B. Creating and Naming Files:

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

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

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

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

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

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

II. FORMATTING AND PAGE LIMITATIONS:

A. Formatting for proposals

1. Proposal page layout shall be letter size 8.5" x 11" for all pages.
2. Proposals shall not include links to internet web site addresses (URLs) or otherwise direct readers to alternate sources of information.
3. Proposals shall not include audio or video files of any type.
4. Font size must be 10 to 12 points.
5. Spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
6. Margins must be at least one-inch on all sides.
7. **Failure to adhere to the formatting requirements above may impact whether your proposal is reviewed in its entirety.**

B. Page limitations:

1. The total page count of the Technical proposal shall not exceed _175_ pages.
2. Total page count does not include:
   a. Title and Back Page; Table of Contents; Section Dividers that do not contain information other than title of Section; and
   b. The Human Subject and Clinical Trial Information Form, if required by the solicitation.
3. Each Curriculum Vitae (CV) shall not exceed _2 to 3_ pages.
4. **Pages exceeding limitations will be removed from the proposal and will not be considered.**

ATTACHMENT 2: PROPOSAL INTENT RESPONSE FORM

RFP No:

RFP Title:

Please review the Request for Proposal (RFP). Furnish the information requested below and return this page to the Contracting Officer/Contract Specialist identified on **Section A-Solicitation/Contract Form** by the following date:

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

Choose one of the following Options:

- (●) Do intend to submit a proposal
- ( ) Do Not intend to submit a proposal

If you are not responding to this RFP, please provide your reason(s):

Please provide the following contact information:

Name (First, Middle Initial, Last):
Title:
Organization:
E-mail:

ATTACHMENT 3: STATEMENT OF WORK

Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases 75N93019R00027

I. BACKGROUND AND INTRODUCTION

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (HHS), strives to understand, treat and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents. This includes basic and applied research to develop and evaluate therapeutics, vaccines, medical devices and diagnostics, which are funded through a variety of research grants and contracts.

The evaluation of new and improved vaccine, device and therapeutic candidates in clinical trials and clinical studies is an essential element of the efforts of DMID. Through an extensive network of grant and contract research programs, DMID supports a broad range of clinical research, including single-site and multi-center clinical research and Phase 0 through 4 clinical trials evaluating bacterial, viral, and parasitic vaccines; therapeutics; and other biologics; drugs; diagnostics; medical devices; and approaches, as preventive and therapeutic measures against infectious diseases in people of all ages and risk categories. Support is also provided for a variety of other studies. Examples include: targeted surveillance for pathogens of interest in study populations; evaluations of novel investigational product delivery systems; and reevaluation of current vaccine formulations, schedules and modes of delivery. Clinical trials and clinical studies are also supported to evaluate the safety and efficacy of vaccines, medical devices and therapeutics for a wide variety of emerging and re-emerging infectious diseases (https://www.niaid.nih.gov/research/emerging-infectious-diseases-pathogens), which include NIAID Category A-C Priority Pathogens to meet critical public health needs.

This contract provides for the establishment and management of a Statistical and Data Coordinating Center (SDCC) to support DMID's extramural clinical research programs through the provision of: computerized systems for the collection, storage, management, reporting, and quality control of study data; preparation of study-related materials; clinical study websites; statistical design and analysis expertise; data management clinical site training, assessment, and technical assistance; electronic specimen tracking system; data storage facility; and project/site management. The SDCC may also be utilized by other Government-supported research projects and research service programs, at the discretion of NIAID.

The current SDCC contract was awarded as contract number HHSN272201500002C, which was effective March 1, 2015 and provides centralized data management and statistical services essential to support a wide variety of clinical research studies/trials across multiple infectious disease programs involving domestic/international sites.

II. SCOPE

The scope of activities to be performed by the Contractor shall encompass development and operational management of a Statistical and Data Coordinating Center.

III. TECHNICAL REQUIREMENTS

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities etc., as needed, to perform the Statement of Work as stated herein, including the following system features and capabilities:

1. Data Collection and Management

The Contractor shall operate and maintain a state-of-the-art computer-based clinical data system for data collection, storage, tracking and retrieval. This system must be in place and fully operational within 60 calendar days from the effective date of the contract. The Contractor shall provide the following system features and capabilities:

a. Receiving, entering, verifying, labeling, processing, coding, editing (including within and across form validity, logic, and consistency checks), updating, correcting, freezing, locking, storing, securing, tracking, and retrieving all clinical and laboratory test results data at a central data management facility.

b. Compliance with all current applicable Federal regulations located at http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/cfrsearch.cfm and http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html (e.g., 21 CFR 11, 21 CFR 50, 56, 312, 612 and 812 as applicable, 45 CFR 46 and/or similar statutes), including U.S. Public Law 110-85 or the Food and Drug Administration Amendments Act of 2007, as well as local regulations, as applicable.

c. Adherence to current globally-accepted standards, including the following:

1) International Conference on Harmonization (ICH) E2, Clinical Safety Data Management, ICH E3 Clinical Study Reports, ICH E6 Good Clinical Practice, located at: http://www.ich.org/products/guidelines.html
2) Compliance with coding to M1 MedDRA Terminology and ICH M5, Data Elements and Standards for Drug Dictionaries, and located at: http://www.ich.org/products/guidelines.html.
3) Compliance with coding to the World Health Organization Drug Dictionary, located at https://www.who-umc.org/whodrug/whodrug-portfolio/, protocol-specific requirements, and all applicable NIH/NIAID/DMID policies andprocedures.
4) Compliance with current industry standards for clinical data management. [Current example – Clinical Data Interchange Standards Consortium (CDISC) located at: http://www.cdisc.org].
5) Provisions to maintain compliance with changing industry standards must be in place, at no cost to the Government.

d. Central computerized study subject registration and randomization, and non-computerized methods, as needed on a limited basis, for select study sites and as a backup process.

e. Computerized study forms and a 21 CFR Part 11-compliant clinical datasystem for remote/direct data entry and transmission of subject data from study sites and laboratories to the central data management facility. Non-computerized methods, when necessary, as designated by the Contracting Officer's Representative (COR) and/or DMID staff designated by the COR.

f. Real-time electronic notification provided to designated DMID personnel in the event of data triggering pre-specified protocol criteria. This includes notification to relevant DMID staff on pre-specified schedule key elements of study status (e.g., enrollment, adverse events of special interest, etc.).

g. Provision of a system for off-line data entry, as necessary. Data shall be transmitted at a later time when internet connection is available.

2. Data Quality Assurance and Control

a. The Contractor shall provide and maintain a quality control system for monitoring the accuracy, completeness and timeliness of the data entered into the SDCC clinical data system, by study sites at each stage of a study, beginning with study initiation/patient enrollment and proceeding to the generation of final data sets. The system shall have the following features and capacities and shall provide for verification of 100 percent of study data:

1) Computerized validation and error-checking (e.g., range checks, user logics) to evaluate and improve the accuracy, timeliness and completeness of data submitted by the clinical sites.
2) Strategies to assure uniform standardized data collection and implementation of multi-center studies across participating clinical sites.
3) A computerized data query system to notify and request resolution from clinical and laboratory sites when aberrant and/or missing data areidentified.
4) Periodic (at least annually) review and revision of manuals and procedures documenting data collection, editing and validation procedures andstandards.
5) Evaluation of the quality of data generated in connection with the clinical studies/trials, with implementation of data quality improvement plans, as necessary.

b. Independent Audits – The Contractor shall undergo independent quality audits initiated by the Government for review of Contractor processes, procedures and operations at the Contractor's central office to ensure regulatory compliance.

1) The COR will notify the Contractor of plans for independent audits two weeks in advance of the scheduled audit. The Contractor shall ensure that designated staff and all necessary information/documents are available.

2) "For cause" audits may also be performed at any time and without advance notice to the Contractor, in instances of non-performance and/or suspected non-compliance with federal and/or local regulatory requirements.

c. The Contractor shall develop a Quality Management Plan (QMP) to cover all contract activities, including a plan to identify any gaps. This initial plan and any updates shall be approved by the COR prior to implementation. The initial draft QMP shall be sent by the Contractor for the COR's review/approval within 30 days of the effective date of the contract. The final initial QMP shall be finalized by the Contractor within 14 days of receiving comments from the COR on the draft document. The Contractor shall also provide performance reports from the QMP for approval by the COR on a schedule to be determined by the COR.

3. Protocol and Other Study-Related Materials

The Contractor shall prepare materials (including revise, finalize and distribute) for the implementation of clinical trials and clinical studies, including electronic Case Report Form (eCRFs), Study Procedure Manuals, and other study related materials, as needed/requested by the COR.

4. Clinical Study Website(s)

Within 60 calendar days after the effective date of the contract, the Contractor shall operate and maintain a website to share clinical research information and study materials with DMID staff and participating study sites. This shall include the following:

a. The establishment, operation, maintenance and updating of a study-specific, password-protected website to access protocol information and real-time study data.

b. Updating the SDCC website documents and materials, including new or modified versions of website materials, during the course of a clinical trial/study and providing timely notifications to participating study sites to alert them about the availability of new or revised materials.

c. The provision of real-time access by DMID and DMID-designated clinical site personnel to aggregate data (study specific and cross study), as well as by pre-specified search criteria for key study matrices. Examples include accrual, adverse event and serious adverse event listings, protocol deviations, specimen tracking and inventory, missing forms, visit schedule compliance, data queries, site performance metrics and progress monitoring information/materials.

d. Grant access for DMID-approved users to the electronic website, data system and related study-specific materials. Develop a procedure for such access granting, monitoring, and revoking. Perform periodic (at least annually) review of users and remove inactive users.

5. Study Communication, Collaboration and Reporting

a. The Contractor shall coordinate and collaborate with DMID and other DMID clinical research support services to facilitate study implementation, assess study progress and evaluate processes and procedures. This shall include coordination and collaboration with the: (i) DMID Clinical Research Operations and Management Support (CROMS) contractor responsible for pharmacovigilance (PVG) and other activities, including Serious Adverse Event (SAE) reporting and safety oversight, collecting essential documents, activating study sites, reporting of clinical trial/study data to ClinicalTrials.gov, clinical site monitoring and quality assurance services; (ii)

DMID Regulatory Affairs Support and Clinical Agents and Specimen Repository contractors responsible for regulatory compliance and the receipt, storage and distribution/shipment of specimens; (iii) Clinical site and other contractor and grantee personnel as designated by DMID; and (iv) NIAID-wide information system t).

b. Specifically, the Contractor shall perform the following:

1) Coordinate and collaborate with the DMID-CROMS contractor regarding the following:

a) *Study initiation*: Participate in study initiation meetings, as needed, withthe relevant DMID staff and the DMID-CROMS contractor staff.
b) *Protocol-specific and site-specific randomization and data entry screens*: Provide site personnel access to protocol-specific and site-specific randomization and the SDCC clinical data system following approval from the COR and/or DMID staff designated by the COR.
c) *Non-serious and Serious Adverse Events*: Compare and reconcile Adverse Events in the SDCC clinical data system with the separate DMID-CROMS pharmacovigilance (PVG) Serious Adverse Event (SAE) database. The Contractor shall develop an SOP to describe the process for such reconciliation in collaboration with the DMID-CROMS contractor, with a delivery schedule for the SOP and any updates determined by the CORand/or DMID staff designated by the COR. SAE reconciliation reports will be provided to the DMID-CROMS contractor, as specified in the SAE Reconciliation Process SOP.
d) *Study data that meets pre-specified protocol criteria*: Provide reports in a timely manner to the DMID study team and/or other personnel, as designated by the COR, immediately after a study meets any pre-specified protocol criteria. This includes provision and maintenance of an alert table/system for notification to appropriate study team members, as determined by the COR and/or DMID staff designated by the COR.
e) *Reports for Safety Oversight Structures*: Generate and submit to theDMID-CROMS contractor reports for distribution to and review by study Safety Oversight Structures as specified by the clinical protocol, the safety charter and the Safety Oversight committees. The Contractor shall develop plansto meet the timelines necessary for DMID review and approval of such reports prior to the distribution to the DMID-CROMS contractor. Such reports will include ad hoc safety profiles of individual subjects.
f) *Study site-specific reports*: Generate site-specific reports for the DMID and the DMID-CROMS contractor. Examples of such reports include accrual, demographics, line-listings of AEs and SAEs, protocol deviations, data queries, timeliness of data submission, and response to queries for quality assurance purposes.
g) *Reports to support clinical site monitoring*: The SDCC clinical data system should include integrated features and functions in support of DMID-CROMS clinical site monitoring requirements as specified in the DMID's study-specific clinical monitoring plan. At a minimum, the system should assist in subject selection, source data verification, manual monitor data query tracking, and data status reports for each study subject at each site. The system report features should also allow for analysis of deficiencies identified during data submission (e.g., out-of-range or out-of-window data) or during previous site visits. A system to provide reports to support clinical site monitoring

requirements shall be in place and fully operational within 60 calendar days from the effective date of the contract.

h) *Randomization and study products:* Assess compliance with randomization and administration of study product.

i) *Reports for the DMID-CROMS data system:* The Contractor shall establish an electronic data exchange system to communicate and provide real-time information for the DMID-CROMS data system. This exchange system shall be due within 60 calendar days from the effective date of the contract. Related reports and data to be exchanged, as well as the timing of that exchange, will be determined by the COR and/or DMID staff designated by the COR. Examples of data exchange categories include safety, regulatory, monitoring, site performance metrics, protocol non-adherence and other protocol-specific data.

j) *Data via electronic data exchanges system with the NIAID-wide information system*: The NIAID-wide information system is a comprehensive system to support NIAID clinical research management and oversight responsibilities. The Contractor shall collaborate with NIAID/DMID to provide data transfer capabilities specified by the COR from the SDCC clinical data system into this NIAID-wide information system. Related reports and data to be exchanged, as well as the timing of that exchange, will be determined by the COR and/or DMID staff designated by the COR. Any timeframe for SDCC implementation of related tasks will be specified by the COR.

k) *Ad hoc reports*. Provide real time ad hoc reports generated from the data system at the request of DMID personnel and/or DMID staff designated by the COR.

2) Coordinate and collaborate with the DMID Clinical Agents and Specimen Repository and Regulatory Affairs Support contractors to perform the following:

   a) *Specimen tracking*: Track information regarding date, time, inventory of study specimens collected at sites, courier service and timeliness of shipments to the repository maintained by the DMID Clinical Agents and Specimen Repository contractor.

   b) *Specimen inventory management*: Generate specimen lists from the electronic specimen inventory and submit to the DMID Clinical Agents and Specimen Repository contractor to select and ship specimens to specified laboratories or other destinations as designated by DMID.

   c) *Regulatory reports:* The Contractor shall provide the clinical data to finalize Clinical Study Reports, Annual Reports, http://clinicaltrials.gov/ results reporting and other reports at intervals designated by the COR and/or DMID staff or contractors designated by the COR to support the Regulatory Affairs Support contract.

3) As requested by the COR, participate in any annual meeting(s) of the contracts and grants supported by this contract.

4) Coordinate and collaborate with DMID clinical research sites, support services, and/or DMID staff designated by the COR on statistical design and analysis and development of protocols and other study related materials.

5) Participate in periodic teleconferences and/or meetings with the COR and/or DMID staff designated by the COR to discuss the status of ongoing clinical trials/studies, identify and develop approaches to resolving problems encountered in study implementation regarding SDCC responsibilities, and review plans for the design and initiation of upcoming studies.

6. Statistical Design and Analysis

The Contractor shall provide expertise, advice and assistance in the development of statistical designs and statistical analysis plans and in the preparation of interim and final analyses for clinical trials/studies supported under DMID-funded clinical research programs. Concepts and protocols for DMID-supported clinical trials/studies will emanate from various sources, including clinical investigators, DMID staff and industry collaborators. Specifically, the Contractor shall work with the COR and/or DMID staff designated by the COR, clinical investigators and industry collaborators designated by the COR to perform the following:

a. Statistical Design

1) Develop and refine experimental study designs, including appropriate control/comparison groups, sample size and power estimates, primary and secondary endpoints, randomization and stratification/blocking methods, and masking approaches for a variety of clinical study and trial designs.

2) Review protocols and provide recommendations on statistical design issues.

3) Develop and refine interim and final data analysis plans.

4) Provide statistical advice concerning issues such as approach, power, sample size, and impact of interim analyses. Provide other statistical analysis as requested by the COR and/or DMID staff designated by the COR (e.g., summary information for FDA submissions, review of Statistical Analysis Plans of other studies, etc.).

5) Develop new applications of statistical or information science theory, as necessary. This includes the provision of: bioinformatics, pharmacokinetic (pK) and pharmacodynamic (pD), genetics, systems biology and other non-conventional statistical design and analysis support; pre-concept early (pre-concept) statistical consultation to DMID and COR-designated site personnel; input to DMID on DMID-designated trials/studies for which another data coordinating center (DCC) is providing related services; the ability to analyze datasets not generated by this contract; and, review of other companies' statistical analysis plans, CSR tables/listings, and safety shells/templates as necessary.

6) Provide statistical input to DMID to assist with DMID decision-making.

7) Provide all Statistical Analysis System (SAS) analysis Programming to the DMID/DMID designee determined by the COR.

b. Statistical Analysis

1) *Statistical Analysis Plan (SAP):* Prior to each clinical study/trial implementation, develop the SAP in accordance with the approved protocol, safety plans and other documents as necessary. Maintain and update the SAP throughout the life of the study/trial.

2) *Interim analyses*: Perform interim analyses for safety, immunogenicity and/or efficacy and other parameters as specified in the SAP. Summarize and present interim findings to the designated Safety Oversight Structures.

3) *Final analyses*: Conduct comprehensive final statistical analyses, in accordance with the SAP. Additional analysis might be performed in support of requests by Safety Monitoring Committees (SMCs), Data Safety Monitoring Boards (DSMBs), DMID, or study investigators, for use in safety monitoring and in the preparation of abstracts, journal articles and scientific presentations. The Contractor shall develop a process for approval and prioritization of such requests.

4) *Regulatory Submissions for Vaccines, Biologics, Drugs and Devices*: Prepare and present, in conjunction with DMID, study investigators and industry collaborators, statistical designs, statistical analysis plans and study-specific analyses for interactions with the U.S. Food and Drug Administration (FDA) in connection with pre- and post-regulatory submissions. Assist DMID, study investigators and industry collaborators in responding to FDA inquiries regarding clinical trial design and analysis at any point during a study.

5) *Expedited analyses*: Conduct expedited analyses of data for selected high-priority studies and provide for the rapid transfer of data, data documentation and analyses to the DMID at any point during a study.

6) *Pre-Publication/Presentation Analyses*: Prior to presentation or submission for publication, review for accuracy all abstracts, manuscripts, and presentations that include data generated from clinical trials and clinical studies supported under this contract.

7) *Ad hoc analyses*: Conduct ad hoc analyses as requested by the COR and/or DMID staff designated by the COR, including analyses on datasets not generated by this contract.

7. Clinical Site Training, Assessment and Technical Assistance

The Contractor shall participate in training of clinical site personnel, along with DMID and other collaborators with respect to procedures for study implementation as they relate to the data management aspect of the clinical study/trial. Specifically, the Contractor shall perform the following.

a. Prepare and make available, to DMID staff and study and laboratory sites, the data entry system user's manual within 60 calendar days after the effective date of the contract.

b. Within 60 calendar days after the effective date of the contract, implement a "training data entry module" on the remote and/or direct data entry system to allow study site staff to learn, practice and refresh skills in the use of the data entry system. The training data entry system should include an electronic audit trail to track completion by different users, thus confirming site staff eligibility to use the system.

c. Prepare instructional materials regarding data management procedures and conduct training sessions for DMID and study site staff via face-to-face meetings,conference

calls and/or webcasts. Examples of training topics include: design of data collection materials; data entry; data management; data validation; audit trails; and use of the electronic specimen tracking system. Training may be provided in a variety of time zones and settings including at clinical sites or at group meetings and may require travel of Contractor staff to domestic and international clinical sites. The Contractor shall submit a written site visit report within 14 calendar days following any training site visit.

d. Provide and maintain a 24 hour/7-day per week accessible help line to receive statistical and data management questions and related requests for SDCC assistance from study sites. This help line shall be in place and fully operational within 60 calendar days from the effective date of the contract. The help line should be accessible from domestic and international locations and should be independent from a site power source. A help line report on the current Help Line operations status and key frequently asked questions (FAQs) is due monthly as specified by the COR.

e. Assess the capabilities of DMID-supported study sites that do not utilize SDCC computerized data entry and management systems in terms of on-site technical expertise and data systems in place to collect, manage, secure, validate, and analyze data. Provide findings of such assessments to these study sites, the COR and/or DMID staff designated by the COR within 15 calendar days of the assessment in a written report, and provide guidance, direction and follow-up to assist such clinical sites in establishing and maintaining data systems in accordance with federal and local regulations and ICH/GCP guidelines http://www.ich.org/products/guidelines.html.

8. Electronic Specimen Tracking System

The Contractor shall provide and maintain an electronic specimen tracking system, for use by the SDCC, study sites, laboratories and others as designated by the COR to track study specimens in real time. This system must be in place and fully operational within 60 calendar days from the effective date of the contract. The electronic specimen tracking system shall have the following features and capabilities:

a. Integration with the SDCC clinical data system, to including reporting, and compliance with regulatory requirements as described under III.1.

b. Use of an automatic labeling system (e.g., bar code) on specimen aliquots that link a unique label to a specific study, subject, study site and time point/visit. Generally, study specimens are collected, processed and stored at the clinical site until they are shipped to the DMID specimen repository. The repository stores the specimens until they are shipped to a central laboratory.

c. Generation of an electronic shipping manifest for receipt by the receiving facility as specimens are being prepared for shipment.

d. Provision of labels to study sites for specimen aliquots, ensuring protection of confidentiality and blinding of laboratory staff to specimen identity.

e. Provision of a real-time global inventory of all study specimens and the location of individual specimens for each specific study.

9. Data Storage

The Contractor shall serve as a DMID clinical data storage facility for those studies conducted by DMID-supported investigators and collaborative groups, and for study sites that do not have access to long-term clinical data storage. Transfer of data, medium, timeframe and other details shall be determined by the SDCC and the transferring study sites or investigators with COR approval. The Contractor shall provide an SOP to the COR for review and approval describing the data storage and transfer process within 60 calendar days from the effective date of the contract.

10. Project Management

a. Overall Contract Project Management

1) Provide for the overall management, integration and coordination of all contract activities, including the management and coordination of activities carried out under subcontracts if applicable. The Contractor shall provide and update, as needed and/or requested by the COR, a comprehensive Project Management Plan (PMP) to be approved by the COR for the effective overall management, budgeting and tracking of contract activities, including work performed by subcontractors if applicable. This PMP is due within 60 calendar days of the effective date of the contract.
2) Provide and maintain an infrastructure to ensure the efficient planning, initiation, implementation and timely completion of all projects carried out under this contract. Provide and maintain effective communications with the COR and Contracting Officer.
3) Provide for a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors if applicable.
4) Ensure the effective and efficient coordination of specified functions identified in the Statement of Work in collaboration with the DMID clinical research support services and clinical sites.

b. Meetings and Teleconferences

1. *Contract Initiation Meeting*: Within 30 calendar days after the effective date of the contract, participate in a one-day Contract Initiation Meeting with the COR, the Contracting Officer and other NIAID personnel designated by the COR to be held at the Contractor's site or a DMID site. The Contractor will generate an agenda in cooperation with the Contracting Officer and COR. The purpose of the Contract Initiation Meeting shall be to orient the Contractor to NIAID contract procedures and to:

    a) Introduce Contractor and DMID staff;
    b) Discuss the terms and conditions of the contract;
    c) Report on progress/accomplishments to date; and
    d) Establish priorities and timelines for specific activities.

2. *Monthly Status Meetings/Teleconferences*: The Contractor's PI and/or designee(s) will participate in meetings at a minimum of monthly intervals, either in person or via teleconference, to review overall progress with the COR and discuss: key issues requiring any SDCC plan(s) for resolution/improvement; quality management plan updates/issues; results of any independent audits made by the government; SDCC accomplishments or challenges; SDCC

performance metrics; any matters relevant to the scientific and financial administration of the contract and future activities; and, any initiatives proposed by the SDCC and/or COR to further support DMID research studies. The schedule of these meetings/teleconferences will be established by the COR and the Contracting Officer after contract award. The Contractor will prepare and distribute the agenda and meeting/teleconference materials to all participants, as well as provide a summary of all meetings and teleconferences in the Semi-Annual Progress Reports.

3. *Annual Site Visits*: At a minimum, one site visit shall be conducted in each contract year by the COR and CO or Contract Specialist (CS) (joint visit). In addition, the COR and CO/CS may elect to perform site visits (or reverse site visits) at any time during the contract period of performance. The Contractor shall organize the annual joint visit by the COR,CO/CS, and DMID Program Staff, during which the following topics will be reviewed and discussed: project progress; problems and obstacles and approaches to overcoming identified problems and obstacles; recommendations for modifications in project timelines, objectives and research approaches/methodologies based on outcomes to date; and, future plans. These site visits shall be attended by the Contractor's Principal Investigator, the Contractor's business representative, and all Contractor key personnel. The Contractor shall be responsible for:

    a) Planning and submitting the agenda to the COR for approval on a timeline agreed upon by the COR;
    b) Developing written and oral presentation materials, with draft versions approved by the COR;
    c) Arranging for the logistics associated with the site visit; and
    d) Preparing and submitting Annual Site Visit reports to the COR and CO within 30 calendar days of completion of each annual site visit.

c. Study/Trial-Specific Project Management Services

1) Provide and maintain study/trial-specific project management support to DMID personnel, as requested by the COR and/or DMID staff designated by the COR. This may include, for example: providing protocol development and implementation status updates to the DMID Clinical Project Manager (CPM)/designee(s) as requested on a frequency established by the COR and/or COR designee; establishing project management timelines; developing a project management plan for protocols with approval by the DMID CPM/designee for the protocol; coordinating and facilitating protocol team calls, including generation of agenda and meeting minutes; revision of documents and generation of lists of changes; serving as a central hub for communications; and generating and posting protocol questions and answers for DMID and site review.

2) As applicable, the COR will approve delivery of project management services by the Contractor for select trials/studies prior to implementation. For those approved trials/studies, the Contractor shall also respond to study/trial-specific project management-related questions in collaboration with the designated DMID project management staff.

11. OPTIONS

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

OPTIONS 1-6: **EXTEND TERM OF THE CONTRACT**

The Government may include Options to extend the period of performance by one (1) year (twelve (12)-months). The total period of performance resulting from the base period plus all potential Term Options is seven (7) years. If Options 1-6 are exercised, the services required will be the same as provided during the base year.

OPTIONS 7-8: **INCREASE IN LEVEL OF EFFORT**

The Government may exercise Options for increased level of effort that may result from unanticipated increases in demand, with the services required under these Options to be of the same scope provided during the base year. The FTEs associated with each Option (7-8) are as follows: Option 7 = 5 FTEs/10,400 hours; Option 8 = 15 FTEs/31, 200 hours.

Should the Government elect to exercise any of these Options, the Contractor shall provide resources for the associated increase in work volume. These Options may be exercised within the base period (and within each year that Options 1-6 are exercised) as needed, up to a maximum of 60 FTEs/124,800 total direct labor hours per year over the total direct labor hours negotiated for the base period of performance (and Options 1-6), using any combination of Options 7 or 8.

Funds and hours for increased quantities of effort may only be used in the contract year in which the Option is exercised and may not be used beyond the applicable one (1) year (12-month) funding period. The exercise of these Options is subject to the availability of funds.

OPTION 9: Initial Transition Effort

Initial Transition from Incumbent SDCC Contractors

The Contractor shall coordinate with the incumbent contractor to ensure an orderly, secure, and efficient transition of contract-related materials and activities to the Government. The new contractor will comply with a transition plan that will be furnished from the incumbent to the new contractor.

OPTION 10: Final Transition Effort

Final Transition

1) The Contractor shall ensure an orderly, secure, and efficient transition of contract-related materials and activities to the successor Contractor or tothe Government, to be completed by the expiration date of the contract.

2) A description of transition activities, timelines, and assigned staff shall be provided in Draft and Final Transition Plans, which will be reviewed and approved by the COR. The Draft Transition Plan shall be submitted 12 months prior to the completion date of the contract, and the Final Transition Plan (approved by the

COR and Contracting Officer) shall be submitted six months prior to the completion date of the contract. The final transition shall be fully completed by the completion date of the contract.

Option 11: Extend Services (52.217-8)

If Option 11 is exercised, the services required will be the same as provided during the performance period just ended.

[END OF STATEMENT OF WORK]

Attachment 4

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

Updated through FAC 2005-95

Last updated: 01/2017

This SECTION is made up of nine parts as follows:

1. **Annual Representations and Certifications, FAR 52.204-8**
2. **Commercial and Government Entity Code Reporting, FAR 52.204-16**
3. **Predecessor of Offeror, FAR 52.204-20**
4. **Information Regarding Responsibility Matters, FAR 52.209-7**
5. **Cost Accounting Standards**
6. **Certification Regarding Trafficking in Persons Compliance Plan**
7. **Certification Regarding Environmental Tobacco Smoke**
8. **Certification of Institutional on Financial Conflicts of Interest**
9. **Disaster or Emergency Area Representation**

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

1. ANNUAL REPRESENTATIONS AND CERTIFICATIONS (JAN 2017), FAR Provision 52.204-8

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is _____ *[insert NAICS code]*.
(2) The small business size standard is_____*[insert size standard]*.
(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b)(1) If the provision at 52.204-7, System for Award Management, is included in this solicitation, paragraph (d) of this provision applies.
(2) If the provision at 52.204-7 is not included in this solicitation, and the offeror is currently registered in the System for Award Management (SAM), and has completed the Representations and Certifications section of SAM electronically, the offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certification in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:
☐ (i) Paragraph (d) applies.
☐ (ii) Paragraph (d) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c)(1) The following representations or certifications in SAM are applicable to this solicitation as indicated:

(i) 52.203-2, Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless—

(A) The acquisition is to be made under the simplified acquisition procedures in Part 13;

(B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or

(C) The solicitation is for utility services for which rates are set by law or regulation.

(ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed $150,000.

(iii) 52.203-18, Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements—Representation. This provision applies to all solicitations.

(iv) 52.204-3, Taxpayer Identification. This provision applies to solicitations that do not include the provision at 52.204-7, System for Award Management.

(v) 52.204-5, Women-Owned Business (Other Than Small Business). This provision applies to solicitations that—

(A) Are not set aside for small business concerns;

(B) Exceed the simplified acquisition threshold; and

(C) Are for contracts that will be performed in the United States or its outlying areas.

(vi) 52.209-2, Prohibition on Contracting with Inverted Domestic Corporations—Representation.

(vii) 52.209-5; Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.

(viii) 52.209-11, Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law. This provision applies to all solicitations.

(ix) 52.214-14, Place of Performance--Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.

(x) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.

(xi) 52.219-1, Small Business Program Representations (Basic & Alternate I). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.

(A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.

(B) The provision with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.

(xii) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.

(xiii) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.

(xiv) 52.222-25, Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.

(xv) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial items.

(xvi) 52.222-57, Representation Regarding Compliance with Labor Laws (Executive Order 13673). This provision applies to solicitations expected to exceed $50 million which are issued from October 25, 2016 through April 24, 2017, and solicitations expected to exceed $500,000, which are issued after April 24, 2017.

Note to paragraph (c)(1)(xvi): By a court order issued on October 24, 2016, 52.222-57 is enjoined indefinitely as of the date of the order. The enjoined paragraph will become effective immediately if the court terminates the injunction. At that time, DoD, GSA, and NASA will publish a document in the Federal Register advising the public of the termination of the injunction.
(xvii) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA-designated items; or include the clause at 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts.
(xviii) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA- designated items.
(xix) 52.223-22, Public Disclosure of Greenhouse Gas Emissions and Reduction Goals—Representation. This provision applies to solicitations that include the clause at 52.204-7.
(xx) 52.225-2, Buy American Certificate. This provision applies to solicitations containing the clause at 52.225-1.
(xxi) 52.225-4, Buy American--Free Trade Agreements--Israeli Trade Act Certificate. (Basic, Alternates I, II, and III.) This provision applies to solicitations containing the clause at 52.225- 3.

(A) If the acquisition value is less than $25,000, the basic provision applies.

(B) If the acquisition value is $25,000 or more but is less than $50,000, the provision with its Alternate I applies.

(C) If the acquisition value is $50,000 or more but is less than $77,533, the provision with its Alternate II applies.

(D) If the acquisition value is $79,507 or more but is less than $100,000, the provision with its Alternate III applies.

(xxii) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.
(xxiii) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan--Certification. This provision applies to all solicitations.
(xxiv) 52.225-25, Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certification. This provision applies to all solicitations.
(xxv) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions.

(2) The following representations or certifications are applicable as indicated by the Contracting Officer:
[Contracting Officer check as appropriate.]
☐ (i) 52.204-17, Ownership or Control of Offeror.
☐ (ii) 52.204-20, Predecessor of Offeror.

☐ (iii) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.
☐ (iv) 52.222-48, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment--Certification.
☐ (v) 52.222-52 Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services--Certification.
☐ (vi) 52.223-9, with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA-Designated Products (Alternate I only).
☐ (vii) 52.227-6, Royalty Information.
☐ (A) Basic.
☐ (B) Alternate I.
☐ (viii) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.
(d) The offeror has completed the annual representations and certifications electronically via the SAM Web site accessed through https://www.acquisition.gov . After reviewing the SAM database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below *[offeror to insert changes, identifying change by clause number, title, date]*. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause	Title	Date	Change

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on SAM.
(End of Provision)

2. COMMERCIAL AND GOVERNMENT ENTITY CODE REPORTING, (JUL 2016) FAR Provision 52.204-16

Note to Offeror: This provision is incorporated by reference and is applicable when the resultant contract will contain FAR Provision 52.204-6 and/or FAR Provision 52.204-7.

3. PREDECESSOR OF OFFEROR, (JULY 2016) FAR Provision 52.204-20

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

"Commercial and Government Entity (CAGE) code" means--

(1) An identifier assigned to entities located in the United States and its outlying areas by the Defense Logistics Agency (DLA) Contractor and Government Entity (CAGE) Branch to identify a commercial or government entity, or

(2) An identifier assigned by a member of the North Atlantic Treaty Organization (NATO) or bythe NATO Support and Procurement Agency (NSPA) to entities located outside the United States and its outlying areas that DLA Commercial and Government Entity (CAGE) Branch records and maintains in the CAGE master file. This type of code is known as a NATO CAGE (NCAGE) code.

"Predecessor" means an entity that is replaced by a successor and includes any predecessors of the predecessor.

"Successor" means an entity that has replaced a predecessor by acquiring the assets and carrying out the affairs of the predecessor under a new name (often through acquisition or merger). The term "successor" does not include new offices/divisions of the same company that only changes its name. The extent of the responsibility of the successor for the liabilities of the predecessor may vary, depending on State law and specific circumstances.

(b) The Offeror represents that it ☐ is or ☐ is not a successor to a predecessor that held a Federal contract or grant within the last three years.

(c) If the Offeror has indicated "is" in paragraph (b) of this provision, enter the following information for all predecessors that held a Federal contract or grant within the last three years (if more than one predecessor, list in reverse chronological order):

Predecessor CAGE code:_____(or mark "Unknown").

Predecessor legal name:_____.
(Do not use a "doing business as" name).

(End of provision)

4. INFORMATION REGARDING RESPONSIBILITY MATTERS, (JUL 2013) FAR Provision 52.209-7

Note to Offeror: This provision is applicable when the resultant contract is expected to exceed $500,000.

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

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

"Federal contracts and grants with total value greater than $10,000,000" means—

(1) The total value of all current, active contracts and grants, including all priced options; and

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

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

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

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

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

(i) In a criminal proceeding, a conviction.

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

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

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

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

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

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

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

(End of provision)

5.COST ACCOUNTING STANDARDS

(1) Cost Accounting Standards Notices and Certification (October 2015), FAR Provision 52.230-1

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

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

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

I. Disclosure Statement -- Cost Accounting Practices and Certification

(a) Any contract in excess of $750,000 resulting from this solicitation will be subject to the requirements of the Cost Accounting Standards Board (48 CFR Chapter 99), except for those contracts which are exempt as specified in 9903.201-1.

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

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

(c) Check the appropriate box below:

☐ (1) ***Certificate of Concurrent Submission of Disclosure Statement***.

The offeror hereby certifies that, as a part of the offer, copies of the Disclosure Statement have been submitted as follows:

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

(ii) One copy to the cognizant Federal auditor.

(Disclosure must be on Form No. CASB DS-1 or CASB DS-2, as applicable. Forms may be obtained from the cognizant ACO or Federal official and/or from the loose-leaf version of the Federal Acquisition Regulation.)

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

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

☐ (2) ***Certificate of Previously Submitted Disclosure Statement****.*

The offeror hereby certifies that the required Disclosure Statement was filed as follows:

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

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

☐ (3) ***Certificate of Monetary Exemption****.*

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

☐ (4) ***Certificate of Interim Exemption****.*

The offeror hereby certifies that

(i) the offeror first exceeded the monetary exemption for disclosure, as defined in (3) of this subsection, in the cost accounting period immediately preceding the period in which this offer was submitted and

(ii) in accordance with 48 CFR 9903.202-1, the offeror is not yet required to submit a Disclosure Statement. The offeror further certifies that if an award resulting from this proposal has not been made within 90 days after the end of that period, the offeror will immediately submit a revised certificate to the Contracting Officer, in the form specified under subparagraph (c)(1) or (c)(2) of Part I of this provision, as appropriate, to verify submission of a completed Disclosure Statement.

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

☐ (5) **Certificate of Disclosure Statement Due Date by Educational Institution.**

(ALTERNATE I - April 1996)

If the offeror is an educational institution that, under the transition provisions of 48 CFR 9903- 202-1(f), is or will be required to submit a Disclosure Statement after receipt of this award, the offeror hereby certifies that **(*check one and complete*):**

☐ (i) A Disclosure Statement filing Due Date of_____has been established with the cognizant Federal agency.

☐ (ii) The Disclosure Statement will be submitted within the 6-month period ending_____months after receipt of this award.

Name and Address of Cognizant ACO or Federal Official Where Filed:

_____

II. <u>Cost Accounting Standards -- Eligibility for Modified Contract Coverage</u>

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

☐ The offeror hereby claims an exemption from the Cost Accounting Standards clause under the provisions of 48 CFR 9903.201-2(b) and certifies that the offeror is eligible for use of the Disclosure and Consistency of Cost Accounting Practices clause because during the cost accounting period immediately preceding the period in which this proposal was submitted, the offeror received less than $50 million in awards of CAS-covered prime contracts and subcontracts. The offeror further certifies that if such status changes before an award resulting from this proposal, the offeror will advise the Contracting Officer immediately.

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

III. <u>Additional Cost Accounting Standards Applicable to Existing Contracts</u>

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

☐ yes ☐ no

(2) <u>Proposal Disclosure-Cost Accounting Practice Changes</u>, (April 2005)(FAR Provision 52.230-7)

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

☐ YES ☐ NO

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

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

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

(End of provision)

6. CERTIFICATION REGARDING TRAFFICKING IN PERSONS COMPLIANCE PLAN (March 2015), FAR Provision 52.222-56

Note to offeror: This provision is applicable when services will be performed outside of the United States; and the estimated value exceeds $500,000.

(a) The term "commercially available off-the-shelf (COTS) item," is defined in the clause of this solicitation entitled "Combating Trafficking in Persons" (FAR clause 52.222-50).

(b) The apparent successful Offeror shall submit, prior to award, a certification, as specified in paragraph (c) of this provision, for the portion (if any) of the contract that—

(1) Is for supplies, other than commercially available off-the-shelf items, to be acquired outside the United States, or services to be performed outside the United States; and

(2) Has an estimated value that exceeds $500,000.

(c) The certification shall state that—

(1) It has implemented a compliance plan to prevent any prohibited activities identified in paragraph (b) of the clause at 52.222-50, Combating Trafficking in Persons, and to monitor, detect, and terminate the

contract with a subcontractor engaging in prohibited activities identified at paragraph (b) of the clause at 52.222-50, Combating Trafficking in Persons; and

(2) After having conducted due diligence, either—

(i) To the best of the Offeror's knowledge and belief, neither it nor any of its proposed agents, subcontractors, or their agents is engaged in any such activities; or

(ii) If abuses relating to any of the prohibited activities identified in 52.222-50(b) have been found, the Offeror or proposed subcontractor has taken the appropriate remedial and referral actions.

(End of provision)

7. CERTIFICATION REGARDING ENVIRONMENTAL TOBACCO SMOKE (December 1994)

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

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

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

8. CERTIFICATION OF INSTITUTIONAL POLICY ON FINANCIAL CONFLICTS OF INTEREST

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

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

(1) there is in effect at the Institution (the term Institution includes any contractor, public or private, excluding a Federal agency) an up-to-date, written and enforced administrative process to identify and manage, financial conflicts of interest with respect to all research projects for which funding is sought or received from the NIH;

(2) the Institution shall promote and enforce Investigator compliance with this part's requirements including those pertaining to disclosure of significant financial interests;

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

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

(5) the Institution shall fully comply with the requirements of 45 CFR Part 94.

9. DISASTER OR EMERGENCY AREA REPRESENTATION, (NOV 2007), FAR Provision 52.226-3

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

(a) Set-aside area. The area covered in this contract is: _____

[Contracting Officer to fill in with definite geographic boundaries.]

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

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

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

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

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

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

(2) Current state licenses;

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

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

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

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

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

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

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

(End of provision)

ATTACHMENT 5: DEFINITIONS And INFORMATION

Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases 75N93019R00027

The following provides information about NIAID resources and support services, including related Contractor interactions, as specified in the Statement of Work.

DMID Clinical Research Operations and Management Support (CROMS)

The DMID-CROMS contractor provides a broad range of services for clinical research operations and management for DMID extramural clinical research programs, including:

a) assistance in preparation/review of protocols and related documents;
b) assistance with site clinical quality management plans and tools for implementation;
c) training related to conduct of studies/trials under DMID's requirements;
d) pre-study activities, including clinical site assessment;
e) clinical site monitoring and reporting;
f) safety monitoring;
g) document management through web-based systems; and
h) receipt, assessment and maintenance of essential regulatory documentation.

Collaboration with the NIAID DMID-CROMS contractor is determined by the COR as specified in the SOW.

Clinical Site

A clinical site is a NIAID contractor, grantee or their subcontractor(s) consisting of a team of healthcare research professionals and the healthcare organization for whom they work. A clinical site conducts clinical research for one or more protocols and transmits protocol-specified clinical data to the SDCC. The SDCC will collaborate with clinical site personnel as specified in the SOW.

Safety Oversight Structures

The Safety Oversight Structure is established by NIAID/DMID and will include, at a minimum, a NIAID/DMID Medical Monitor, and as required, an Independent Site Monitor (ISM), and a NIAID/DMID-appointed Safety Monitoring Committee (SMC) or Data and Safety Monitoring Board (DSMB). The SDCC Contractor will collaborate with DMID staff and/or other personnel as designated by the COR to provide reports based on data in the SDCC clinical data system, as specified in the SOW.

NIAID-Wide Information System

The NIAID-wide information system is a comprehensive system to support NIAID clinical research management and oversight responsibilities. The SDCC Contractor will collaborate with DMID staff and/or other personnel as designated by the COR to provide data exchange/transfer capabilities, as specified by the COR.

DMID Regulatory Affairs Support and Clinical Agents and Specimen Repository Contractors

The DMID Regulatory Affairs Support and Clinical Agents and Specimen Repository Contractors are responsible for regulatory compliance and the receipt, storage, distribution and shipment of specimens from DMID clinical trials/studies. The SDCC Contractor will collaborate with DMID staff and/or other personnel as designated by the COR to provide related reports and tracking, as specified in the SOW.

ATTACHMENT 6: REPORTING REQUIREMENTS AND DELIVERABLES

Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases
75N9301900027

ARTICLE C.2. REPORTING REQUIREMENTS

a. Technical Reports

☒ (1) Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

a. The *Monthly Electronic Technical Progress Report* shall include a summary description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The Report shall also identify any problems encountered for subsequent discussion with the Contracting Officer's Representative (COR).
The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month. The format will be proposed by the Contractor, discussed with the COR and approved by the COR.

Other pertinent contract activities shall also be reported in this Monthly Electronic Progress Report, including:

1) The number of reports generated for Safety Oversight Structures and/or annual Investigational New Drug (IND) submissions;
2) The number of operational web sites and web pages;
3) the number and types of training provided, including title of training, presenters, recipients, locations and methods of training;
4) A description of paper, poster, manuscript review or development activities;
5) Activities related to tracking specimen inventory;
6) Activities related to ad-hoc statistical consultations; and
7) Any significant question and answer interaction(s) between the Contractor and clinical site personnel, including the name(s) of the key clinical site personnel involved and the Contractor personnel involved.

The content and/or format of this report may be further modified at the discretion of the COR as needed to support DMID requirements.

b. The *Monthly Electronic Study Status Report* shall include a listing of all studies, identified by study number, in which the Contractor is actively engaged. The format will be proposed by the Contractor in collaboration with the COR and approved by the COR.
The report shall include a column with the following categories/stages of clinical studies:

1) studies in development;
2) studies open and enrolling;
3) studies in follow-up; and
4) closed studies with analytic and report activities in progress.

Other report fields/columns shall capture: protocol number, disease, DMID Branch, sample size (n=), PI, DMID Clinical Project Manager (CPM)/Program Officer(PO), study title, enrollment goal, current enrollment, clinical sites or expected number of sites, enrollment open/close date, projected or actual last subject last visit date, projected or actual clinical database lock date, projected or actual non-clinical data completion date, projected or actual tables, figures, and listings completion date, initial Clinical Study Report (CSR) completion projection, projected or actual current CSR completion date, forecast for CSR projection change, http://clinicaltrials.gov/ results due or submitted from the Contractor, comments and/or action items, and assigned Contractor staff (including at a minimum the Contractor Project Manager and Statistician). The format will be proposed by the Contractor in collaboration with the DMID COR and approved by the COR. The content and/or format of this report may be further modified at the discretion of the COR as needed to support DMID requirements.

c. The *Monthly Electronic Expenditure Report* shall include cumulative spending for each protocol as well a breakdown of expenditures for each protocol, including; personnel (number of hours expended for each study and cumulative overall), consultants (identify specific protocol and role), materials and supplies, equipment (specify), staff travel (identify protocol and purpose of travel), and other direct costs.

☐ (2) Quarterly Progress Report

(a) This report shall include a [☐ summation of the Monthly Progress Reports ☐ a description of the activities during the reporting period] and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

(b) A Monthly Progress Report will not be submitted for the final month of aquarter.

☒ (3) Semi-Annual Progress Report

(a) This report shall include a [☒summation of the Monthly Progress Reports ☒ a description of the activities during the reporting period] and the activities planned for the ensuing reporting period. The initial report will be submitted for the first full six months of the contract performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of six full calendar months.

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

☒ (4) Annual Progress Report

This report includes a summation of the results of the entire contract work for the period covered. An Annual Progress Report will not be required for the period when the Final Report is due. A [☐ Monthly ☐ Quarterly ☒ Semi-Annual] Progress Report shall not be submitted when an Annual Progress Report is due.

Use the below narrative if the Contracting Officer's Representative requests a draft annual report.

☐ The Contractor shall provide the Contracting Officer's Representative and Contracting Officer with [*Insert Number*] copies of the Annual Progress Report in **draft** form [☐ in accordance with the DELIVERIES Article in SECTION F of this contract ☐ [*Insert Number*] calendar days prior to the delivery date for the Final Version of the Annual Progress Report.] The Contracting Officer's Representative will review the draft report and provide the Contracting Officer with comments within [*Insert Number*] calendar days after receipt. The Annual Progress Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

☒ (5) Annual Technical Progress Report for Clinical Research Study Populations - *required in all RFPs and contracts for clinical research involving human subjects*

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The Contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in Section J of the contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the Final Report.

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

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October 2001, applies. If this contract is for Phase 3 clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm.

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the Contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

☒ (6) Final Report

Use the following for completion type cost-reimbursement or fixed-price contracts that require the submission of a final report.

☐ This report is to include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. A/An [☐ Annual ☐ Semi-Annual ☐ Quarterly ☐ Monthly] Progress Report will not be required for the period when the Final Report is due.

Use the following for term (level of effort) type cost-reimbursement contractsthat require the submission of a final report.

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

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

The Contractor shall provide the Contracting Officer's Representative and Contracting Officer with one electronic copy of the Final Report in **draft** form [☒in accordance with the DELIVERIES Article in SECTION F of this contract ☒ 90 calendar days prior to the completion date of this contract. The Contracting Officer's Representative will review the draft report and provide the Contracting Officer with comments within 15 calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

☒ (7) Summary of Salient Results - *required for all R&D contracts.*

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

b. Other Reports and Deliverables

In addition to the above reports, the following are considered other reports and deliverables under this contract and are identified in the Statement of Work. A listing is included in the DELIVERIES Article in SECTION F.

(1) Computer-based system for clinical data management/collection, storage and quality control, compliant with current industry standards (e.g., CDISC), federal regulations and NIAID informatics requirements, as per the SOW - Due to be in place and fully operational within 60 calendar days from the effective date of the contract.

(2) Electronic specimen tracking system – The Contractor shall provide and maintain an electronic specimen tracking system, for use by the SDCC, study sites, laboratories and others as designated by the COR to track study specimens in real time. This system must be in place and fully operational within 60 calendar days from the effective date of the contract. This electronic specimen tracking system shall have the features and capabilities specified in the SOW.

(3) Quality Management Plan (QMP) to cover all contract activities, including a plan to identify gaps – An initial draft QMP is due from the Contractor within 30 calendar days from the effective date of the contract for CO and COR review/approval. The final QMP is due within 14 days of receiving comments from the COR on the draft document with prior CO/COR approval due as specified by the COR. Updated Plan versions are due to the CO and COR for approval as specified by the COR. The Contractor shall also provide performance reports from the QMP for approval by the COR on a schedule to be determined by the COR.

(4) Clinical Study Websites - The Contractor shall provide and maintain a website to share clinical research information and study materials with the DMID staff and participating study sites. This is due to be in place and fully operational within 60 calendar days from the effective date of the contract.

(5) SAE Reconciliation Process SOP – The Contractor shall compare and reconcile Adverse Events in the SDCC clinical data system with the separate DMID-CROMS pharmacovigilance (PVG) Serious Adverse Event (SAE) database. The contractor will develop an SOP to describe the process for such reconciliation in collaboration with the DMID-CROMS contractor, with a delivery schedule for the SOP and any updates determined by the COR and/or DMID staff designated by the COR. SAE reconciliation reports will be provided to the DMID-CROMS contractor as specified in the SAE Reconciliation Process SOP.

(6) Reports to DMID staff and other personnel designated by the COR regarding a study meeting pre-specified protocol criteria – The Contractor shall report in a timely manner to DMID and other personnel as designated by DMID immediately after a study meets any pre-specified protocol criteria. This includes provision and maintenance of an alert table/system for notification to appropriate study team members as determined by the COR and/or DMID staff designated by the COR.

(7) Reports for Safety Oversight Structures - The Contractor shall generate and submit to the DMID-CROMS contractor reports for distribution and review by study Safety Oversight Structures as specified by the clinical protocol, the safety charter and the Safety Oversight committees. The contractor will develop plans to meet the timelines necessary for DMID review and approval of such report prior to the distribution to the DMID-CROMS contractor. Such reports will include ad hoc safety profiles of individual subjects. Delivery schedules will be determined by the COR and/or DMID staff designated by the COR.

(8) Study site-specific reports – The Contractor shall generate site-specific reports for the DMID and the DMID-CROMS contractor as per the SOW. The delivery schedule for these reports will be determined by the COR and/or DMID staff designated by the COR.

(9) Reports to support clinical site monitoring - The SDCC clinical data system shall include integrated features and functions in support of DMID-CROMS clinical site monitoring requirements as specified in the Sponsor's study-specific clinical monitoring plan. A system to provide clinical site monitoring reports per the SOW shall be in place and fully operational within 60 calendar days from the effective date of the contract.

(10) Data via electronic data exchange system with DMID-CROMS data system - The Contractor shall establish an electronic data exchange system to communicate and

provide real-time information for the DMID-CROMS data system. This exchange system shall be due within 60 calendar days from the effective date of the contract. Related reports and data to be exchanged, as well as the timing of that exchange, will be determined by the COR and/or DMID staff designated by the COR.

(11) Data via electronic data exchange system with the NIAID-wide information system- The NIAID-wide information system is a comprehensive system to support NIAID clinical research management and oversight responsibilities. The Contractor shall collaborate with NIAID/DMID to provide data transfer capabilities and related reports specified by the COR from the SDCC clinical data system into this NIAID-wide information system. Related reports and data to be exchanged, as well as the timing of that exchange, will be determined by the COR and/or DMID staff designated by the COR.

(12) Ad hoc reports generated from the database at the request of DMID personnel. The requestor will provide the specification and data required for each report. The Contractor will generate the report requested in real time as necessary and determined by the COR and/or DMID staff designated by the COR.

(13) Regulatory reports– The Contractor shall assist with regulatory annual reports, final Clinical Study Report (CSR) generation and any other assistance as designated by the COR and/or DMID staff designated by the COR to support the Regulatory Affairs Support contract.

(14) Statistical Analysis Plan (SAP) - Prior to each clinical study/trial implementation, the Contractor shall develop the SAP in accordance with the approved protocol, safety plans and other documents as necessary and determined by the COR and/or DMID staff designated by the COR.

(15) Statistical designs, analysis plans and study-specific analyses for regulatory submissions - The Contractor shall prepare and present, in conjunction with DMID, study investigators and industry collaborators, statistical designs, statistical analysis plans and study-specific analyses for interactions with the U.S. Food and Drug Administration (FDA) in connection with pre- and post-regulatory submissions. Any requirements will be specified by the COR and/or DMID staff designated by the COR.

(16) Clinical data entry Systems User's Manual and Training Data Entry Module - Within 60 calendar days after the effective date of the contract the Contractor shall provide and maintain the following.
   (a) System User's Manual – Prepare and make available to DMID staff and study and laboratory sites an internet data entry system user's manual.
   (b) Training Data Entry Module – Implement a training data entry module on the remote and/or direct data entry system for study site staff.

(17) Site Visit Reports - The Contractor shall submit a Site Visit Report within 14 calendar days following each training clinical site visit providing the following information:
   (a) the date of the visit;
   (b) the site visited;
   (c) the purpose and objectives of the visit;
   (d) the participating staff (Contractor and site personnel);

(e) the visit findings;
(f) any issues and/or problems identified during the visit; and
(g) any actions taken to resolve issues/problems or recommendations for follow-up.

(18) Help Line for SDCC questions – The Contractor shall provide and maintain a 24 hour/7-day per week accessible help line to receive statistical and data management questions and related requests for SDCC assistance from study sites. This help line shall be in place and fully operational within 60 calendar days from the effective date of the contract. A help line report on the current help line operations status and key frequently asked questions (FAQs) is due monthly or as specified by the COR.

(19) Site Assessment Visit Reports - The Contractor shall submit a written Site Assessment Visit Report within 15 calendar days following completion of each clinical site assessment visit, providing the following information:
(a) the date of the visit;
(b) the site visited;
(c) the participating staff (Contractor and site personnel);
(d) the findings of the visit;
(e) any issues or problems identified during the visit; and
(f) any actions taken to resolve issues/problems or recommendations for follow-up.

(20) SOP for data storage and data transfers – The Contractor shall serve as a DMID clinical data storage facility for those studies conducted by DMID-supported investigators and collaborative groups, and for study sites that do not have access to long-term clinical data storage. Transfer of data, medium, timeframe and other details shall be determined by the SDCC and the transferring study sites or investigators with COR approval. The Contractor shall provide an SOP to the COR for review and approval describing the data storage and transfer process within 60 calendar days from the effective date of the contract.

(21) Overall Project Management Plan – The Contractor shall provide and update, as needed and/or requested by the COR, a comprehensive Project Management Plan (PMP) to be approved by the COR for the effective overall management, budgeting and tracking of contract activities, including work performed by subcontractors if applicable. This PMP is due within 60 calendar days of the effective date of the contract.

(22) Contract Initiation Meeting and Agenda - Initiate/hold Contract Initiation Meeting within 30 calendar days from the effective date of the contract. Draft and final agendas are due as specified by CO and/or COR.

(23) Monthly Status meetings/teleconferences with agendas/materials – The Contractor's PI and/or designee(s) will participate in meetings at a minimum of monthly intervals, either in person or via teleconference, to review overall progress with the COR and the Contracting Officer/designee and discuss key issues as per the SOW. The schedule of these meetings/teleconferences will be established by the COR and the Contracting Officer after contract award. The Contractor will prepare and distribute the agenda and meeting/teleconference materials to all participants as specified by the COR and/or DMID staff designated by the COR, as

well as provide a summary of all meetings and teleconferences in the Semi-Annual Progress Reports.

(24) Annual Site Visit Reports - The Contractor shall arrange for and conduct annual site visits for NIAID contract and DMID program staff to review and discuss project progress, issues and recommendations as per the SOW. These site visits shall be attended by the Contractor Principal Investigator, the Contractor's business representative, and all Contractor key personnel. A report is due within 30 calendar days of completion of each annual site visit.

(25) Study/trial-specific project management support services – The Contractor shall provide and maintain study/trial-specific project management support to DMID personnel, as requested by the COR and/or DMID staff designated by the COR. The COR will approve delivery of project management services by the Contractor for select trials/studies prior to implementation.

(26) Draft Final Transition Plan – The Contractor shall provide a draft description of transition activities, timelines, and assigned staff, which will be reviewed and approved by the COR. The Draft Transition Plan shall be submitted 12 months prior to the completion date of the contract, as requested by the Contracting Officer.

(27) Final Transition Plan – The Contractor shall provide a description of transition activities, timelines, and assigned staff in a Final Transition Plan, which will be reviewed and approved by the CO and COR. The Final Transition Plan shall be submitted to the CO and COR six months prior to the completion date of the contract. The final transition shall be fully completed by the completion date of the contract.

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

REPORTS AND DELIVERABLES

Check all that apply

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

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

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

☒ **Source Code and Object Code -** *Use when software is used, produced, modified or enhanced.*
Unless otherwise specified herein, the Contractor shall deliver to the Government, upon the expiration date of the contract, all source code and object code developed, modified, and/or enhanced under this contract.

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

SECTION D – PACKAGING, MARKING, AND SHIPPING

Use the following when no specific packaging, marking and shipping instructions are required.

☒ **Special packaging, marking and shipping specifications are NOT required.**

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.

☐ **Special packaging, marking and shipping specifications are required.** *Use all three items below, for RFPs & contracts that will require special packaging, marking and shipping specifications. Tailor each Article of this section in the event certain deliverables must be especially packaged and marked. Examples of deliverables which would be included in this category could be, but are not limited to, the following:*

- *Tissues, cells, etc., packaged in dry ice;*
- *Animals in specific containers;*
- *Blood samples in specific containers; and,*
- *Drugs in specific containers.*

ARTICLE D.1. PACKAGING

ARTICLE D.2. MARKING

ARTICLE D.3. SHIPPING

ARTICLE F.3 – DELIVERIES

Complete the following Tables with the Reports and Deliverables relevant to the requirement. Sample language is provided as guidance only.

a. Technical Progress Reports

Item	Reports	Recipients	Delivery Schedule
1.	Monthly Electronic Technical Progress Report	1 secure electronic copy to both COR and CO	Each report shall be submitted on or before the 15th of the month following each reporting period based on a 30-day reporting cycle, unless otherwise agreed to by the COR. The technical report format is subject to change by COR direction. **Example:** If award is made between December 1-31, the first monthly technical report is due on January 15th, for the entire month of December. On February 15th, the monthly technical report for the entire month of January will be due. Note: Delivery schedule will be established prior to award.
2.	Monthly Electronic Study Status Report	1 secure electronic copy to both COR and CO	Each report shall be submitted on or before the 15th of the month following each reporting period based on a 30-day reporting cycle, unless otherwise agreed to by the COR. The technical report format is subject to change by COR direction. **Example:** If award is made between December 1-31, the first monthly technical report is due on January 15th, for the entire month of December. On February 15th, the monthly technical report for the entire month of January will be due. Note: Delivery schedule will be established prior to award.
3.	Monthly Electronic Expenditure Report	1 secure electronic copy to both COR and CO	Each report shall be submitted on or before the 15th of the month following each reporting period based on a 30-day reporting cycle, unless otherwise agreed to by the COR. The technical report format is subject to change by COR direction. **Example:** If award

Item	Reports	Recipients	Delivery Schedule
			is made between December 1-31, the first monthly technical report is due on January 15th, for the entire month of December. On February 15th, the monthly technical report for the entire month of January will be due. Note: Delivery schedule will be established prior to award.
4.	Semi-Annual Progress Report	1 secure electronic copy to both COR and CO Hard copies only as directed by the CO and/or COR	The first report is due on/before six months from the award date, including any fractional part of the initial month. Thereafter, the reporting period shall consist of six full calendar months. Monthly reports will not be submitted the month the Semi-Annual Technical Progress Report is due. A Semi-Annual Technical Progress Report is not due when an Annual Technical Progress Report or Final Report is due. **Example:** If award is made between December 1-31,2020 the first report is due on or before June 30, 2021. Note: Delivery schedule will be established prior to award.
5.	Annual Progress Report	1 secure electronic copy to both COR and CO Hard copies only as directed by the CO and/or COR	The first report is due on/before the 30th of the month following the anniversary date of the contract. Thereafter, reports are due on/before the 30th of the month following each anniversary date of the contract. Semi-annual reports will not be submitted the month the Annual report is due. **Example:** If award is made between December 1-31,2020 the first report is due on or before December 31, 2021. Note: Delivery schedule will be established prior to award.
6.	Annual Technical Progress Report for Clinical Research Study Populations	1 secure electronic copy to both COR and CO	The first report is due on/before the 30th of the month following the anniversary date of the contract. Thereafter, reports are due on/before the 30th of the month

Item	Reports	Recipients	Delivery Schedule
			following each anniversary date of the contract. **Example:** If award is made between December 1-31,2020 the first report is due on or before December 31, 2021. Note: Delivery schedule will be established prior to award.
7.	Draft Final and Final Report and Summary of Salient Results	1 secure electronic copy to both COR and CO	Draft Final Report is due 90 calendar days prior to the completion date of contract. Final Report is due on/before the completion date of the contract.
8.	Annual Utilization Report	1 secure electronic copy to both COR and CO	Due on/before the 30th of the month following each anniversary date of the contract.
9.	All reports and documentation including the invention disclosure report, the confirmatory license, and the government support certification	1 secure electronic copy to OPERA	As required by FAR Clause 52.227-11.

b. Other Reports and Deliverables (Delivery Schedule)

1.	Computer-based system for clinical data management/collection, storage and quality control, compliant with current industry standards (e.g. CDISC), federal regulations and NIAID informatics requirements	1.C. 4)	1 secure electronic copy of memo confirming system readiness to CO and COR	Due to be in place and fully operational within 60 calendar days from the effective date of the contract
2.	Electronic specimen tracking system	1.8.	1 secure electronic copy of memo confirming system readiness to CO and COR	Due to be in place and fully operational within 60 calendar days from the effective date of the contract

3.	Draft and Final Quality Management Plans to cover all contract activities, including a plan to identify gaps	2.c.	1 secure electronic copy to CO and COR of draft and final plans 1 secure electronic copy of QMP performance reports to COR	Draft Plan due within 30 calendar days from the effective date of the contract for CO and COR review/approval Final Plan due within 14 days of receiving comments from the COR on the draft document , with prior CO/COR approval due as specified by the COR Updated Plan versions due to CO and COR for approval as specified by the COR Performance reports from the QMP for approval by the COR on a schedule to be determined by the COR.
4.	Protocol and Other Study-Related Materials	3.	Secure electronic copies as determined by the COR and/or DMID staff designated by the COR	As determined by the COR and/or DMID staff designated by the COR
5.	Clinical Study Websites	4.	1 secure electronic copy of memo confirming website readiness to CO and COR	Due to be in place and fully operational within 60 calendar days from the effective date of the contract
6.	SAE reconciliation Process SOP	5.b.1) c)	1 secure electronic copy to COR	SOP and any updates determined by the COR and/or DMID staff designated by the COR SAE reconciliation reports to be provided to the DMID-CROMS contractor as specified in the SAE Reconciliation Process SOP
7.	Reports to DMID and other personnel designated by DMID regarding a study meeting pre-specified protocol criteria	5.b.1) d)	1 secure electronic copy to COR of reporting table/system	As determined by the COR and/or DMID staff designated by the COR
8.	Reports for Safety Oversight Structures	5.b.1) e)	Secure electronic copies as determined by the COR and/or DMID staff designated by the COR	As determined by the COR and/or DMID staff designated by the COR
9.	Study site-specific reports	5.b.1) f)	1 secure electronic copy to COR	As determined by the COR and/or DMID staff designated by the COR

10.	Reports to support clinical site monitoring requirements	5.b. 1) g)	1 secure electronic copy of memo confirming system readiness to CO and COR	A system to provide reports to support clinical site monitoring shall be in place and fully operational within 60 calendar days from the effective date of the contract.
11.	Data via electronic data exchange system with DMID-CROMS data system	5.b. 1) i)	1 secure electronic copy of memo confirming system readiness to CO and COR	Due within 60 calendar days from the effective date of the contract Related reports and data to be exchanged and timing of that exchange to be determined by the COR and/or DMID staff designated by the COR.
12.	Data and related reports via electronic data exchange system with the NIAID-wide information system	5.b. 1) j)	1 secure electronic copy to COR	As determined by the COR and/or DMID staff designated by the COR
13.	Ad hoc reports	5.b. 1) k)	1 secure electronic copy to the requestor	At the requested time
14.	Regulatory reports	5.b. 2) c)	Secure electronic copies as determined by the COR and/or DMID staff designated by the COR	As determined by the COR and/or DMID staff designated by the COR
15.	Statistical Analysis Plan (SAP)	6. b. 1)	Secure electronic copies as determined by the COR and/or DMID staff designated by the COR	Prior to each clinical study/trial implementation, as determined by the COR and/or DMID staff designated by the COR
16.	Statistical designs, analysis plans and study-specific analyses for regulatory submissions	6. b. 4)	Secure electronic copies as determined by the COR and/or DMID staff designated by the COR	As determined by the COR and/or DMID staff designated by the COR
17.	Clinical data entry system User's Manual and Training Data Entry Module	7. a. and b.	1 secure electronic copy of each to CO and COR	Each is due within 60 calendar days from the effective date of the contract

18.	Site Visit Reports	7.c.	1 secure electronic copy to CO and COR	Due within 14 calendar days following completion of each site training visit
19.	Help Line for SDCC questions	7.d.	1 secure electronic copy of memo confirming system readiness to CO and COR 1 secure electronic monthly report on current Help Line operations status and key FAQs to CO and COR	Due to be in place and fully operational within 60 calendar days from the effective date of the contract Help line report on current help line operations status and key frequently asked questions (FAQs) due monthly as specified by COR
20.	Site Assessment Visit Reports	7.e.	1 secure electronic copy to CO and COR	Due within 15 calendar days following completion of each site assessment visit
21.	SOP for data storage and data transfers	9.	1 secure electronic copy to COR	Due within 60 calendars days from the effective date of the contract
22.	Overall Project Management Plan	10. a. 1)	1 secure electronic copy to CO and COR	Due within 60 calendar days from the effective date of the contract
23.	Contract Initiation Meeting and Agenda	10. b. 1)	1 secure electronic copy each of draft and final Agendas	Initiate/hold Contract Initiation Meeting within 30 calendar days after the effective date of the contract Draft and final agendas due as specified by CO and/or COR
24.	Monthly status meetings/teleconferences with agenda/materials distributed to participants	10. b. 2)	Copies as determined by the COR and/or DMID staff designated by the COR	As determined by the COR and/or DMID staff designated by the COR
25.	Annual Site Visit Reports	10.b.3) d)	1 secure electronic copy to CO and COR	Report due within 30 calendar days of completion of each annual site visit
26.	Study/trial-specific project management support services	10.c.1).	Copies as determined by the COR and/or DMID staff designated by the COR	As determined by the COR and/or DMID staff designated by the COR prior to implementation
27.	Draft Final Transition Plan	11.Option 10	1 secure electronic copy of report to CO and COR Hard copies only as directed by the CO and/or COR	Due 12 months prior to the completion date of the contract
28.	Final Transition Plan	11. Option 10	1 secure electronic copy of report to CO and COR Hard copies only as directed by the CO and/or COR	Due 6 months prior to the completion date of the contract

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

Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases
75N93019R00027

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

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

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

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

Offerors must refer to the solicitation Attachment entitled "Packaging and Delivery of the Proposal," which details strict guidelines, including page limitations, formatting and layout of proposals, and prohibits the offerors use of links to internet web site addresses (URLs) to direct readers to alternate sources of information.
~~*Include the Attachment "Packaging and Delivery of the Proposal", with the SP.*~~

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1:

1) PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, and identify if the proposal is an original or a copy. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall also include the legend regarding Restriction on Disclosure and Use of Data prescribed by FAR 52.215-1(e)]
2) TABLE OF CONTENTS
3) As part of the Technical Proposal, the Offeror will be required to submit a cross-reference between the RFP and the Technical Proposal to assist the Government in its review.

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested 5-page maximum)

Provide a brief overview of the Technical Proposal, including:

A. The activities to be performed by the offeror and all proposed subcontractors, including the identification of the proposed subcontractors and a list of key personnel of the offeror and the proposed subcontractors with degrees and titles.

B. The key features of the proposed 21 CFR Part 11 compliant computer-based clinical data system for:

- data collection, processing and reporting;
- data storage and transfer;
- data tracking and retrieval;
- electronic specimen tracking;
- web-based training and secured access website; and
- quality assurance/control for monitoring the data accuracy, security, completeness and timeliness of all clinical data received.

Note: Any proposed system should be comparable to current industry accepted standards for computer-based clinical data systems in compliance with all regulatory requirements.

C. The key features of the biostatistical support, expertise and innovation proposed.

D. Qualification and experience of the proposed PI and key personnel supporting the operation of the SDCC.

E. By area of expertise, provide the total number of staff, the number available to be assigned to the contract for the offeror and all proposed subcontractors, and total number of additional staff to be hired and trained.

F. The facilities and equipment to be made available by the offeror and all proposed subcontractors, including:

- the central facility for data collection, computer processing, storage, tracking and retrieval of all study data and data-related information;
- the off-site facility for back-up copies of data;
- the electronic specimen tracking system, including provision of related labels; and
- remote audio and video capabilities.

SECTION 3: TECHNICAL PLAN/APPROACH

A. Data Collection, Management, Quality Control and Storage (SOW items 1, 2 and 9)

Describe past experience and proposed plans/procedures to establish, operate, maintain and update a state-of-the art computer-based clinical data collection system to provide for the data collection, retrieval, tracking, quality control, transfer and storage of all

clinical and laboratory data at a central data management facility. Specifically, address the following in terms of both past experience and proposed plans/procedures.

1. The scope of the data collection system to be developed and the associated rationale.

2. The data entry system to be used. Include the minimal requirement for data entry infrastructure at the study sites. Discuss the security of the data entry system and granting, monitoring and revoking such access. Discuss experience, plans and procedures for accommodating offline use of the data system. Discuss other approaches for data entry as applicable. Discuss integration with clinical data systems (e.g., EHR) and laboratory systems at the sites.

3. Computerized validation, data queries, data editing and error-checking. Address issues of data integrity and evaluation and improvement of the accuracy, timeliness and completeness of data submitted by the clinical sites. Discuss timing, scope, user verification, notifications and security considerations, documentation and established procedures.

4. Data system features to verify 100 percent of study data. Describe details regarding receiving, entering, verifying, labeling, processing, coding, editing, updating, correcting, freezing, locking, storing, securing, tracking and retrieving all clinical and laboratory test results data at the central data management facility. Include timing, reversibility and quality assurance plans for database freezing and locking.

5. Standardization of study data collection, materials and uniform quality control. Discuss strategies to ensure uniform standardized data collection, queries and reports across multiple participating sites, including evaluation of the quality of data and implementation of related data quality improvement plans. Include plans for periodic review of manuals and procedures documenting data collection, editing and validation procedures/standards. Discuss features of a computerized data query system to notify and request resolution from clinical and laboratory sites. Discuss provision of site performance metrics reports.

6. Compliance with regulatory requirements, international guidelines and current globally-accepted standards. Discuss compliance with current applicable federal regulatory requirements, including 21CFR11, U.S. Public Law 110-85 or the Food and Drug Administration Amendments Act of 2007, local regulations, and current globally-accepted standards such as ICH guidelines, MedDRA terminology, the WHO Drug Dictionary, the Clinical Data Interchange Standards Consortium (CDISC) standards for clinical data management, and other standards.

7. Real-time electronic notifications of pre-specified protocol criteria for DMID-designated personnel. Describe experience, plans and procedures for handling pre-specified protocol criteria alerts such as halting rules triggers and other notifications. Include timing, scope, user verification, notification types and security considerations.

8. Data storage plans. Include a description of back-up procedures, disaster recovery procedures and query abilities. Describe experience and processes for storing data for studies for study sites that do or do not have access to long-term clinical data storage. Provide an SOP describing the data storage and transfer process.

9. The data reporting system. Discuss timing, adaptability and distribution of reports, describing plans for safety reporting, clinicaltrials.gov results reporting and quality performance reports. Discuss experience with reporting on study data for IND, IDE, BLA, NDA, PMA, 510(k) and their international equivalents as well as related regulatory reports, data management and quality control, data transfer capabilities, safety reporting and clinical site monitoring.

10. Quality Management Plan (QMP). Describe a QMP to cover all contract activities, including a plan to identify any gaps. Discuss implementation issues andexecution of QMP findings. Discuss how the QMP will be integrated into the general Project Management of this contract.

11. Computer-based registration and randomization. Discuss experience, plans and procedures regarding computer-based registration and randomization. Include non-computerized methods as a backup process.

12. Provision of datasets to regulatory agencies and industry collaborators. Discuss experience, plans and procedures related to providing datasets to regulatory entities and industry collaborators. Include general plans for establishing related timelines and standardized formats.

B. Study-Related Materials and Clinical Study Websites (SOW items 3 and 4)

1. Study-Related Materials

Describe past experience and proposed plans/procedures to develop, maintain and update study-related materials. Specifically address the following in terms of both past experience and proposed plans/procedures.

a) Generation of electronic CRFs (eCRFs). Provide examples of non-generic eCRFs produced for vaccine, therapeutic and device clinical trials.
b) Study materials templates. Provide examples of previously generated templates.
c) Reviewing, updating and distributing study-related materials to DMID, study sites, industry collaborators and regulatory bodies. Include past experience inthe execution of similar collaboration processes.

2. Clinical Study Websites

Describe past experience and proposed plans/procedures to establish, maintain and update a study-specific, secured access website to access protocol information and real-time study data/materials with DMID and participating study sites. Specifically, address the following in terms of both past experience and proposed plans/procedures.

a) The content and format for the website.
b) The system to be used to ensure secured access on a protocol-specific basis. Describe the development of a procedure for granting, monitoring andrevoking such access. Discuss the plan to perform periodic review of users and remove inactive users.
c) Provision of real-time access to study data, to aggregate study data as well as by pre-specified search criteria for key study matrices. Discuss the ability to generate real-time, user defined reports while maintaining data integrity.

d) A description of similar websites designed, maintained and updated by the offeror in support of clinical research programs. Address experience with secure access, maintenance of credentials, system availability and user satisfaction.
e) Updates to the SDCC website documents and materials during the course of a clinical trial/study. Describe plan for posting of new or modified versions of website materials. Discuss plans for future integration with the NIAID-wide document management system.

C. Study Communication, Collaboration and Reporting (SOW item 5)

Describe past experience in overall coordination and collaboration with similar scope contracts and proposed plans/procedures for overall coordination and collaboration with DMID and other DMID clinical research support services to facilitate study implementation, monitor study progress and evaluate SDCC processes and procedures. Include coordination and collaboration with the: (i) DMID Clinical Research Operations and Management Support (CROMS) contractor responsible for pharmacovigilance (PVG) and other activities, including Serious Adverse Event (SAE) reporting and safety oversight, collecting essential documents, activating study sites, reporting of clinical trial/study data to Clinicaltrials.gov, clinical site monitoring and quality assurance services; (ii) DMID Regulatory Affairs Support and Clinical Agents and Specimen Repository contractors responsible for regulatory compliance and the receipt, storage and distribution/shipment of specimens; (iii) Clinical site personnel as designated by DMID; and (iv) NIAID-wide information system. Specifically address the following in terms of both past experience and proposed plans/procedures.

1. Coordination and collaboration with the DMID-CROMS Contractor

a. Specifically address past experience, coordination and collaboration with clinical monitoring, PVG and other clinical support functions and future plans to coordinate and collaborate with the DMID-CROMS contractor to facilitate study implementation, monitor study progress and evaluate processes and procedures with respect to the following activities as specified in the SOW:
1) study initiation meetings/teleconferences;
2) approval for study implementation;
3) comparison and reconciliation of the clinical Adverse Event (AE) database with the PVG database and other related activities, including development of an SOP to describe the reconciliation process;
4) reporting on pre-specified protocol criteria/events such as halting rules, including provision/maintenance of an alert/notification system to notify appropriate study team members;
5) coordination, collaboration and reporting for independent data and safety oversight committees/structures, including plans for meeting the timelines for DMID review/approval and provision of individual subject safety profiles;
6) study site-specific reporting, including site performance metrics;
7) system/reports to support clinical site monitoring and related system features/capabilities;
8) reporting of study data for the Clinicaltrials.gov system; and
9) reports for the DMID-CROMS data system through an electronic data exchange system to provide real-time information.

b. Discuss the access that the DMID-CROMS contractor will have to the database, addressing such issues as format of data presented, and tools available to allow efficient monitoring of clinical trials.

2. Coordination and collaboration with the DMID Clinical Agents and Specimen Repository and Regulatory Affairs Support (or comparable) Contractors

   a. Describe past experience in coordination and collaboration with repositories and future plans to coordinate and collaborate with the DMID Clinical Agents and Specimen Repository contractor with respect to specimen tracking andinventory. Discuss tracking information regarding date, time, inventory of study specimens collected at sites, courier service and timeliness of shipments to the repository maintained by the DMID Clinical Agents and Specimen Repository contractor. Describe generation of specimen lists from the electronic specimen inventoryand submission to the DMID Clinical Agents and Specimen Repository contractor to select and ship specimens to specified laboratories or other destinations as designated by DMID.

   b. Describe past experience in coordination and collaboration with regulatory function and future plans to coordinate and collaborate the DMIDRegulatory Affairs Support contractor. Discuss past experience and future plans for reporting on study data for IND, IDE, BLA, NDA, PMA, 510(k) and their international equivalents.

3. Coordination and collaboration with DMID clinical research sites, supportservices and/or DMID staff designated by the COR on statistical design and analysis and development of protocols and other study related materials.
   a. Describe past experience in coordination and collaboration with similar scope contracts and proposed plans/procedures for overall coordination and collaboration, specifically on statistical design and analysis and development of protocols and other study related materials.

4. Coordination and collaboration with the NIAID wide information system.
   a. Describe transfer of data via an electronic data exchange system with the NIAID wide information system.

D. <u>Statistical Design and Analysis</u> (SOW item 6)

1. Statistical Design

Describe past experience and proposed plans/procedures in development and implementation of statistical study designs. Specifically address the following in terms of both past experience and proposed plans/procedures.

   a. Developing and refining experimental study designs, including appropriate control/comparison groups, inclusion and exclusion criteria, sample size and power estimates, primary and secondary endpoints, randomization and stratification/blocking methods, masking approaches and other innovative statistical approaches for a variety of clinical study and trial designs, including Phase 0-4 vaccine and therapeutic trials (including PK data analysis) and device trials. In particular discuss cases relevant to infectious disease protocols. Also include experience with vaccine, therapeutics and device research, particularly addressing experience with pK/pD trials, large phase 3

trials, epidemiology studies, systems biology research, trials with adaptive design and other special statistical designs.

b. Review of protocols and provision of recommendations on statistical design issues and developing/refining interim and final data analysis plans.

c. Provision of statistical advice concerning issues such as approach, power, sample size, and impact of interim analyses as well as other statistical analysis as requested by DMID.

d. Development of new applications of statistical or information science theory. Include the provision of: bioinformatics, pharmacokinetic (pK) and pharmacodynamic (pD), genetics, systems biology and other non-conventional statistical design and analysis support; pre-concept early statistical consultation to DMID and DMID-designated site personnel; input to DMID on DMID-designated trials/studies for which another data coordinating center (DCC) is providing related services; the ability to analyze datasets not generated by this contract; and, review of other companies' statistical analysis plans, CSR tables/listings, and safety shells/templates.

e. Discuss provision of statistical input to DMID to assist with DMID decision-making. Include independent review and analysis of statistical designs, experience in reviewing research proposals at the concept level, protocollevel and reviewing other DCC designs and implementation.

2. Statistical Analyses
Describe past experience and proposed plans/procedures in development and implementation of statistical analyses plans, interim analyses, final analyses, regulatory submissions, expedited analyses, pre-publication/presentation analyses and ad hoc analyses. Discuss innovative approach for statistical analysis and reporting. Specifically address the following in terms of both past experience and proposed plans/procedures.

a. *Statistical Analysis Plan (SAP):* Discuss timing and content of the SAP in accordance with the approved protocol, safety plans and other documents. Include description of maintenance and updates to the SAP throughout the life of the study/trial and any related timeline(s).

b. *Interim analyses*: Discuss performing interim analyses for safety, immunogenicity and/or efficacy and other parameters as specified in the SAP. Include a discussion of how offeror will summarize and present interim findings to the designated Safety Oversight Structures.

c. *Final analyses*: Describe conducting comprehensive final statistical analyses, in accordance with the SAP. Describe past experience in providing reports for independent data and safety oversight committees.

d. *Additional analyses*: Discuss how additional analysis are performed in support of requests by Safety Monitoring Committees (SMCs), Data Safety Monitoring Boards (DSMBs), DMID, or study investigators, for use in safety monitoring and in the preparation of abstracts, journal articles and scientific presentations. Discuss plan to develop a process for approval and prioritization of such requests.

e. *Regulatory Submissions for Vaccines, Biologics, Drugs and Devices*: Describe experience with and plans to prepare and present, in conjunction with DMID, study investigators and industry collaborators, statistical designs, statistical analysis plans and study-specific analyses for interactions with the U.S. Food and Drug Administration (FDA) in connection with pre- and post-regulatory submissions. Describe past experience in regulatory submissions at the individual trial level (IND, IDE and their international equivalents) as well as the product level (NDA, BLA, PMA, 510(k) and their internationalequivalents). Discuss plans to assist DMID, study investigators and industry collaborators in responding to FDA inquiries regarding clinical trial design and analysis at any point during a study.

f. *Expedited analyses*: Discuss plan to conduct expedited analyses of data for selected high-priority studies and provide for the rapid transfer of data, data documentation and analyses to the DMID at any point during a study.

g. *Pre-Publication/Presentation Analyses*: Prior to presentation or submission for publication, describe plan to review for accuracy all abstracts, manuscripts, and presentations that include data generated from clinical trials and clinical studies supported under this contract.

h. *Ad hoc analyses*: Discuss process to conduct ad hoc analyses as requested by DMID, including the ability to analyze datasets not generated by thiscontract.

E. Clinical Site Training, Assessment and Technical Assistance (SOW item 7)

Describe past experience and proposed plans/procedures in development and implementation of clinical site training, assessment and technical assistance. Discuss past experience in performing clinical site assessment for adequacy for electronic data systems and providing clinical trial site training on the electronic data capture system. Discuss on-site, remote and written training provided. Specifically address the following in terms of both past experience and proposed plans/procedures.

1. Clinical Site Training

   Training clinical site personnel, including all levels of experience and responsibilities, with respect to the collection, management, quality control and transfer of study data to the central data management facility. Discuss both past experience and plans for the following.

   a. Providing data entry system training materials. Discuss how training will be tracked.
   b. Instructional materials regarding data management procedures and training sessions. Include description of training topics via written, on-site and remote methods. Discuss plan to present information in a variety of time zones and settings.

2. Clinical Site Assessment

   Describe past experience and proposed plans/procedures for ensuring the adequacy of site-specific infrastructure, procedures and training with respect to data collection, entry, validation and transfer. Discuss past experience, proposed plans and

activities conducted regarding assessing the on-site capabilities of DMID-supported clinical study sites in terms of on-site technical expertise and data systems in place to collect, manage, secure, validate and analyze data.

3. Clinical Site Technical Assistance

    a. Consultation and assistance to sites. Describe past experience in and plans/procedures for provision of consultation and assistance to clinical sites in facilitating computerized data entry and management.
    b. Help line. Describe past experience and plans/procedures for designing, operating, updating and staffing a 24-hour/7 days per week telephone help line support system to address data management questions.

F. Electronic Specimen Tracking System (SOW item 8)

Describe past experience with and proposed plans/procedures for design, implementation, operation and updating of an electronic specimen tracking system for use by the SDCC, clinical sites and laboratories to track study specimens in real time. Specifically address the following in terms of both past experience and proposed plans/procedures regarding the required features/capabilities of the specimen tracking system.

1. Scope of and integration with the clinical data management system. Include discuss compliance with regulatory requirements as described in the Statement of Work Section III.1, experience, plans and procedures regarding provision of shipment assistance and reporting capabilities.
2. Use an automatic labeling system on specimen aliquots.
3. Generation of an electronic shipping manifest for receipt by the receiving facility.
4. Provision of labels to study sites for specimen aliquots, ensuring protection of confidentiality and blinding of laboratory staff to specimen identity.
5. Provision of a real-time global inventory of all study specimens and the location of individual specimens for each specific study.

SECTION 4: SCIENTIFIC AND TECHNICAL PERSONNEL

The Technical Proposal should include all information relevant to document individual training, education, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Proposals should include a Staffing Plan for the conduct of the Statement of Work with role descriptions and level of effort of scientific and technical personnel, including scientific and technical personnel of all proposed subcontractors. Clearly identify who is to be assigned as Key Personnel. Limit CVs to 2-3 pages and provideselected references for publications relevant to the scope of the contract, and include experience with projects of similar scope, size and complexity carried out by the offer and any proposed subcontractors over the past 5 years.

1) Principal Investigator: Describe the education, training, experience, expertise, qualifications, and percentage of effort of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract, including:
    1. Experience in overseeing a contract with similar scope and size;
    2. Coordination and oversight of a broad range of support services for large and complex clinical research programs;

3. Design, development and implementation of data management systems;
4. Biostatistical experience in design, development and implementation of all phases of clinical trials for the evaluation of candidate vaccines, therapeutics, devices and biologics for infectious diseases, as well as other types of evaluations and analyses in compliance with applicable local and international regulations and internationally recognized guidances;
5. Experience in implementation of ICH standards, MedDRA terminology, WHO Drug Dictionary, CSDIC standards; and,
6. Preparation of and reporting on study data for IND, IDE, BLA, NDA, PMA, 510(k) and their international equivalents as well as related regulatory reports, data management and quality control, data transfer capabilities, safety reporting and clinical site monitoring. Discuss experience and expertise in innovative approaches for the analysis and design of those reports.

2) Other Key Scientific and Technical Personnel: Describe the education, training, experience, expertise, qualifications, and percentage of effort for all proposed key scientific and technical personnel of the offeror and all proposed subcontractors. Document relevant qualifications for: statisticians, research staff, systems analysts, programming and information technology professionals. Discuss experience in implementation of ICH guidance, CDISC standards, MedDRA terminology, and WHO Drug dictionary. Also discuss experience in preparation of and reporting on study data for IND, IDE, BLA, NDA, PMA, 510(k) and their international equivalents as well as related regulatory reports, data management and quality control, data transfer capabilities, safety reporting and clinical site monitoring.

SECTION 5: FACILITIES, EQUIPMENT, AND OTHER RESOURCES

The Technical Proposal should document availability and adequacy of facilities, equipment, space and all support resources necessary to carry out the Statement of Work for the offeror and any proposed subcontractor(s). Specifically address the following in terms of both past experience and proposed plans/procedures.

A. A central facility for data collection, computer processing, storage, tracking and retrieval of all study data and study-related information, a list of equipment and resources dedicated to the project, and the location(s) and features of the facility

B. An off-site facility for back-up copies of data, including discussion of security and redundancy

C. Computers, hardware and software, computer equipment and servers, including a description of security systems in place

D. Resources to ensure secure internet access

E. Dedicated space for staff and equipment

F. Controlled access areas for secure storage of study data and confidential study information

SECTION 6: PROJECT MANAGEMENT

A. Overall Contract Project Management

Discuss past experience in managing a project of this size and scope. In particular address past experience with Government contracts, development and implementation of Project Management Plans, selection and monitoring performance of subcontractors, implementation of Work Breakdown Structures (WBS), implementation of Earned Value Management (EVM), and establishment of a communication plan with the COR (or equivalent). Discuss problem resolution strategies as well as continuous improvement strategies. Specifically address the following in terms of both past experience and proposed plans/procedures.

1. A comprehensive Project Management Plan (PMP) for the overall management, budgeting and tracking of contract activities, including work performed by consultants and/or subcontractors as applicable. If consultants and/or subcontractors are proposed, include a process to manage, coordinate, and oversee the work performed by consultants and/or subcontractor(s). Describe project organization, staffing, and management regarding the planning, initiation, implementation, conduct, monitoring and completion of tasks identified in the Statement of Work. Describe in detail the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants. Provide an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel. Include a chart of the proposed organizational/management structure for the contract.
2. Project management systems that will be used to track activities and to keep multiple activities on time and within budget. Include a description of the quality control methods that will be used to ensure the effective and efficient initiation, implementation, management, and oversight of contract requirements.
3. Discussion, provision and maintenance of an infrastructure to ensure the efficient planning, initiation, implementation and timely completion of all projects carried out under this contract and effective communications with the COR and the Contracting Officer.
4. Provision of a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring and reporting onproject status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors if applicable.
5. Effective and efficient coordination of specified functions identified in the SOW regarding collaboration with the DMID clinical research support services and clinical sites.

B. Meetings, Teleconferences and Annual Site Visits

Specifically address the following in terms of both past experience and proposed plans/procedures.

1. Conducting contract initiation meeting, including an agenda and purpose as described in the SOW.
2. Participating in monthly status meetings/teleconferences to review overall progress with the COR and Contracting Officer/designee as per the SOW, including the process for distributing agendas and a summary of all meetings/teleconferences in the Semi-Annual Progress Reports.

3. Participating in an annual site visit with the COR and Contracting Officer/designee(s). Discuss plan to arrange and manage site visits.

C. Study/Trial-Specific Project Management Services

Describe past experience with and proposed plans/procedures for providing study-specific project management. Discuss in particular the organizational structure to support those activities, project management plans, avoidance of scope creep, WBS, EVM and communication plans. In addition, specifically describe the following.

1. Provision and maintenance of study/trial-specific project management support to DMID personnel, including coordinating and facilitating protocol team calls, including generation of agenda and meeting minutes; revision of documents and generation of list of changes; and serving as central hub for communications.
2. Responding to study/trial-specific project management-related questions in collaboration with the designated DMID project management staff, including a process for initial COR approval for study/trial-specific project management services.

SECTION 7: OPTIONS

Options should be presented as a separate part of the Technical Proposal and clearly identified as such.

1) OPTIONS 1 through 6: Extend the Term of the Contract

Discuss plans and procedures for continuing and providing the same services indicated in the Statement of Work beyond the contract Base period. To address these Options, offerors should describe the methods and procedures to maintain the operations specified in the Statement of Work beyond the Base period, including retaining or recruiting necessary staff, and maintaining and/or acquiring required equipment and facility space.

OPTION 11: EXTEND SERVICES (FAR 52.217-8)
Discuss plans and procedures for continuing and providing the same services indicated in the Statement of Work beyond the contract Base period and Options 1-6 for up to an additional 6 months. To address this Option, offerors should describe the methods and procedures to maintain the operations specified in the Statement of Work beyond the Base period and Options 1-6, including retaining or recruiting necessary staff, and maintaining and/or acquiring required equipment and facility space.

2) OPTION 7-8: Increase Level of Effort

Describe past experience with and plan for increasing level of effort in similar contracts. In particular address issues of recruiting appropriate personnel in a timely manner. Describe an implementation plan to increase the level of effort that may result from unanticipated increases in demand, with the services required under these Options to be of the same scope provided during the Base year.

3) TRANSITION

A. Option 9: Initial Transition
Describe past experience with transition into and out of a contract with similar scope. In particular discuss problems and their resolutions encountered during initial transitions. Discuss past experience with and plan for transitioning materials, data and programs to another contractor. Provide detailed plans for transitioning of materials, data and programs, and how the ability to seamlessly continue operations will be maintained.

B. Option 10: Final Transition
Describe past experience, plans and related personnel to implement a secure, orderly and efficient transition of contract-related materials and activities to the Government to be completed by the expiration date of the contract, including clinical and laboratory data, study-related materials, and other contract-generated resources. Discuss the soundness, appropriateness, adequacy and feasibility of the plans and procedures for the initial draft and final transitions addressing: transition timelines; ability to affect a seamless transition for all studies that are currently enrolling, producing final study reports and other required regulatory reports for completely enrolled studies; and, access to archived data

SECTION 8: OTHER CONSIDERATIONS

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

This section of the Technical Proposal should document other resources not covered in Sections 1 through 7 above necessary to carry out the Statement of Work, including:

Section L of the RFP provides minimum documentation requirements for the following items. The required information described in Section L should be assembled together, in the following clearly marked sections of the Technical Proposal. Refer to Section L of the RFP for specific requirements. Read each section below carefully. In some cases, offerors may be asked to provide documentation which is in addition to the minimum requirements identified in Section L.

1) Obtaining and Disseminating Biomedical Research Resources

Section L of the RFP specifies the minimum documentation requirements for this element. The Technical Proposal should document all information necessary to evaluate this issue.

2) Sharing Research Data (Plan)

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

~~3) Information Technology (IT) Systems Security~~

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

ATTACHMENT 8: ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

Statistical and Data Coordinating Center (SDCC) for Clinical Research in Infectious Diseases
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In addition to the format requirements for the Business Proposal that are contained in Section L of the solicitation, the information presented in this section of the RFP is intended to provide uniform cost assumptions and business clarifications.

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

BUSINESS PROPOSAL – TABLE OF CONTENTS

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

SECTION 2 – COST OR PRICE SUPPORT

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

SECTION 3 – UNIFORM COST ASSUMPTIONS

1) Technical Cost Assumptions

a.		**Ongoing** Activities **at Contract Award** (assume responsibility for)	Assumptions
	1)	*Clinical Trials/Studies*	**Assume**: • 30 Phase 1-4 clinical trials and other studies *in development* ➢ *Of the 30, assume one Phase 4 clinical trial in development and 1 device study in development* • 85 active Phase 1-4 clinical trials and other studies, including one Phase 4 trial, and one device IDE study

			• 80 completed trials for which final clinical study reports are pending • 200 completed trials/studies for which data are archived
	2)	*Clinical Specimens*	**At the time of award, assume that**: • 2,700,000 million specimens are in the specimen tracking system
	3)	*Study Websites*	**Assume**: 300 clinical trial-specific websites involving, 20,000 web reports; 7200 documents posted; and 2500 active website users at the time of award
b.		**New** Clinical Trials/Studies	Assumptions
	1)	*Number*	**Assume**: • 44 new protocols will enter development each year of the contract period of performance • There may be as many as 170+ trials/studies in development, in accrual, in follow-up or analysis at any point in time

	2)	*Phase/Device Type/Other*	**Assume, per year**:
			• 30 of the 44 new clinical trials will be Phase 0-2 clinical trials
			  ○ 22 trials will be 50 subjects or less
			  ○ 5 will be 50-100 subjects
			  ○ 3 will be 100-200 subjects
			• 2 will be a Phase 3 clinical trial
			• 1 will be Phase 4 trial
			• 2 will be device studies under a full IDE
			• 2 will be observational studies
			• 7 "other" research studies (non-IND/IDE)

	3)	*Candidate vaccines/therapeutics/devices and other research study participants*	**Assume, per year**: • 33 of the new clinical trials/studies will be trials in healthy subjects, although some of these trials may include special populations such as the elderly, i.e. greater than 65 years, pediatric populations and pregnant women • 10 of the new clinical trials/studies will be treatment trials in subjects who are ill with the disease under study, which may include special populations • 1 of the new clinical trials/studies will be a large observational study

	4)	*Duration*	**Assume**: • the duration of 22 of the new clinical trials/studies per year will be 1 yearor less

			• 15 of the trials/studies will be 18 months- 2 years • 7 trials/studies will be 3 years in duration
	5)	*Clinical sites*	**Assume**: • 30 of the new clinical trials per year will be multi-center • 14 of the new clinical trials will be performed at a single clinical site
	6)	*Study website*	**Assume for all new clinical trials the Contractor will be responsible for**: • the design and maintenance of one dedicated web page for each new clinical trial, each containing 70 web reports; and 30 documents posted • a total of 5,000 users requiring access to various websites at any time
	7)	*Study website training materials*	**Assume that training webcasts or videos posted/maintained per year will be as follows:** • 15 videos related to electronic clinical data entry • 10 videos related to the electronic specimen tracking system • 7 videos for site monitors/managers on the electronic clinical data system • 4 videos for general website and safety-related training • 1 foreign language video
	8)	*Study initiations*	**Assume**: • study initiations for 40 new clinical trials/studies per year • 34 will be conducted via teleconference or webcast • 4 will require visits to domestic clinical sites • 2 will require visits to foreign clinical sites
	9)	*Clinical specimens*	**Assume that each of the new clinical trials will require**: • 8 specimens per subject • each divided into 10 aliquots (total 80 aliquots per subject per trial) • to be collected, bar coded and tracked via an electronic tracking system • with 6400 specimen shipments per year
	10)	*Site assessments*	**Assume**: • 6 site assessments per year for new clinical trials: 4 site assessments for domestic clinical sites and 2 site assessments for foreign clinical sites
	11)	*Study site visits*	**Assume:**

			• 7 site ad hoc visits: 5 domestic clinical sites and 2 foreign clinical sites will be conducted in each year of the contract to address special issues
	12	*Study Reports*	**Assume:** • 25 final Clinical Study Reports (CSRs)/year • 50 IND reports/year • 25 ClinicalTrials.gov study results reporting/year • 12 interim analyses reports/year
	13	*Safety Committee Reports*	**Assume:** • 80 DSMB/SMC reports at various frequencies each year, including subject safety profiles
	14	*Pharmacovigilance*	**Assume:** • SAE reconciliation reports will be provided monthly to CROMS contractor • Biweekly AE reports for 10 high risk studies per year
	15	*Data Transfers*	**Assume:** • 25 protocol datasets to be transferred to collaborators per year

2) Travel

	Activity to be performed	Assumptions
a.	*Contract Initiation Meeting*	**Assume:** • 1 meeting in Bethesda, Maryland within 30 calendar days after effective date of contract, with a 1-night stay • attendance by the Contractor's key personnel
b.	*Site Assessments*	**Assume**: • 6 site assessments per year • conducted by 2 individuals • 4 days total (one day each) for 4 domestic clinical sites • 4 days total (two days each) for 2 foreign clinical sites
c.	*Study Initiations*	**For each year of the contract, assume travel for:** • 1 person for study initiation visits to 4 domestic clinical sites • travel for 1 person for study initiation visits to 2 foreign clinical sites. • all study initiations can be completed in 1 day
d.	*Study Site Visits*	**Assume**: • 7 ad hoc study site visits per year • conducted by 2 individuals • 5 days total (one day each) for 5 domestic sites • 4 days total (two days each) for 2 foreign clinical sites

3) **Special Shipping and Packaging** - ***NA***

4) **Storage** *DATA STORAGE ESTIMATES/ASSUMPTIONS AREALREADY DESCRIBED ABOVE.*

5) Government Furnished Equipment (GFE)

☐ Government Furnished Equipment available to be transferred from incumbent contractor.

If this initiative is a recompetition, the ***Contract Specialist*** *will provide a listing of all Government Furnished Equipment that has been purchased under the incumbent contract with contract funds. The CS will include this listing as an attachment to the RFP and potential offerors will be advised that this equipment is available to be transferred to the successful offeror.*

☒ The purchase of Government Furnished Equipment will not be authorized as a direct charge under this contract.

SECTION 4 – OPTIONS

A separate section of the business proposal to include a cost spreadsheet and supporting documentation must be presented for **each** Option identified below. The proposed budgets for Options 7-10 shall be based upon SOW Section 11: OPTIONS and submission of responses to the instructions provided in Section 7: OPTIONS of the Attachment entitled "Additional Technical Proposal Instructions." Sufficient cost information shall be provided that will allow the government to determine the offeror's understanding of the cost of implementing these Options and the reasonableness of the estimated costs.

OPTIONS 1-6: Extend Term of the Contract
The Government may include Options to extend the period of performance by up one (1) year (twelve (12)-months). The total period of performance resulting from the base period plus all potential Term Options is seven (7) years. If Options 1-6 are exercised, the services required will be the same as provided during the base year.

OPTION 11: Extend Services
The Government expects to include an Option to extend the period of the contract up to six (6) additional months. The total period of performance resulting from the Base period plus all potential Term Options. If Option 11 is exercised, the services required will be the same as provided under the Base or Term Options. Although, Option 11 can be exercised at any time during the performance of the contract, for purposes of this Solicitation, assume it would be exercised after option 6 to extend the Period of performance of the contract from 7 years to 7.5 years.

OPTIONS 7-8: Increase in Level of Effort
Refer to SOW Section 11: OPTIONS and the instructions provided in Section 7: OPTIONS of the Attachment entitled "Additional Technical Proposal Instructions."

OPTION 9: Initial Transition Effort
Refer to SOW Section 11: OPTIONS and the instructions provided in Section 7: OPTIONS of the Attachment entitled "Additional Technical Proposal Instructions."

OPTION 10: Final Transition Effort
Refer to SOW Section 11: OPTIONS and the instructions provided in Section 7: OPTIONS
of the Attachment entitled "Additional Technical Proposal Instructions."

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

1) Small Business Subcontracting Plan

Section L of the RFP specifies the minimum documentation requirements for completing a subcontracting plan. This plan should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

2) Extent of Small Disadvantaged Business Participation

Section L of the RFP specifies the minimum documentation requirements for small disadvantaged business utilization. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

3) Past Performance Data, including references

Section L of the RFP specifies the minimum documentation requirements for providing past performance information. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

ATTACHMENT 9: ADVANCE UNDERSTANDINGS

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Check the appropriate box.

☐ There are ***NO*** Advance Understandings applicable to this solicitation. ☒ The below Advance Understandings are applicable to this solicitation.

All data and other information pertaining to product supplied by Companies serving as industry collaborators ("the companies") for the clinical trials to be undertaken by the Contractor, or supplied by the Contracting Officer's Representative (COR), shall be assumed to be confidential unless specifically identified as not confidential in writing by the COR. The Contractor agrees that its Principal Investigator and/or any other employees or agents of the Contractor will provide the data generated under this contract exclusively to the NIAID or, if directed by the NIAID, to the Companies, the U.S. Food and Drug Administration (FDA) or other third parties.