

SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended		
2. Request for Proposal (RFP) Number: NIH-NIAID-DMID-AI2008041	3. Issue Date: October 15, 2008	4. Set Aside: ☒ No ☐ Yes See Part IV Section L
5. Title : Animal Models of Infectious Diseases		
6. ISSUED BY: Brian Jamieson, Contract Specialist National Institute of Allergy and Infectious Diseases National Institutes of Health 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892		7. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.
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 4:00 pm local time on February 17, 2009. 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 TO TWO DIFFERENT LOCATIONS. THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY IS THE ADDRESS PROVIDED FOR THE OFFICE OF ACQUISITIONS AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS, AND REVISIONS" LOCATED IN SECTION L.1. OF THIS SOLICITATION.		
10. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. http://www.ccr.gov		
11. FOR INFORMATION CALL: Brian Jamieson, Contract Specialist PHONE: 301-451-3678 e-MAIL: bjamieson@niaid.nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.		
		Yvette R. Brown, Contracting Officer MID RCB-A, OA, NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20892

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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 Animal Models of Infectious Diseases program will provide NIAID with a broad and flexible range of animal model capabilities for human infectious diseases or diseases of human importance caused by infectious agents. The broad scope will allow NIAID to respond to changing priorities as scientific and public health needs shift, including rapid responses to public health emergencies. The scope of work encompasses all animal work needed for infectious disease research, to include new animal model development and refinement of existing models, routine screening of products, efficacy testing to support Investigational New Drug (IND) applications or clinical trials, and efficacy testing in support of Biologic License Application/New Drug Application (BLA/NDA) submissions to the FDA under Good Laboratory Practices (GLP, 21 CFR Part 58). Also included is the use of laboratory animals to generate pathogens and pathogen-specific reagents that are not commercially available but required for research or product development.

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. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

In addition, the following advance understandings are applicable to this solicitation:

- a. CONFIDENTIALITY

Maintaining confidentiality of information is crucial to the success of this program. There are two types of confidential information to be shared:

1. Proprietary data

This information is related to the products being tested in animal models. Contractors will be bound to restrict access and disclosure of proprietary information that may be shared with them from third party submitters in order to conduct the animal studies. A sample Non-Clinical Evaluation Agreement to be signed by NIAID and the third party sponsor is found at Attachment 7.

2. Animal models developed through these contracts

This information may be shared by NIAID with interested third parties and will be protected prior to publication as Confidential Information, under a separate Confidential Disclosure Agreement between NIAID and the third party(ies) as long as this is not in conflict with the NIH Model Organisms Sharing Policy.

b. PUBLICATIONS

NIAID encourages publication of animal model research as one means of sharing information with the scientific community. For animal models that are pivotal for FDA licensure of various products, animal models will be shared with FDA through final study report submissions to a NIAID held FDA Master File.

c. GLP COMPLIANCE

Task orders and studies conducted under Good Laboratory Practices as set forth in 21 CFR Part 58 (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58>), may be the subject of NIAID directed technical and/or compliance site visits and/or audits using NIAID consultants. Particular aspects of quality assurance or GLP compliance will be negotiated for each Task Order as necessary.

d. INTELLECTUAL PROPERTY

The NIAID plans to seek a deviation from FAR clause 52.227-11, Patent Rights-retention by the Contractor (Short Form) (June 1989). Pursuant to a Determination of Exceptional Circumstances (DEC) as required by FAR 27.303, the NIAID plans to modify clause at FAR 52.227-11, Patent Rights-retention by the Contractor (Short Form) (June 1989) to restrict the contractor's rights to subject inventions arising under the contract. Specifically, the contractor will be required to assign to the Government or, if deemed appropriate by the NIAID and subject to certain rights reserved to the Government, to a collaborating party designated by the Government the entire right, title and interest throughout the world to each subject invention, except to the extent that rights are retained by the Contractor under the Greater Rights Determination provision of the clause. The contractor may request greater rights to an identified invention, and the NIH will consider whether granting the requested rights will interfere with rights of the Government or any collaborating party or otherwise impede the ability of the Government or others to develop new candidates for therapies, disease prevention and diagnosis as useful for anti-pathogen discovery and development. Contractors are encouraged to request greater rights where inventions relate to technology outside NIAID's program and where the contractor has negotiated with a supplier of proprietary composition for the disposition of patent rights concerning a subject invention related to the composition.

Furthermore, the timing of data publication will need to be restricted to allow adequate time for patent applications to be filed on inventions arising from the contracts. This would be accomplished by a deviation from FAR clause 52.227-14, Rights in Data-General (June 1987). Specifically, although NIAID encourages the publication of articles on research results, FAR 52.227-14, Rights in Data-General (June 1987) will be narrowly modified to restrict the Contractor's right to use, release to others, reproduce, distribute, and publish data produced or used by the contractor in the performance of the contract or allow adequate time for the filing of patent applications and to protect data that will be submitted as part of a regulatory filing. NIAID will reserve the right to coordinate the timing of

data publication so that appropriate domestic and international invention applications may be filed as appropriate.

Because these clause deviations are not yet approved, their text is not available for publication. However, it is NIAID's intention that the finalized versions of the deviated FAR clauses will be available before award of any contract resulting from this initiative. Instead, the aforementioned description of how these clause deviations will be practiced under the resultant contract is provided. Potential Offerors are afforded an opportunity to comment on their understanding of what NIAID is planning and to identify what impact these deviations may have on their conduct of the work should they be awarded a contract. Responses should be provided, in writing, to the Point of Contact for this RFP. See the bottom of the front page of this RFP for the individual's name and contact information. Comments should be provided within 30 days of the issue date of this RFP. Therefore, NIAID will consider this input and determine whether alternative courses of action may be necessary. Decisions regarding these deviations will be made in consideration of the outcomes of the NIAID request for a determination of exceptional circumstances.

Intellectual Property Option to be offered to the NIAID's Third Party Providers of Proprietary Material and Protection of Resultant Proprietary Data.

This Article must be Included in any subcontract for evaluation of material. The subcontractor shall then have all the obligations of the Contractor.

The goal of this contract is to promote the development of critical biological information by evaluating various materials for anti-microbial activity. For the purposes of this agreement, "material" includes compositions of matter, and associated information such as methods of making or using the compositions. It is expected that the great majority of materials will be proprietary to third parties. It is clear from the NIAID's experience that third party providers ("Provider") will not provide their proprietary material ("Material") without assurance that the intellectual property rights associated with their Materials will be protected. Accordingly, to encourage Providers to provide their Materials for evaluation under this contract the Contractor agrees to this Article, which requires the Contractor and its subcontractors to provide a research use license and a commercialization license option to Subject Inventions made under the contract to the Providers as follows:

The Contractor agrees to promptly notify the NIAID and the Provider in writing of any Subject Inventions of the Contractor, its principal investigator and/or any other employees or agents of the Contractor, whether patentable or not, which are conceived and/or first actually reduced to practice in the performance of work under this contract using a Provider's Material (hereinafter "Contractor Invention"). The notice shall inform the Provider(s) of its right to the option set forth herein. This may be accomplished by attaching a copy of this Article to the notice.

1. Single Provider

With respect to Contractor Inventions resulting from the use of Material provided by one Provider, the Contractor agrees to grant to the Provider: (i) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (ii) a time-limited first option to negotiate an exclusive, world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to any Contractor Invention on terms to be negotiated in good faith by the Provider and the Contractor, subject to the following conditions:

The Contractor will allow Provider three (3) months from the date the Contractor sends written notice to the Provider of the existence of a Contractor Invention (or such additional period as the Provider and the Contractor may agree) to notify the Contractor in writing, whether or not it wants to obtain an exclusive license to the Contractor Invention.

If the Provider fails to notify the Contractor, in a timely fashion then the Contractor's obligation to offer Provider a license option with respect to that Contractor Invention will expire, and the Contractor will be free to dispose of its interests in such Contractor

Invention in accordance with the Contractor's policies. If the Contractor and the Provider fail to reach agreement within ninety (90) days, (or such additional period as the Provider and the Contractor may agree) on the terms for an exclusive license for a particular Contractor Invention, then for a period of six (6) months thereafter the Contractor will not offer to license that Contractor Invention to any third party on materially better terms than those last offered to the Provider without first offering such terms to the Provider, in which case the Contractor will offer the Provider a period of thirty (30) days in which the Provider can accept or reject the offer.

2. Multiple Providers

With respect to a Contractor Invention resulting from the use of Materials provided by multiple Providers, but which is an improvement only to a Material of a specific Provider, the Contractor agrees to grant to that Provider the rights described above in (a).

With respect to any Contractor Inventions resulting from the use of Material from multiple Providers, but that are not improvements to or specific to a single Material, the Contractor agrees to grant to each Provider who provided Material: (i) a paid-up nonexclusive, nontransferable, royalty-free, world-wide license to all Contractor Inventions for research purposes only; and (ii) a time-limited first option to negotiate a co-exclusive, world-wide royalty-bearing license for all commercial purposes, including the right to grant sub-licenses, to all such Contractor Inventions on terms to be negotiated in good faith by each Provider and the Contractor subject to the following conditions:

The Contractor will allow each Provider three (3) months from the time the Provider is sent written notice by the Contractor of the existence of a Contractor Invention (or such additional period as each Provider and the Contractor may agree) to notify the Contractor, in writing, whether or not the Provider wants to obtain a co-exclusive license to the Contractor Invention. If a Provider fails to notify the Contractor, in a timely fashion then Contractor's obligation to offer that Provider a license option with respect to that Contractor Invention will expire and the Contractor will continue to offer an option to a co-exclusive license to the other Providers as set forth herein. If there is a single other Provider, it shall be offered an option to an exclusive license as though it were a single Provider. If no Provider notifies the Contractor in a timely fashion the Contractor will be free to dispose of its interests in such Contractor Invention in accordance with the Contractor's policies.

3. Provider Inventions

The Contractor agrees that notwithstanding anything herein to the contrary, any invention or discovery, whether patentable or not, which is not a Subject Invention as defined in 35 USC 201(e)¹ but arises out of an intentional and unauthorized use or modification of the Provider's Material by the Contractor and/or any other employees or agents of the Contractor, will be the property of the Provider (hereinafter "Provider Invention"). The Contractor will promptly notify the Provider in writing of any such Provider Inventions and, at the Provider's request and expense, the Contractor will take such further action as necessary to ensure that the Provider shall have all right, title and interest in and to any such Provider Inventions and give Provider any assistance reasonably necessary to obtain patents (including causing the execution of any invention assignment or other documents). The NIAID recognizes that the Contractor may also be conducting other research using the Provider's Material under the authority of a separate agreement with the Provider during the term of this contract; any invention arising under such separate agreement will not be subject to the terms of this provision entitled, "Provider Inventions."

4. Protection of Proprietary Data

All Materials, data and other information supplied by the Provider or the Project Officer shall be assumed to be confidential unless specifically identified as not confidential in writing by the Project Officer. 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 Provider and the FDA or other appropriate Federal agency. The Contractor understands that the NIAID must negotiate individual agreements with the various Providers to obtain Materials and that the terms of the agreements may vary. The NIAID intends that these agreements will provide for the Contractor's right to publish results generated by the Contractor under this contract after a reasonable period of time to allow the Provider to file patent applications and to protect its proprietary information. The Contractor agrees to enter into confidentiality agreements with Providers when required by the Providers as a condition for the Contractor to receive Materials. Such agreements shall reference this contract by contract number and shall be consistent with any agreement the NIAID has entered into with the Provider to obtain Materials. In the event the Contractor reasonably objects to the terms of the confidentiality agreement, the Contractor shall promptly bring such objection to the attention of the Contracting Officer for an appropriate resolution.

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated September 2, 2008, 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 (1) hardcopy of each report shall be submitted to the Contracting Officer, unless otherwise specified.

- 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.]*

The Contractor shall submit to the Contracting Officer and the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to technical inspection and requests for clarification by the Project Officer. These reports shall be brief and factual and prepared in accordance with the format described below and in accordance with the DELIVERIES ARTICLE in SECTION F.

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

- Contract Number, Task Order Number (Designation) and Task Order Title
- Period of Performance Being Reported
- Contractor's Name and Address
- Author(s)
- Date of Submission
- Delivery Address

Regular Task Order Progress Reports will be required and the frequency will be specified in Task Order Reporting Requirements. These reports will be monthly, bimonthly, or quarterly. The only technical progress report associated with the base contract will be the Annual Report on Animal Models.

Monthly

A monthly report will be required if specified in the Task Order Reporting Requirements. 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.

Bimonthly

A bimonthly report will be required if specified in the Task Order Reporting Requirements. 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 two months of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of two full calendar months.

Quarterly

A quarterly report will be required if specified in the Task Order Reporting Requirements. This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full three months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full calendar months.

Annually

This report shall provide an annual update of all the animal models to be made available through the contract. This update will be in the form of a table for each Part (A - D) awarded, and will include at a minimum, the following information:

- Host species/strain
- Pathogen and strain
- Route of challenge
- Challenge dose
- Primary endpoints
- Secondary endpoints
- An assessment of the development stage of the model, using an assessment tool to be provided by the Project Officer after award of the first Task Order
- Publications using this model.

Additional elements to be included in the Annual Report will be discussed with and approved by the Project Officer.

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

This report is to include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An annual report will not be required for the period when the Final Report is due.

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.

3. Report on Select Agents or Toxins and/or Highly Pathogenic Agents

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

a. Any changes in the use of the *Select Agent or Toxin* and/or a *Highly Pathogenic Agent*, that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the Institutional Biosafety Committee (IBC) or equivalent body or institutional biosafety official.

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

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

ii. A description of the work that will be done with each new or additional *Select Agent or Toxin* and/or a *Highly Pathogenic Agent*;

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

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

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

b. Other Reports/Deliverables

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

1. Animal Models

Animal models and protocols developed or refined, including Technology Transfer Packages.

2. Assays

All assays, reagents and protocols developed under this contract, including Technology Transfer Packages.

3. Pathogens

Pathogens that were not obtained from a repository will be deposited in a centralized repository. The Government reserves the right to share these pathogen strains with others. Master and/or working banks will be deposited as appropriate, including procedures for propagation and characterization, strain provenance and history, and data supporting its use in animal studies.

4. All product(s) remaining from studies.

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 Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

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

Contracting Officer
National Institutes of Health
National Institute of Allergy and Infectious Diseases
Office of Acquisitions
6700-B Rockledge Drive
MSC 7612, Room 3214
Bethesda, Maryland 20892- 7612

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 encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (<http://www.iedison.gov>), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the Project Officer is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at:

National Institutes of Health
National Institute of Allergy and Infectious Diseases
6610 Rockledge Drive
Bethesda, Maryland 20892

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

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

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

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

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

a. Technical Progress Reports

Item	Reports	Recipients	Delivery Schedule
1.	Regular Task Order Progress Report	1 original to CO 1 elec. copy to PO and CO	Regular Task Order Progress Reports will be specified in the Task Order Reporting Requirements, typically monthly, bimonthly or quarterly. For monthly reports, the first report is due six weeks after Task Order award. Thereafter, each report is due on/before the 15 th of each month following each reporting period.
2.	Annual Report	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	The first report is due on/before 12/31/2010. Thereafter, each report is due on/before the 30 th of the month following each anniversary date of the contract.
3.	Draft Final and Final Report and Summary of Salient Results	2 hard copies of Final to PO 1 original to CO 1 elec. copy of Draft and Final to PO and CO	Draft Final Report is due 30 calendar days prior to the completion date of contract. Final Report is due on/before the completion date of the contract.

b. Other Reports and Deliverables (Delivery Schedule)

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
1.	Draft and Final Study, Qualification and Validation Protocols with SAP	General SOW, 1B	1 elec. copy to PO	15 calendar days prior to initiating each study.
2.	Standard Operating Procedures (SOPs)	General SOW, 1B	1 elec. copy to PO	15 calendar days prior to initiating each study.
3.	Draft and Final Study, Qualification and Validation Study Reports with Statistical Analyses (SA)	General SOW, 1E	1 elec. copy to PO 2 hard copies of Final to PO 1 original to CO	Within 30 calendar days after completion of each study.
4.	Animal Model Technology Transfer Package	General SOW, 4.A.1.	Project Officer or designated third party	To be specified in Task Order Deliverables

Item	Deliverables	SOW Reference	Recipient	Delivery Schedule
5.	Assay Technology Transfer Package	General SOW, 4.A.2.	Project Officer or designated third party	To be specified in Task Order Deliverables
6.	Pathogen Technology Transfer Package	General SOW, 4.A.3.	Project Officer or designated third party	To be specified in Task Order Deliverables
7.	Pathogen(s) and Reagent(s)	General SOW, 4.B	NIAID Repository or designated third party	To be specified in Task Order Deliverables

ARTICLE F.2. 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: <http://www.acquisition.gov/comp/far/index.html>

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989) with **Alternate I** (April 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

[to be specified in resultant contract(s)]

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

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

(End of Clause)

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

Name	Title
[To be specified in resultant contract(s)]	

ARTICLE G.3. METHOD OF ORDERING

The Federal Acquisition Streamlining Act (FASA) requires that each awardee under a multiple award contract, such as the resultant base IDIQ contracts for the Animal Models of Infectious Diseases, be given a fair opportunity to be considered for each order in excess of \$3,000, unless a statutory exception applies. Government Contracting Officers have broad discretion to determine how work will be issued to awardees under multiple award IDIQ contracts, provided the procedures and selection criteria to be used are included in the Request for Proposal(s) and resultant base IDIQ contracts and the procedures allow for consideration of all awardees. Please also be advised that allocation or "equitable distribution" of orders, or placing order ceilings (under which the total value of orders must stay for each contractor), is contrary to the intent of FASA.

Contractors that have received a base IDIQ contract award for Parts A, B, C, or D are only eligible to receive Task Orders for Task parts which they have been awarded. For example offerors that have received a base IDIQ contract award for Part A will only be eligible to receive Task Orders for Part A.

The NIAID intends to use various methods to provide Contractors that received a base IDIQ contract a fair opportunity to be considered for subsequent Task Orders. Past Performance factors such as the overall quality of prior work, timeliness, and cost control; potential impact on previous orders; and minimum order requirements may be used.

Each Task Order Request (TOR) issued by the NIAID will include the Statement of Work, Evaluation Factors for award of the Task Order, Reporting Requirements and Deliverables, required components of the offer to be submitted, format for submission, and any other issues pertinent to the Task Order, including information on whether it is anticipated that the Task Order will be awarded with or without discussions. Contractors will not be required to propose on all TORs. Those eligible Contractors that decide not to submit a proposal must notify the NIAID Contracting Officer in writing of their intention not to submit a proposal on or before the closing date and time established in the TOR.

An election not to propose on a given TOR will not negatively affect or prohibit a Contractor from competing on future TORs. However, it may affect the Contractor's eligibility for continuations or extensions of the given Task Order.

EXCEPTIONS TO THE FAIR OPPORTUNITY TO BE CONSIDERED CLAUSE

In accordance with FAR 16.504, the requirement for the Fair Opportunity consideration does not apply to orders under \$3,000 or to orders above \$3,000 where the NIAID Contracting Officer determines that one of the following statutory exceptions applies:

- 1) The need for the Task Order is so urgent that providing such opportunity would result in unacceptable delays.
- 2) Only one Contractor in a given part is capable of providing the services required at the level of quality required because the services are highly specialized.
- 3) The Task Order should be issued on a sole-source basis in the interest of economy and efficiency as a logical follow-on to a Task Order already issued given that all awardees were given a fair opportunity to be considered on the original order
- 4) It is necessary to place an order to satisfy a minimum order guarantee under a base IDIQ contract.

TASK ORDER PROCEDURES

In providing services under this contract, the following procedures shall apply to the award of Task Orders.

All work required under this contract shall be authorized through execution of an agreement, "Task Order," signed by the Contractor and the Contracting Officer. Task Orders may be awarded at any time within the contract period.

When the Government elects to fill a requirement that is estimated to exceed \$3,000, the Contracting Officer shall provide a TOR to the awardees that received contracts for the particular Part for which responses are being solicited. A TOR shall, at a minimum, include a Statement of Work, evaluation factors, specific reporting requirements, deliverables and delivery schedule, the relevant importance of technical and cost factors, and any special instructions.

If necessary, the Contracting Officer shall arrange a meeting between contractors and members of the sponsoring office to discuss the proposed Task Order prior to submitting Task Order proposals (technical and business). Business proposals shall include appropriate support for all costs proposed as necessary for performing the task. Task Order proposals shall generally be limited to twenty (20) pages, including attachments.

Within the time allowed for proposal preparation (time allowed for proposal preparation and submission will vary depending on the task and will be designated in each TOR), Contractors shall submit their proposals in response to a TOR, which shall include, but not necessarily limited to the following information:

- (i) A statement of the contractor's clear understanding of the task requirements;
- (ii) A statement of technical and managerial resources and expertise the contractor can provide to satisfy the requirement;
- (iii) An approach to perform the work;
- (iv) The labor category necessary, and the number of hours for each labor category necessary, and an explanation of the rationale for determining hours;
- (v) Resumes with identification of the actual personnel proposed for the work;

- (vi) A schedule of performance identifying major milestones, deliverables and delivery date, and task completion; and
- (vii) An itemization of all costs, both direct and indirect, (i.e. personnel, fringe benefits, equipment, travel, supplies, other direct costs, overhead, etc.) necessary to complete the work.

The Government will evaluate proposals and conduct negotiations as necessary. Task Orders will be awarded to the contractor whose proposal is determined to be the most advantageous to the Government based on the technical and cost factors specified in the TOR. The Government reserves the right to make an award on the most favorable initial proposal without discussion.

The Contracting Officer is the only individual authorized to issue TOR or award a Task Order under this contract. Unless specifically authorized by the Contracting Officer, the contractor shall not commence work on a requirement until a fully executed Task Order has been awarded.

It is anticipated that Task Orders will be awarded within sixty (60) calendar days from receipt of Task Order proposals. Each Task Order shall, at a minimum, contain the following information:

- Date of order
- Contract number and Task Order number sequentially
- Description of services and estimated cost
- Performance period
- Name and address of sponsoring office
- Name of Contracting Officer's Technical Representative
- Place of performance
- Packaging and shipping instructions, if any
- Accounting and appropriation data
- Pricing Arrangements
- Any other pertinent information

Contractors are required to propose hourly rates for each labor classification in their response to each TOR with cost reimbursable contract line items proposed for other elements of cost (i.e. fringe benefits, supplies, travel, equipment, other direct costs, indirect costs, fee, etc.) The subsequent negotiation of TORs issued to successful contractors eligible to submit a proposal under a TOR for which they qualify will focus on the number of hours proposed for each labor category and the estimated costs required for all other elements.

No protest under FAR Subpart 33.1 is authorized in connection with the issuance or proposed issuance of a Task Order under this contract except for a protest on the grounds that the order increases the scope, period, or maximum value of the contract. Task Orders awarded under this contract are not subject to the competition requirements of FAR Part 6.

ARTICLE G.4. INDEFINITE DELIVERY CONTRACT PAYMENT METHOD

To initiate and receive prompt payment, the Contractor shall comply with the following procedure:

- a. A Task Order Number shall be given to you at the time the order is placed. The Contractor is cautioned not to accept an order unless this number is issued.
- b. Invoices shall be submitted monthly for each Task Order issued to the address indicated in ARTICLE G.5. INVOICE INSTRUCTIONS of this contract. Invoices shall cite the Contract Number and the Task Order Number for each order for which payment is being requested. See ARTICLE G.5. INVOICE INSTRUCTIONS for more information about submission of a proper invoice.

ARTICLE G.5. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

- a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 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 as follows:

- a. One original 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 to the following approving official:

Contracting Officer
Office of Acquisitions
National Institute of Allergy and Infectious Diseases NIH
6700-B Rockledge Drive Room 3214
Bethesda, MD 20892 MSC 7612

E-Mail: [to be specified at award]

The Contractor shall submit an electronic copy of the payment request to the approving official in lieu of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in a format compatible with the computer systems at NIH [e.g., MS Word, MS Excel, or Adobe Portable Document Format (PDF)]. ***[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 Subpart 32.905 for a proper invoice, the Contractor shall include the following information on the face page of all payment requests:

- a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Institute of Allergy and Infectious Diseases .
- b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAIDOAInvoices .
- c. 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 address. 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.
- d. DUNS number or DUNS+4. 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 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.

- e. Invoice Matching Option. This contract requires a Two-Way match.
- f. 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.
- 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 the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H 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 the SALARY RATE LIMITATION LEGISLATION PROVISIONS Article in SECTION H of the above referenced contract."

ARTICLE G.6. 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
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC-7540
BETHESDA MD 20892-7540

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

ARTICLE G.7. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "Contractor's Guide for Control of Government Property," which can be found at:

<http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm>.

ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on the base contract in accordance with FAR 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) shall be submitted at the completion of each Task Order.

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.

b. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

<http://oamp.od.nih.gov/OD/CPS/cps.asp>

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact who will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 30-day time frame.

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. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (Including Human Gene Transfer Research)

All research involving Recombinant DNA Molecules shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>) and the September 24, 2007 Notice, "Reminder of NIH Policy for Enhancing the Science, Safety, and Ethics of Recombinant DNA Research" (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-07-096.html>) (and any subsequent revisions to the Guide Notice) which stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the Guidelines). These guidelines apply to both basic and clinical research studies.

The Recombinant DNA Advisory Committee (RAC) is charged with the safety of manipulation of genetic material through the use of recombinant DNA techniques. Prior to beginning any clinical trials involving the transfer of recombinant DNA to humans, the trial must be registered with the RAC. If this contract involves new protocols that contain unique and/or novel issues, the RAC must discuss them in a public forum and then the Institutional Biosafety Committee (IBC), the Institutional Review Board (IRB), and the Project Officer and Contracting Officer must approve the protocol prior to the start of the research.

Failure to comply with these requirements may result in suspension, limitation, or termination of the contract for any work related to Recombinant DNA Research or a requirement for Contracting Officer prior approval of any or all Recombinant DNA projects under this contract. This includes the requirements of the Standing Institutional Biosafety Committee (IBC) (See <http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm>).

As specified in Appendix M-1-C-4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the Project Officer and Contracting Officer. (http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836).

ARTICLE H.3. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

ARTICLE H.4. NEEDLE EXCHANGE

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.5. PRESS RELEASES

Pursuant to the current HHS annual appropriations act, 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.6. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to disseminate scientific information that is deliberately false or misleading.

ARTICLE H.7. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

ARTICLE H.8. SALARY RATE LIMITATION LEGISLATION PROVISIONS

- a. Pursuant to the current HHS annual appropriations act, the Contractor shall not use NIH Fiscal Year funds to pay the direct salary of an individual through this contract at a rate in excess of Executive Level I. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" 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. The annual salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.
- b. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred. See the following Web site for Executive Schedule rates of pay: <http://www.opm.gov/oca/>. *(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 / cursor to bottom of page and select year / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

ARTICLE H.9. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:

<http://grants1.nih.gov/grants/olaw/references/phspol.htm>.

ARTICLE H.10. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

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

<http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/>

ARTICLE H.11. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

1. The Small Business Subcontracting Plan, dated [TBD at time of award] 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 Contracting Officer shall be included as a contact for notification purposes at the following e-mail address:

[TBD at time of award]
Contracting Officer

ARTICLE H.12. INFORMATION SECURITY

The Statement of Work (SOW) requires the Contractor to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies, the Contractor and any subcontractor performing under this contract shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>

a. Information Type

[X] Administrative, Management and Support Information

☐ Mission Based Information

b. Security Categories and Levels

Confidentiality Level: ☒ Low ☐ Moderate ☐ High

Integrity Level: ☒ Low ☐ Moderate ☐ High

Availability Level: ☒ Low ☐ Moderate ☐ High

Overall Level: ☒ **Low** ☐ **Moderate** ☐ **High**

c. Position Sensitivity Designations

1. The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.
☒ **Level 1: Non Sensitive (Requires Suitability Determination with an NACI).** Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).
2. The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: <http://ais.nci.nih.gov/forms/Suitability-roster.xls>.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification.

Contractor/subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

3. Contractor/Subcontractor employees shall comply with the HHS criteria for the assigned position sensitivity designations prior to performing any work under this contract. The following exceptions apply:

Levels 5 and 1: Contractor/Subcontractor employees may begin work under the contract after the Contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c. (2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the pre-appointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the Contractor/Subcontractor employee to work under the contract.

d. Information Security Training

The Contractor shall ensure that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: <http://irtsectraining.nih.gov/> prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract.

The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working under this contract that has completed the NIH required training. Any additional security training completed by Contractor/Subcontractor staff shall be included on this listing. The listing of completed training shall be included in the first technical progress report. Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report.

e. Rules of Behavior

The Contractor/Subcontractor employees shall comply with the NIH Information Technology General Rules of Behavior at: <http://irm.cit.nih.gov/security/nihitrob.html>.

f. Personnel Security Responsibilities**Contractor Notification of New and Departing Employees Requiring Background Investigations**

1. The Contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer **within five working days** before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The Government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.
2. New employees: Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.
3. Departing employees:
 - Provide the name, position title, and security clearance level held by or pending for the individual.
 - Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

g. Commitment to Protect Non-Public Departmental Information Systems and Data

1. Contractor Agreement

The Contractor and its subcontractors performing under this SOW shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

- 18 U.S.C. 641 (Criminal Code: Public Money, Property or Records)
- 18 U.S.C. 1905 (Criminal Code: Disclosure of Confidential Information)
- Public Law 96-511 (Paperwork Reduction Act)

2. Contractor-Employee Non-Disclosure Agreements

Each Contractor/Subcontractor employee who may have access to non-public Department information under this contract shall complete the Commitment to Protect Non-Public Information - Contractor Agreement. A copy of each signed and witnessed Non-Disclosure agreement shall be submitted to the Project Officer prior to performing any work under the contract.

h. NIST SP 800-53 Self-Assessment

The contractor shall annually update and re-submit its Self-Assessment required by NIST SP 800-53, *Recommended Security Controls for Federal Information Systems*. (<http://csrc.nist.gov/publications> - under Special Publications).

Subcontracts: The Contractor's annual update to its Self-Assessment Questionnaire shall include similar information for any subcontractor that performs under the SOW to (1) develop a Federal information system(s) at the Contractor's/Subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the Contractor's/Subcontractor's facility.

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer with the annual report.

i. Information System Security Plan

The Contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

Following approval of its draft ISSP, the Contractor shall update and resubmit its ISSP to the Project Officer every three years or when a major modification has been made to its internal system. The Contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, Guide to Developing Security Plans for Federal Information Systems. (<http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>). The details contained in the Contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

Subcontracts: The Contractor shall include similar information for any subcontractor performing under the SOW with the Contractor whenever the submission of an ISSP is required.

j. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

ARTICLE H.13. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (January 2008)

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, and/or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each order/contract exceeding \$100,000 when the order/contract duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

In the event of a modification(s) to the contract/order, which adds new EIT products and services or revised the type of, or specifications for, products and services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products and services support Section 508 accessibility requirements. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

[(End of HHSAR 352.270-19(b))]

Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding increment funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Contracting Officer's Technical Representative (also known as Project Officer or Contracting Officer's Representative). Unless otherwise directed by the Contracting

Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available at: <http://508.hhs.gov/> under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding incremental funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report:

"To be determined at time of award"

[End of HHSAR 352.270-19(c)]

ARTICLE H.14. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor 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 principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under NIH contracts) will not be biased by any conflicting financial interest. 45 CFR Part 94 is available at the following Web site: <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=cc7504e541bc62939c52389e9afc27d5&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>

As required by 45 CFR Part 94, the Contractor shall, at a minimum:

- a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.
- b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in NIH-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a *Significant Financial Interest* could directly and significantly affect the design, conduct, or reporting of the NIH-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.
- c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.
- e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the NIH-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in NIH-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94.

The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular 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 Contractor has not managed, reduced, or eliminated the conflict of interest. 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 conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

ARTICLE H.15. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.270-6, Publications and Publicity** incorporated by reference in SECTION I of this contract, the Contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. [to be specified at contract award]"

ARTICLE H.16. TASK ORDER/DELIVERY ORDER CONTRACT OMBUDSMAN

In accordance with FAR 16.505(b)(5), the following individual has been designated as the NIH Ombudsman for task order and delivery order contracts.

Dr. Walter Schaffer
NIH Competition Advocate
6705 Rockledge Drive, Room 3537
Bethesda, MD 20817
Phone: (301) 435-2687
FAX: (301) 480-0146
e-mail: schaffew@od.nih.gov

ARTICLE H.17. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

ARTICLE H.18. YEAR 2000 COMPLIANCE

In accordance with FAR 39.106, Information Technology acquired under this contract must be Year 2000 compliant as set forth in the following clause(s):

1. Service Involving the Use of Information Technology**YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY**

The Contractor agrees that each item of hardware, software, and firmware used under this contract shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations.

(End of Clause)

ARTICLE H.19. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

Unique research resources arising from NIH-funded research are to be shared with the scientific research community. NIH provides guidance, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]), concerning the appropriate terms for disseminating and acquiring these research resources. This guidance, found at : <http://ott.od.nih.gov/NewPages/64FR72090.pdf> is intended to help contractors ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

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

Sharing of Model Organisms for Biomedical Research

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

ARTICLE H.20. SHARING RESEARCH DATA

The Contractor's data sharing plan, dated [TBD at contract award] 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.21. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

The contractor shall not conduct work involving select agents or toxins under this contract until it and any associated subcontractor(s) comply with the following:

For prime or subcontract awards to **domestic institutions** that possess, use, and/or transfer Select Agents under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part

331, and/or 9 CFR part 121 (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) as required, before using NIH funds for work involving a *Select Agent or Toxin*. **No NIH funds can be used for research involving a *Select Agent or Toxin* at a domestic institution without a valid registration certificate.**

For prime or subcontract awards to ***foreign institutions*** that possess, use, and/or transfer a *Select Agent or Toxin*, before using NIH funds for any work directly involving a *Select Agent or Toxin*, the foreign institution must provide information satisfactory to the NIAID that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 are in place and will be administered on behalf of all *Select Agent or Toxin* work supported by these funds. The process for making this determination includes inspection of the foreign laboratory facility by an NIAID representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. **No NIH funds can be used for work involving a *Select Agent or Toxin* at a foreign institution without written approval from the Contracting Officer.**

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at <http://www.cdc.gov/od/sap/> and <http://www.cdc.gov/od/sap/docs/salist.pdf>.

Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at: http://www.aphis.usda.gov/programs/ag_selectagent/index.html and: http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html

For foreign institutions, see the NIAID Select Agent Award information: (http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm).

ARTICLE H.22. 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://www.usfa.fema.gov/hotel/index.htm>.

ARTICLE H.23. 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.24. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

Beginning April 7, 2008, 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-08-033.html>.

ARTICLE H.25. CONSTITUTION DAY

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

ARTICLE H.26. GUIDELINES FOR INCLUSION OF WOMEN, MINORITIES, AND PERSONS WITH DISABILITIES IN NIH-SUPPORTED CONFERENCES

Pursuant to the NIH Revitalization Act (P.L. 103-43, Section 206), which adds Section 402(b) to the Public Health Service Act, it is required that NIH, "in conducting and supporting programs for research, research training, recruitment, and other activities, provide for an increase in the number of women and individuals from disadvantaged backgrounds (including racial and ethnic minorities) in the fields of biomedical and behavioral research." In addition, Section 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act of 1990 require reasonable accommodations to be provided to individuals with disabilities.

It is NIH policy that organizers of scientific meetings should make a concerted effort to achieve appropriate representation of women, racial/ethnic minorities, and persons with disabilities, and other individuals who have been traditionally underrepresented in science, in all NIH sponsored and/or supported scientific meetings.

Therefore, it is the contractor's responsibility to ensure the inclusion of women, minorities, and persons with disabilities in all events when recruiting speakers and/or participants for meetings or conferences funded by this contract.

See the policy announcement for additional details and definitions at:
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-066.html>

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:

<http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clausesDGS.jsp>

General Clauses for a Cost-Reimbursement Contract with Educational Institutions

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 Clauses **52.215-15, Pension Adjustments And Asset Reversions** (October 2004); **52.215-18, Reversion Or Adjustment Of Plans For Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, 52.215-19, **Notification Of Ownership Changes** (October 1997), are deleted in their entirety.
- b. **Alternate IV** (October 1997) of FAR Clause **52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data--Modifications** (October 1997) is added.
- c. **Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (April 2008) is added.
- d. FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. **[NOTE: When each task order is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

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** (December 2007).
2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

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

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	http://www.oig.hhs.gov/hotline/OIG_Hotline_Posters.pdf

3. FAR Clause **52.204-9, Personal Identity Verification of Contractor Personnel** (September 2007).
4. FAR Clause **52.216-15, Predetermined Indirect Cost Rates** (April 1998).
5. FAR Clause **52.216-18, Ordering** (October 1995).

"(a)Such orders may be issued from [to be specified at award] through [to be specified at award].
6. FAR Clause **52.216-22, Indefinite Quantity** (October 1995).

"(d) ...the Contractor shall not be required to make any deliveries under this contract after [TBD at award] "
7. FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

"(c) Waiver of evaluation preference.....
 [] Offeror elects to waive the evaluation preference."
8. FAR Clause **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (April 2008).
9. FAR Clause **52.227-17, Rights in Data--Special Works** (December 2007).

10. FAR Clause **52.229-8, Taxes-Foreign Cost-Reimbursement Contracts** (March 1990).
11. FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).
12. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (April 1998).
13. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (March 2008).
14. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).
15. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
16. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).
17. FAR Clause **52.246-23, Limitation of Liability** (February 1997).
18. FAR Clause **52.251-1, Government Supply Sources** (April 1984).

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

1. *HHSAR Clause **352.223-70, Safety and Health** (January 2006).*
2. *HHSAR Clause **352.224-70, Confidentiality of Information** (January 2006).*
3. *HHSAR Clause **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).*
4. *HHSAR Clause **352.270-9(b), Care of Live Vertebrate Animals** (January 2006).*

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

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

1. ***NIH (RC)-7, Procurement of Certain Equipment** (April 1984).*

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.

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

a. FAR Clause **52.216-19, Order Limitations** (October 1995)

(a) **Minimum Order.** When the Government requires services covered by this contract in an amount of less than the amount stated in the table below, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those services under the contract.

(b) **Maximum Order.** The Contractor is not obligated to honor--

(1) Any order for a single item in excess of the amount stated in the table below.

(2) Any order for a combination of items in excess of stated in the table below; or

(3) A series of orders from the same ordering office within days that together call for quantities exceeding the limitation in subparagraph (1) or (2) above.

(c) If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) above.

(d) Notwithstanding paragraphs (b) and (c) above, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

	Minimum Order	Maximum Order
Part A	\$50,000	\$20,000,000
Part B	\$100,000	\$40,000,000
Part C	\$150,000	\$60,000,000
Part D	\$25,000	\$10,000,000

b. FAR Clause **52.219-28, Post-Award Small Business Program Representation** (June 2007).

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

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the exercise date specified in the contract for any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at <http://www.sba.gov/services/contractingopportunities/sizestandardstopics/>.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the rerepresentation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure they reflect current status. The Contractor shall notify the contracting office by e-mail, or otherwise in writing, that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it ☐ is, ☐ is not a small business concern under NAICS Code assigned to contract number.

[Contractor to sign and date and insert authorized signer's name and title].

(End of clause)

c. **FAR Clause 52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees (December 2004)**

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

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) *Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union*

membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

*National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)*

To locate the nearest NLRB office, see NLRB's website at <http://www.nlrb.gov>.

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to--

(1) Contractors and subcontractors that employ fewer than 15 persons;

(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting

requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and

(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 2021, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at <http://www.olms.dol.gov>; or

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c).

For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

(End of Clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal (R & D)	See Attachment Section at the end of the RFP.
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at the end of the RFP.
Attachment 3:	Statement of Work	See Attachment Section at the end of the RFP.
Attachment 4:	Additional Technical Proposal Instructions	See Attachment Section at the end of the RFP.
Attachment 5:	Additional Business Proposal Instructions	See Attachment Section at the end of the RFP.
Attachment 6:	Additional RFP Specific Materials	See Attachment Section at the end of the RFP.
Attachment 7:	Sample NIAID Non-Clinical Evaluation Agreement	See Attachment Section at the end of the RFP.
Attachment 8:	Government Furnished Property	

TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 9:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 10:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm

BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 11:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 12:	Small Business Subcontracting Plan	http://www.hhs.gov/osdbu/read/SampleSubcontractingPlan.doc
Attachment 13:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	http://oamp.od.nih.gov/contracts/BUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls
Attachment 14:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 15:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sfillin.pdf

INFORMATIONAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 16:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 17:	Safety and Health, HHSAR Clause 352.223-70	http://rcb.cancer.gov/rcb-internet/forms/safety&health-1-06.pdf
Attachment 18:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 19:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sfillin.pdf
Attachment 20:	Commitment to Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 21:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 22:	Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/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 Online Representations and Certifications Application (ORCA) at: <https://orca.bpn.gov/> and complete the Representations and Certifications; and
2. Complete, and include as part of your BUSINESS PROPOSAL, SECTION K which can be accessed electronically from the INTERNET at the following address:
<http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2006)]

(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, and 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, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department 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 contract 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 541711.
2. The small business size standard is 500 employees.

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

c. TYPE OF CONTRACT AND NUMBER OF AWARDS

It is anticipated that multiple IDIQ awards will be made from this solicitation and that the award(s) will be made on/about January 26, 2010.

It is anticipated that the awards from this solicitation will be a multiple-year Cost-Reimbursement type Completion contracts with a term of seven (7) years, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

d. ESTIMATE OF EFFORT

It is expected that multiple Indefinite Delivery, Indefinite Quantity completion type contracts will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 4.85 FTE (Part A); 5.75 FTE (Part B); 7.75 FTE (Part C); and 2.15 FTE (Part D). **This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.**

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. 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 RFP. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

g. 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.

h. PREPARATION COSTS

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

i. 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:

Contracting Officer
Office of Acquisitions
National Institute of Allergy and Infectious Diseases
6700-B Rockledge Drive MSC 7612
Bethesda, MD 20892- 7612

(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)

j. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70 (January 2006)

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

(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 Indefinite Delivery, Indefinite Quantity type contracts with cost-reimbursement task orders 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 and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP 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 technical proposals in accordance with the criteria set forth in PART IV, SECTION M of this RFP.

7. Potential Award Without Discussions

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

8. Use of the Metric System of Measurement

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

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

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

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

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

9. Standards for Privacy of Individually Identifiable Health Information

The Department of Health and Human Services (DHHS) issued final modifications to the "Standards for Privacy of Individually Identifiable Health Information," the "Privacy Rule," on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as "covered entities" must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply).

Decisions about the applicability and implementation of the Privacy Rule reside with the Contractor and his/her institution. The OCR Web site (<http://www.hhs.gov/ocr/>) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on "Am I a covered entity?" Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

10. Privacy Act - Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

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

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

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

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

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

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

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

11. Selection of Offerors

- a. The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -
 1. Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

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

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

While it is NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected source in accordance with HHSAR 315.370.

- e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror.
- f. The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

12. Institutional Responsibility Regarding Conflicting Interests of Investigators

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 conflicting financial interest of an Investigator. The Institution shall comply with all requirements of 45 CFR Part 94 at <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&sid=cc7504e541bc62939c52389e9afc27d5&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>.

13. ROTC Access and Federal Military Recruiting on Campus

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

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

14. Past Performance Information

- a. 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 AWARDED currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government,

agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as any proposed subcontracted effort at or greater than \$550,000.

Include the following information for each contract or subcontract listed:

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

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

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

15. Electronic and Information Technology Accessibility, HHSAR 352.270-19(a) (January 2008)

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 Provisions (36 CFR part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit:

1. Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and
2. Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.

Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility provisions. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

The Section 508 standards applicable to this solicitation are identified in the Statement of Work/ Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products

and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products and/or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products and/or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government - i.e., after award of a contract/order, that products and/or services delivered do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its expenses.

(End of provision)

16. 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.

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. *Data Universal Numbering System (DUNS) Number, FAR Provision 52.204-6 (April 2008).*
- b. *Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).*
- c. *Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).*
- d. *Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).*
- e. *Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).*
- f. *Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).*
- g. *SAFETY Act--Equitable Adjustment, FAR Clause 52.250-5, (November 2007).*

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, as applicable, as well as for the overall program. 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. Care of Live Vertebrate Animals

- a. The following notice is applicable when contract performance is expected to involve care of live vertebrate animals:

Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, HHSAR 352.270-9(a) (January 2006)

The PHS Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before award may be made to an applicant organization, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No award involving the use of animals shall be made unless OLAW approves the Animal Welfare Assurance. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information contact OLAW, at NIH, Bethesda, Maryland 20892 (301-496-7163).

(End of Provision)

The following specific address for OLAW is provided for ease of contact:

Office of Laboratory Animal Welfare

National Institutes of Health
 RKL 1 - Suite 360, MSC 7982
 6705 Rockledge Drive
 Bethesda, MD 20892-7982 (For Hand-delivered/express mail use Zip code 20817)

FAX copies of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at <http://www.grants.nih.gov/grants/olaw/olaw.htm>.

b. The following information must be included in the offerors technical proposal:

- identification of the species and approximate number of animals to be used;
- rationale for involving animals, and for the appropriateness of the species and numbers used;
- a complete description of the proposed use of the animals;
- a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
- a description of any euthanasia method to be used.

c. If an Animal Assurance is already in place, the offeror's proposal shall include:

- The Animal Welfare Assurance number.
- The date last certified by OLAW. (i.e. assurance letter from OLAW)
- Evidence of recent AAALAC Accreditation, if required by the SOW contained in this solicitation.

5. Possession, Use and Transfer of Select Biological Agents or Toxins

Notice to Offerors of Requirements of: 42 CFR Part 73, Possession , Use, and Transfer of Select Agents and Toxins (relating to public health and safety):

(http://www.cdc.gov/od/sap/42_cfr_73_final_rule.pdf);

7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins (relating to plant health or plant products) (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf); and, 9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins (relating to human and animal health, animal health or animal products)

(http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) - March 18, 2005.

These regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the Agricultural Bioterrorism Protection Act of 2002. They are designed to improve the ability of the United States Government to prevent, prepare for, and respond to bioterrorism and other public health emergencies. These regulations establish requirements regarding registration, security risk assessments, safety plans, security plans, emergency response plans, training, transfers, record keeping, inspections, and notifications.

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at <http://www.cdc.gov/od/sap/> and <http://www.cdc.gov/od/sap/docs/salist.pdf>. Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at http://www.aphis.usda.gov/programs/ag_selectagent/index.html and http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html. For foreign institutions, see the NIAID Select Agent Award information (http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm).

If the proposed contract will not involve Select Agents, the offeror must include a statement in its technical proposal that the work does not now nor will it in the future (i.e. throughout the life of the award) involve Select Agents.

Domestic Institutions

For prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, the domestic institution must:

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.
- comply with 42 CFR part 73, 7 CFR part 331 and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf, as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

Foreign Institutions

For prime or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, the foreign institution must:

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.
- when requested during negotiations, provide information satisfactory to the NIAID/NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at:

http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf for U.S. institutions are in place and will be administered on behalf of all Select Agent work under the resulting contract. The process for making this determination includes inspection of the foreign laboratory facility by an NIAID representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents.

An NIAID chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the facility inspection, the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at:

http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf.

The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No NIH funds can be used for research involving Select Agents at a foreign institution until NIAID grants this approval.

6. 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 Contracts," (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://ott.od.nih.gov/NewPages/64FR72090.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>

If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan.

b. Sharing of Model Organisms for Biomedical Research

The NIH Research Tools Policy (http://www.ott.nih.gov/policy/research_tool.html) also referred to as NIH Principles and Guidelines for Sharing of Biomedical Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042 at:

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html>), dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066 at:

(<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html>), the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

Offerors must include in their technical proposal a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding

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

- Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) at:
(http://ott.od.nih.gov/forms_model_agreements/forms_model_agreements.html#MTACTA)
for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (<http://www.autm.net/aboutTT/> , then search "Implementing Letter")
- How will inappropriate "reach-through" requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?
- How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

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

7. **Information Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled, "INFORMATION SECURITY."

The Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source. The National Institute of Standards and Technology (NIST) has issued a number of publications that provide guidance in the establishment of minimum security controls for management, operational and technical safeguards needed to protect the confidentiality, integrity and availability of a Federal information system and its information.

The Statement of Work (SOW) requires the successful offeror to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies the following requirements apply to this solicitation:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>

a. Information Type

☒ Administrative, Management and Support Information

☐ Mission Based Information

b. Security Categories and Levels

Confidentiality Level:	☒ Low ☐ Moderate ☐ High
Integrity Level:	☒ Low ☐ Moderate ☐ High
Availability Level:	☒ Low ☐ Moderate ☐ High

Overall Level: ☒ **Low** ☐ **Moderate** ☐ **High**

c. Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each Contractor (including subcontractor) employee that the successful offeror proposes for work under the contract. For proposal preparation purposes, the following designations apply:

☒ **Level 1: Non Sensitive (Requires Suitability Determination with an NACI).**
Contractor employees assigned to a Level 1 position are subject to a National Agency Check and Inquiry Investigation (NACI).

Upon award, the Contractor will be required to submit a roster of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a federal information system(s). The Government will determine and notify the Contractor of the appropriate level of suitability investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at:

<http://ais.nci.nih.gov/forms/Suitability-roster.xls>

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov>.

Contractor/Subcontractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

d. Information Security Training

HHS policy requires Contractors/Subcontractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: <http://irtsectraining.nih.gov/> prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

Additional security training requirements commensurate with the position may be required as defined in NIST Special Publication 800-16, Information Technology Security Training Requirements (<http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf>). This document provides information about information security training that may be useful to potential offerors.

e. Offeror's Official Responsible for Information Security

The offeror shall include in the "Information Security" part of its Technical Proposal the name and title of its official who will be responsible for all information security requirements should the offeror be selected for an award.

f. NIST SP 800 53 Self Assessment

The offeror must include in the "Information Security" part of its Technical Proposal, a completed Self-Assessment required by NIST Draft SP 800-53, Recommended Security Controls for Federal Information Systems. (<http://csrc.nist.gov/publications> - under Special Publications).

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW to (1) develop a Federal information system(s) at the offeror's/subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the offeror's/subcontractor's facility.

g. Draft Information System Security Plan

The offeror must include a draft Information System Security Plan (ISSP) using the current template in Appendix A of NIST SP 800 18, Guide to Developing Security Plans for Federal Information Systems (<http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>). The details contained in the offeror's draft ISSP must be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels.

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW with the offeror whenever the submission of an ISSP is required.

Note to Offeror: The resultant contract will require the draft ISSP to be finalized in coordination with the Project Officer no later than 90 calendar days after contract award. Also, a contractor is required to update and resubmit its ISSP to NIH every three years following award or when a major modification has been made to its internal system.

h. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

i. References

1. Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>
2. DHHS Personnel Security/Suitability Handbook: <http://www.hhs.gov/ohr/manual/pssh.pdf>
3. NIH Computer Security Awareness Training Course: <http://irtsectraining.nih.gov/>

The following NIST publications may be found at the following site: <http://csrc.nist.gov/publications/>

[Note: The search tool on the left side of this page provides easy access to the documents.]

4. NIST Special Publication 800-16, Information Technology Security Training Requirements; and Appendix A-D
5. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems
6. NIST SP 800-26, Revision 1, Computer Security

7. NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems
8. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I; and Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C, and Appendix D
9. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle
10. FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems
11. FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems

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 cost or pricing data are not required but information to help establish price reasonableness or cost realism is necessary. Such information is not considered cost or pricing data, and shall not be certified in accordance with FAR 15.406-2.

3. Information Other than Cost or Pricing Data

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

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by 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 information submitted shall be at the level of detail described below.

1. Direct Labor

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

2. Materials

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

3. Subcontracted Items

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over \$550,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

4. Raw Materials

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

5. Purchased Parts

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

6. Fringe Benefits

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

7. Indirect Costs

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

8. Special Equipment

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

9. Travel

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

10. Other Costs

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

4. Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)]

(a) Exceptions from cost or pricing data.

(1) In lieu of submitting 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 cost or pricing data. If the offeror is not granted an exception from the requirement to submit cost or pricing data, the following applies:

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15.2 of FAR 15.408.

(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 in Fiscal Year 2008

Offerors are advised that pursuant to P.L.110-161, no NIH Fiscal Year 2008 (October 1, 2007 - September 30, 2008) 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 I* (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 I*. The salary rate limitation set by P.L. 110-161 applies only to Fiscal Year 2008 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 110-161 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual through a grant or other extramural mechanism at a rate in excess of Executive Level I*."

LINK TO EXECUTIVE SCHEDULE SALARIES: <http://www.opm.gov/oca/08tables/pdf/ex.pdf>

***Note to Offerors:** The current Fiscal Year Executive Level I Salary Rate should 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 I Salary rates.

6. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of \$550,000 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 \$550,000 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:

30% for Small Business; 11% 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. HUBZone Small Business Concerns

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

8. Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$550,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: <http://www.sba.gov/size>

The Department of Commerce website for the annual determination for NAICS codes* is: <http://www.arnet.gov/References/sdbadjustments.htm>.

** Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the Prime Contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	SDB Percentage of Total Contract Value	SDB Dollars
Total Contract Value- \$1,000,000	25%	\$250,000
SDB Participation by Prime	10%	\$100,000
(Includes joint venture partners and team arrangements)*		
SDB Participation by subcontractors	15%	\$150,000

*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential Prime Contractor, or a potential Prime Contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

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 (FEBRUARY 1993).

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. The voluntary consensus standard or industry leading practices and standards to be used in the management of Government property, or existing property management plans, methods, practices, or procedures for accounting for property.

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from the Contractor possessing Government property, and for evaluation purposes only, adjust the offers using a rental equivalent evaluation factor, as appropriate.

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, Contractors Guide for Control of Government Property, which can be found at: <http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm>

b. Submission of Electronic Funds Transfer Information with Offer, FAR Clause 52.232-38 (MAY 1999)

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 Central Contractor Registration.

- (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. Incremental Funding

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provision is applicable:

Incremental Funding, HHSAR 352.232-75 (January 2006)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds as specified in FAR 52.232-22. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. The Government intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modifications. However, the Government is not obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor is the Contractor obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract, as specified in FAR 52.232-22, shall supersede the Limitation of Cost clause found in the Section I, Contract Clauses.

(End of provision)

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) ***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.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

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. Representations and Certifications - SECTION K

One copy of SECTION K (which includes FAR Clause 52.204-8 Annual Representations and Certifications) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of SECTION K shall be submitted from any proposed subcontractor. SECTION K can be found at: <http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf>

15. 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.

16. 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 four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation 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 RFP. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

2. 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.

3. EVALUATION OF PLAN FOR SHARING MODEL ORGANISMS FOR BIOMEDICAL RESEARCH

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

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

4. TECHNICAL EVALUATION CRITERIA

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

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO - Additional Technical Proposal Instructions
- OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE
PREPARATION OF TECHNICAL PROPOSALS.

CRITERIA WEIGHT**CRITERION 1: TECHNICAL PLAN/APPROACH****55**

A. Soundness, feasibility, completeness of, and experience with the technical approach for animal studies, to include provision of animals and animal models, new animal model development, protocol and assay development, conduct of product efficacy studies, and supportive measurements (immunological, pharmacological, clinical, pathological, etc.).

B. Soundness, feasibility and completeness of the technical approach to pathogen production and characterization, including overall understanding of the pathogen and its behavior in animal models.

C. Soundness, feasibility and completeness of the technical approach to the Sample Task Order, including feasibility and detailed description of subtasks to be performed.

D. Capability to comply with Good Laboratory Practices (21 CFR Part 58) will be evaluated for Part B, Part C and Part D. Adequacy and completeness of the documented evidence of the availability of trained study directors, maintained facilities and equipment, SOPs, a Quality Assurance Unit, and documentation procedures. Adequacy and appropriateness of previous institutional experience and proven track record in the evaluation of products under GLP.

CRITERION 2: PERSONNEL AND PROJECT MANAGEMENT**25**

A. Principal Investigator (PI): Appropriateness and adequacy of the education, training, experience, expertise, qualifications and effort of the proposed PI to fulfill the requirements of the Statement of Work for the animal models and pathogens proposed.

B. Scientific and Technical Personnel: Appropriateness and adequacy of the experience, expertise, qualifications and effort for all proposed scientific and technical personnel, including proposed subcontractors, to fulfill the requirements of the Statement of Work for the animal models and pathogens proposed.

C. Adequacy, appropriateness, and feasibility of the proposed organization and staffing to ensure efficient planning, initiation, implementation, conduct, and completion of all activities carried out under this contract, including plans for communication and sharing of research resources.

CRITERION 3: FACILITIES, EQUIPMENT AND OTHER RESOURCES**20**

A. Availability of adequate, accredited animal facilities, with biocontainment appropriate for the pathogens proposed.

B. Availability and appropriateness of equipment and other resources necessary for the proposed animal studies including IT systems, data management, and capabilities for the receipt, storage, shipping and inventory of products, pathogens, specimens, and reagents.

C. Institutional biosafety program adequate to oversee the safe conduct of the proposed studies.

TOTAL POSSIBLE WEIGHT:**100****5. PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted, for all offerors found to be technically acceptable, prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than past performance.

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

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

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

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

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

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

6. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusions about overall commitment and realism of the offeror's SDB Participation targets will be used in determining the relative merits of the offeror's proposal and in selecting the offeror whose proposal is considered to offer the best value to the Government.

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the offeror's proposal. The Government is seeking to determine whether the offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offers will be evaluated on the following sub-factors:

- a. Extent to which SDB concerns are specifically identified
- b. Extent of commitment to use SDB concerns
- c. Complexity and variety of the work SDB concerns are to perform
- d. Realism of the proposal
- e. Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
- f. Extent of participation of SDB concerns in terms of the value of the total acquisition.

PACKAGING AND DELIVERY OF THE PROPOSAL

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals.

SUBMISSION OF PROPOSALS BY FACSIMILE OR E-MAIL IS NOT ACCEPTABLE.

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

**"RFP NO. NIH-NIAID-DMID-AI2008041
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"**

B. PAPER COPIES and CD-Rom to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Brian Jamieson Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Brian Jamieson Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

NOTE: All material sent to this office by Federal Express should be sent to the Hand Carried Address.

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (JAN 2006).

C. NUMBER OF COPIES:

TOTAL PAGE COUNT DOES NOT INCLUDE: Cover/Title Page and Back Page; NIH-2043; Table of Contents; Section Dividers that do not contain information other than title of Section.

PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES.

FORMATTING AND LAYOUT:

Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals. ***If documents are submitted using Adobe .pdf, the document should be submitted using a .pdf searchable format.***

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).
- Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

CREATING AND NAMING ELECTRONIC FILES:

1. A separate CD should be submitted for the Technical Proposal and Business Proposal information.
Offerors who submit both Technical and Business Proposals on the same CD will be required to resubmit them on separate CDs.
2. Files on CDs should be named using the following format:

Company name / RFP number / technical / ** /date

****** if multiple files are submitted for the technical proposal, please include the name of the section in the file name.

EXAMPLE: XYX Company/AI2008038/Technical/Approach/3-6-06

Company name / RFP number / business / ** / date

****** if multiple files are submitted for the business proposal, please include the name of the section in the file name.

EXAMPLE: XYX Company/AI2008038/Business/Staffing/3-6-06

THE NUMBER OF COPIES AND APPLICABLE PAGE LIMITATIONS REQUIRED OF EACH PART OF YOUR PROPOSAL ARE AS SPECIFIED BELOW.

PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

OFFERORS MUST CERTIFY THAT THE INFORMATION IN THE PAPER AND ELECTRONIC COPIES IS EXACTLY THE SAME.

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices and Case Studies	<u>PAPER</u> One (1) unbound SIGNED ORIGINAL. Eleven (11) unbound COPIES <u>ELECTRONIC FILES ON CD</u> Three (3) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices and Case Studies)	Not to Exceed 200 pages
Business Proposal	<u>PAPER</u> One (1) unbound SIGNED ORIGINAL. Four (4) unbound COPIES <u>ELECTRONIC FILES ON CD</u> Three (3) Compact Disks containing an electronic copy of the Business Proposal	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk. See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.	N/A

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-AI2008041
RFP Title: Animal Models of Infectious Diseases

Please review the attached Request for Proposal. Furnish the information requested below and return this page by December 19, 2008. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

☐ DO INTEND TO SUBMIT A PROPOSAL
☐ DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):

(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
OA, DEA, NIAID, NIH
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

Attn: Brian Jamieson
RFP-NIH-NIAID-DMID-AI2008041
FAX# (301) 480-4675
Email: bjamieson@niaid.nih.gov

STATEMENT OF WORK

ANIMAL MODELS OF INFECTIOUS DISEASES

BACKGROUND and INTRODUCTION:

Research supported by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH) 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 all infectious agents other than HIV. This includes basic and applied research to develop and evaluate therapeutics, vaccines and other preventatives, and diagnostics that is funded through a variety of research grants and contracts. Toward this aim, DMID supports an array of research services. Included are programs that provide and make available to investigators, genomic data and technologies; organisms and state-of-the-art reagents; biocontainment facilities; and preclinical and clinical translational research services (<http://www3.niaid.nih.gov/research/resources/dmid>).

NIAID's role in developing medical products to counter emerging, re-emerging and other infectious diseases, as well as agents of bioterrorism, is part of a larger national strategy, involving multiple governmental agencies. As such, NIAID supports integrated efforts in basic and applied research, product development, and technology development based on national priorities for medical products. Since 2001, NIAID has established a comprehensive infrastructure with extensive resources that support all levels of biodefense research. With this solid framework of research and product development resources for biodefense in place, NIAID is now transitioning this infrastructure to provide the flexibility required to meet the challenges of emerging, re-emerging and other infectious diseases in addition to biodefense.

The use of animal models helps advance our understanding of infectious diseases as well as the development of therapeutics and vaccines. For example, animal models are used to evaluate product candidates; provide data in support of Investigational New Drug (IND) applications; guide the selection of human dose levels and the design of clinical studies/trials; and provide pivotal efficacy data for products to be licensed under FDA's "[Animal Efficacy Rule](#)" (21 CFR 314.610 and 601.91), when clinical trials are not ethical or feasible. In addition, for emerging and rare diseases, understanding the disease in animals may provide relevant information when little can be learned directly from humans. Therefore, DMID is committed to developing and providing animal models to benefit the research community and public health.

For the most part, animal model services and other research resources are currently provided through multiple, specialized programs. DMID now seeks to adopt an integrated approach to the provision of services and resources by creating unified, comprehensive, coordinated programs. This strategy is being employed to: advance science by promoting cross-fertilization across and within disciplines and approaches; serve the research community more conveniently; achieve efficient use of resources through economy of scale and avoidance of duplication; and provide the flexibility needed to respond to changing priorities. Accordingly, DMID is establishing the Animals Models of Infectious Diseases program.

In order to meet the demand for a wide array of animal models for biodefense pathogens, NIAID awarded contracts in 2003 and 2004 under the *In Vitro* and Animal Models for Emerging Infectious Diseases and Biodefense program, using the Indefinite Delivery, Indefinite Quantity (IDIQ) contract mechanism. Under IDIQ contracts, base contract awards are made to multiple offerors that successfully propose a general approach to the technical requirements of the solicitation, providing a guaranteed minimum award. Task orders for specific tasks requiring specialized expertise are solicited and funded within the program Contractor pool. DMID is replacing multiple pathogen or class specific programs with one broad IDIQ solicitation for multiple contracts to cover all areas of current and potential future interests. Animal models currently covered by existing pathogen-specific contracts will not be re-competed separately upon completion; however, they could be awarded as task orders under this program, upon expiration of those contracts.

DMID is also establishing the Microbiology and Infectious Diseases Biological Research Resources (MID-BRR) program, which will serve as a central repository for microbiology and infectious disease researchers. The MID-BRR will integrate and consolidate the functions currently carried out by numerous NIAID-supported repositories. The Animal Models of Infectious Diseases program will ensure a supply for the MID-BRR of pathogens that must be grown in animals and reagents integral to research on these organisms. In this regard, the Animals Models of Infectious Diseases program will be closely connected with the MID-BRR program and the Microbiology and Infectious Diseases Specialized Biological Resource program, which also will produce organisms and reagents for distribution to the research community. Separate and complementary RFP's will solicit proposals for these two programs. Contracts awarded in response to these solicitations are expected to interact within and across programs as well as with other DMID-sponsored research service programs.

Sharing research resources is fundamental to progress in science. The NIH is interested in ensuring that research resources developed with NIH funding are made available to the research community for further research, development, and application, in the expectation that this will further the research enterprise and accelerate the development of products and knowledge of benefit to the public. 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. Therefore, the animal models, pathogens, reagents, protocols and procedures developed through this program must be shared among contractors within the program as well as with the wider research community.

SCOPE:

The Animal Models of Infectious Diseases program will provide NIAID with a broad and flexible range of animal model capabilities for human infectious diseases or diseases of human importance caused by infectious agents. The broad scope will allow NIAID to respond to changing priorities as scientific and public health needs shift, including rapid responses to public health emergencies. The scope of work encompasses all animal work needed for infectious disease research, to include new animal model development and refinement of existing models, routine screening of products, efficacy testing to support Investigational New Drug (IND) applications or clinical trials, and efficacy testing in support of Biologic License Application/New Drug Application (BLA/NDA) submissions to the FDA under Good Laboratory Practices

(GLP, 21 CFR Part 58). Also included is the use of laboratory animals to generate pathogens and pathogen-specific reagents that are not commercially available but required for research or product development.

The Technical Requirements have been assembled into the following sections:

- o **General Statement of Work**, which specifies the basic technical requirements for all contracts.
- o **Part Statements of Work**, which specify additional technical requirements for contracts awarded to support one or more of four specific Parts:

Part A – Small Animal Models

Part B – GLP Small Animal Models

Part C – Non-Human Primate Models (+/- GLP)

Part D – Nontraditional Animal Models (+/- GLP)

For the purposes of this contract:

- *Small animals* (Parts A and B) are defined as traditional small laboratory animal species, such as mice, rats, guinea pigs, hamsters, ferrets, chinchillas, and rabbits.
- *Non-human primates* (Part C) include various species, such as macaques, including Chinese and Indian rhesus macaques (*Macaca mulatta*), cynomolgous macaques (*Macaca fascicularis*), and pig-tailed macaques (*Macaca nemestrina*), etc. Excluded are baboons and chimpanzees.
- *Nontraditional animals* (Part D) are defined as specialty laboratory animal species not covered in Small Animal or Non-Human Primate Models (Parts A – C), which may have requirements not met in typical biomedical laboratory animal facilities, such as armadillos, woodchucks, snails, other invertebrates, and goats, swine, horses, cattle, etc.
- *Products* to be evaluated in these animal models are broadly defined to include vaccines and other prevention strategies (e.g. microbicides), therapeutics targeting the host or the pathogen, including immunotherapeutics, and diagnostics. Products will be provided to the Contractor by the Project Officer or a third party after Project Officer approval.
- *Pathogens of interest* must be pathogens of human concern and not only of animal concern; however surrogate human pathogen/animal combinations may be used for diseases where human pathogens cannot be studied in animal models.
- *Pathogens* are defined as bacteria, viruses, parasites, fungi, toxins, and other agents such as prions, including NIAID Category A, B and C Priority Pathogens (<http://www3.niaid.nih.gov/topics/BiodefenseRelated/Biodefense/research/CatA.htm>).
- *Reagents* are defined as biochemical, genomic, molecular, cellular, and immunologic materials integral to research on these pathogens.

NOTE: This contract will **not** support:

- GLP toxicology testing
- Animal models for diseases only of animal and not human concern.

Part A, Small Animal Models will support the development and use of small animal models for routine screening and early efficacy testing for products against a wide range of pathogens.

Part B, GLP Small Animal Models will support the refinement and use of existing small animal models in preparation for the conduct of GLP studies, as well as GLP testing of products against a wide range of pathogens.

Part C, Non-Human Primate Models will support the development, refinement and use of non-human primate models, and may include both GLP and non-GLP studies (as specified in the Task Order Statement of Work), for testing products against a wide range of pathogens.

Part D, Nontraditional Animal Models will support the development, refinement and use of non-traditional animal models, and may include both GLP and non-GLP studies (as specified in the Task Order Statement of Work), for testing products against a wide range of pathogens. This part will also support the production of pathogens and/or reagents for distribution to the research community directly or through a central NIAID repository.

NIAID recognizes that a single organization or institution may not have the expertise and facilities required to perform all of the activities set forth in the Statement of Work and, consequently, that the Contractor may need to be supported to a certain extent by the expertise and resources of subcontractors to perform some of the activities required. However, the Contractor shall be responsible for ALL work performed under this contract including that performed by any subcontractor(s).

TECHNICAL REQUIREMENTS:

GENERAL STATEMENT OF WORK FOR ALL PARTS

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, animals, materials, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work below. All Contractors shall perform the work described below in addition to one or more Parts A – D.

Specifically, the Contractor shall:

1. Perform Animal Studies

As specified in the Task Order Statement of Work, develop, refine and/or provide one or more animal model(s) of human infection and/or diseases for state-of-the-art evaluation of products including, vaccines and other prevention strategies, therapeutics, and diagnostics. The Contractor may be required, at the request of the Project Officer, to use animal models other than those proposed if another animal model becomes available.

A. Provision of Animal Models

- 1) Provide and/or update existing infection models that are efficiently established and the level of infection/challenge and/or disease

pathogenesis reflects as closely as possible the corresponding human infection/disease.

- 2) Develop and evaluate new animal models required for new/emerging pathogens and models/species. The following types of studies are included:
 - a. the determination of median infective and/or lethal doses
 - b. serial pathogenesis studies with a multiple of the median infective/lethal dose
 - c. natural history studies with a multiple of the median infective/lethal dose
 - d. additional studies to ensure reproducibility.
- 3) Develop and/or provide animals for other models, for example, mice transgenic with the human virus receptor gene or animals implanted with virus-infected human tissues
- 4) Incorporate standardized methods, when provided by the Project Officer.

B. Protocol Development

Studies for protocol development may be proposed by the Contractor or the Project Officer and include animal study protocols, assay protocols, development, qualification or validation protocols, and Standard Operating Procedures (SOPs) or study-specific protocols.

- 1) As specified in the Task Order Statement of Work, develop, in conjunction with the Project Officer, other NIAID staff, and as necessary, the sponsor of the product, protocols that outline and describe the study/assay/validation/etc. to be performed. Submit draft protocols to the Project Officer for review and approval. Within 7 calendar days of receiving Project Officer review, revise the draft protocols as necessary, and submit the final protocols for Project Officer approval.
- 2) Written approval by the Project Officer of the final protocol shall be required prior to study initiation. Once a study has been initiated, the protocol shall only be amended after concurrence of the Project Officer.
- 3) Prepare and utilize SOPs for the activities delineated in approved protocols. Submit SOPs to the Project Officer for review and approval at the time of protocol submission. Additional, subsequent SOPs and modifications to current SOPs shall be submitted for Project Officer review and approval.

C. Product Efficacy Evaluations

- 1) Perform efficacy evaluations of experimental products. Products will be provided to the Contractor by the Project Officer or a third party after Project Officer approval. As specified in the Task Order Statement of Work, conduct studies to evaluate novel strategies for product delivery and dosing, including combinations of drugs, combinations of drugs and vaccines, vaccines and adjuvants, sequential drug administration and vaccine prime/boost strategies. These studies may require, as specified in the Task Order Statement of Work, pharmacokinetic/pharmacodynamic (PK/PD) evaluations of

single and combination therapies. These studies shall include appropriate uninfected and/or untreated controls and may involve aerosol challenge of some pathogens.

- 2) Evaluation capabilities shall include, but not be limited to, the following quantitative and/or qualitative assessments, which detect differences with a level of statistical confidence between treatment groups of animals, including:
 - a. General indicators of morbidity and mortality.
 - b. Microbiological and histological analyses to document the identity, severity, pathology, and location of the animal infection.
 - c. Necropsy/pathology.
 - d. Appropriate observations and measures of general toxicity, to include body weight, blood chemistries, hematologic measures, body temperature, behavior, effects on indigenous microflora and other indicators of general health.
 - e. Determination of initial serum levels of and pharmacology studies for products to support PK/PD studies.
 - f. PK/PD studies relevant to the product, which will require either the transfer of product-specific analytical methods to the Contractor by the third party supplier or the transfer of samples by the Contractor to another laboratory for analysis.
 - g. Immunogenicity and/or innate and adaptive immune responses when appropriate for the product.
- 3) As directed by the Task Order Statement of Work, ensure that FDA regulations for Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies are followed (21 CFR Part 58; <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58>)

D. Assay Development and Reagents

- 1) Develop and/or provide assays for new/emerging pathogens and models/species, as well as update existing assays to allow for state-of-the art evaluation of products.
 - a. Develop immunologic or diagnostic assays including:
 - i. the development of positive and negative control samples
 - ii. optimization of assay parameters
 - iii. qualification with a variety of study samples
 - iv. other studies to explore whether new assays are meaningful for the intended purpose
 - v. quality testing of reagents, as appropriate
 - vi. Qualify and/or validate, as requested by the Project Officer, assays and reagents that become integral features of the animal model.

- 2) Produce reagents as needed after receiving approval by the Project Officer. Production of reagents may be new reagents or may include the generation and/or expansion of renewable reagents.

E. Final Reports

- 1) Submit draft Final Study, Qualification and Validation Reports to the Project Officer, for review within 14 calendar days of completion of the animal study. The content of the Final Study Report will be outlined in the specific Task Order. Revise and submit the Final Study Report to the Project Officer within 14 calendar days of receipt of Project Officer comments. When appropriate, the Project Officer will request comments from the product sponsor within the same timeframe.
- 2) Provide all data, information, records and reports to the Project Officer, who will share them with a third party, whether a product sponsor or the FDA, as appropriate. Reports may be animal study reports, assay reports, development, qualification or validation reports, and final SOPs or study-specific protocols.
- 3) FDA documents may be in various formats for submission to a Master File, Investigators Brochure, and documents related to IND submission and maintenance. Documents will be specified by the Project Officer and specific Task Order. Submission of documents to FDA is beyond the scope of this contract.

F. Acquisition, Care and Housing of Animals

- 1) Acquire, as necessary, sufficient numbers of animals to carry out the specific task. The decision of which animal species is to be used and any requirements for specific-pathogen free (SPF) animals shall be made jointly by the Project Officer and the Contractor, with the Project Officer having final approval authority.
- 2) House and maintain the animals in well-equipped facilities with Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) International Accreditation or the equivalent.
- 3) Comply with all applicable laws, policies and guidelines regarding the care and use of laboratory animals, including the PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants1.nih.gov/grants/olaw/references/phspol.htm>).
- 4) Provide routine care and health surveillance for laboratory animals including on-call veterinary coverage 24 hours per day, seven days a week. Provide at least daily observations of the health status of each animal, including weekends and holidays.
- 5) Record and maintain detailed records on the health status of each animal, including clinical observations and testing, any treatments received, the results of periodic weighing and any other care or procedures required during the course of the contract.

G. Material Receipt, Storage, Shipping and Inventory

- 1) Develop and maintain efficient and effective procedures sufficient to support contract activities for receiving, storing, shipping and inventory of products, pathogens, specimens and reagents.
- 2) Obtain the appropriate licenses and permits required by international, Federal, state, and local authorities for the safe transport, storage, and distribution of products, pathogens, specimens and reagents.
- 3) Provide for safe packing, labeling, and shipping of products, pathogens, specimens and reagents, so that shipments are coordinated for timely receipt.
- 4) Provide shipping containers that comply with domestic and international postal requirements; pertinent International Air Transport Association (www.iata.org); and the International Civil Aviation Organization (www.icao.int) requirements. The shipping containers shall provide a sufficient margin of safety for maintaining appropriate environmental safeguards and desired refrigeration levels for specific products in transit, depending on the mode of transportation employed.
- 5) Provide secure, safe and stable storage of products, pathogens, specimens, and reagents under the required conditions (e.g., Biosafety Level, GLP, aseptic) and according to specifications provided by the supplier, as applicable.
- 6) Establish and maintain an electronic inventory of all products, pathogens, specimens, materials, and reagents received, produced, stored, and shipped, such as in an Excel spreadsheet or database, compatible with Microsoft Office XP or software currently used and approved by NIAID, that includes searchable information, such as compound identifiers, amounts available, storage locations, shipping data and other biological and chemical characteristics of the compound.

2. Production and Characterization of Pathogen(s)

- A. Provide microbiological support for the pathogen(s) specified in the Task Order Statement of Work, including quality-controlled master and working banks; SOPs for producing and characterizing challenge material under standardized media and growth conditions; and master and working banks for cell lines where applicable. Use specific strains as required in Task Order Statement of Work.
- B. Characterize pathogens to include the following types of parameters: identity, purity, titer, virulence, microscopic characteristics, growth characteristics, special plating and/or stains, sequencing, etc.
- C. Develop and/or provide acceptance criteria for the use of challenge material in animal model studies.

- D. Confirm challenge dose for each experiment or animal as required in the Task Order Statement of Work. Provide confirmation of infection/intoxication in animals, to include re-isolation of pathogens and further characterization.

3. Biocontainment Facilities & Safety

- A. Provide safe facilities and resources and conduct work with hazardous biological materials in compliance with the Biosafety in Microbiological and Biomedical Laboratories (BMBL), 5th Edition, guideline available at: http://www.cdc.gov/OD/OHS/biosfty/bmbl5/BMBL_5th_Edition.pdf
- B. Where applicable, ensure that the Select Agent Regulations through CDC and/or USDA are followed ([42 CFR Part 73](#), [7 CFR Part 331](#), and/or [9 CFR Part 121](#)). Conduct work in accordance with all applicable Federal, state and local laws, codes, ordinances and regulations.

4. Sharing Research Resources

- A. As requested by the Project Officer or as directed in the Task Order Statement of Work, prepare, and submit to the Project Officer for review and approval, Technology Transfer Packages or operational instructions for the transfer of animal models, pathogens, assays, processes, SOPs, reagents, products or other materials generated under the contract, to another Contractor, third party designated by the Project Officer, or directly to the Project Officer.

- 1) Technology Transfer Packages for animal models shall include a description of all the critical features of the model, including:
 - a. animals (species, strain, age, weight, sex, source, health status, exclusion criteria, etc.)
 - b. challenge material (strain of pathogen, production methods, characterization methods and acceptance criteria, source of pathogen, etc.)
 - c. challenge methods (detailed procedures including all critical parameters or ranges, challenge doses)
 - d. outcomes, including all parameters monitored with methods and expected responses or ranges
 - e. any critical components that are commercially available, such as assay kits, equipment, reagents, etc.
 - f. development, qualification and validation reports, as applicable
- 2) Technology Transfer Packages for assays shall include a description of all the critical features of the assay(s) and information on performing them, including:
 - a. commercially available components, such as equipment, plates, cell lines, reagents, etc.
 - b. control materials, such as reference standards, proficiency panels, quality control reagents, antigens, immunological reagents, etc.

- c. reagents (immunological, histochemical or other materials needed for assay conduct).
 - d. development, qualification and validation reports, as applicable
- 3) Technology Transfer Packages for pathogens shall include a description of all the critical features of the pathogen, including:
 - a. Growth conditions, including all media components and methods.
 - b. Quality control methods, including tests for identity, purity, titer, virulence, microscopic characteristics, growth characteristics, special plating and/or stains, sequencing, etc.
 - c. Strain history, including information on original isolation, *in vitro/in vivo* passaging, and data supporting its use
- B. Submit reagents and pathogens generated under this contract to an NIAID-supported central repository, as directed in the Task Order Statement of Work, including documentation to support the production, characterization and history.
- C. Participate in annual meetings with other "Animal Models of Infectious Diseases" and other research resource contractors for informal exchange of technologies, models, assays, data, etc. The meetings shall be attended by a maximum of 5 individuals from each contract, including subcontractor personnel, unless otherwise specified by the Project Officer, as well as the Project Officer, the Contracting Officer and other key NIAID and NIH staff. The Project Officer will schedule the meetings and be responsible for all the logistical arrangements.

5. Data Management and Reporting

- A. Provide and maintain a secure, internal IT system architecture and computational infrastructure to support the data management, data analysis and other computational needs of the contract. The Contractor's institutional security policies and guidelines must be followed.
- B. Provide and maintain a secure network infrastructure that allows the Contractor's investigators access to the computational and database resources and software applications, and facilitates data sharing and electronic communication exchanges. The database will contain confidential proprietary information that cannot be used for data-mining purposes by the Contractor or subcontractors.
- C. Ensure secure electronic communications, including e-mail, word processing and transmission of data files, among the Contractor, NIAID staff, subcontractors and consultants.
- D. Provide and maintain an in-house database management system using a software application approved by the Project Officer. The database must support all data types, protocols, and experimental results generated by, or related to, the requirements of the contract. The database shall provide the capability to conduct queries and analyses, export data in a variety of

formats, disseminate data, and submit experimental data to the Project Officer.

- E. Organize, maintain, and transfer information on protocols and test results into the database, and provide electronic copies of all reports to the Project Officer in a format to be specified by the Project Officer.
- F. As requested by the Project Officer, transfer information on protocols, data, etc., from the Contractor's in-house database to a government-owned, secure database, currently under development. Some or all of the data may be transferred into the NIAID data management system. The Contractor(s) shall work with the Project Officer and database developer on a transition plan to transfer data and data structure to the NIAID database. Thereafter, the Contractor shall continue to support data collection and/or data entry and quality assurance/quality control activities as needed for the data uploaded into the NIAID database.
- G. The Government reserves the right to have complete access to the databases, provide access to third parties, and to transfer all rights and custody to a successor contractor.

6. Project Management

A. Overall Project Management

- 1) Provide and implement plans for the overall management, integration and coordination of all contract activities, timelines and task-linked budgets including the management and coordination of activities carried out under subcontracts.
- 2) Provide a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation and timely completion of all projects carried out under this contract and effective communications with the Project Officer and the Contracting Officer.
- 3) Provide appropriate personnel with responsibility for:
 - a. overall project management and communications
 - b. tracking of projects
 - c. ensuring quality assurance/quality control
 - d. fostering internal/external communications
 - e. monitoring and reporting on project status and progress
 - f. preparing other deliverable documentation
 - g. recommending modifications to project requirements, timelines and budget, including projects undertaken by subcontractors.

B. Meetings and Teleconferences

The following types of meetings should be expected and the frequency will be specified in the Task Order Statement of Work.

1) Task Order Initiation Meeting(s)

Within 30 calendar days of the effective date of each Task Order award, participate in a Task Order Initiation Meeting with the Project Officer, the Contracting Officer and other NIAID personnel designated by the Project Officer to be held at a location determined by the Project Officer. The purpose of the Task Order Initiation Meeting will be to orient the Contractor to NIAID task order procedures, review contract requirements, and to plan implementation of initial task order activities.

2) Regular Meeting(s)/Teleconference(s)

Plan and conduct meetings of the Task Order key personnel with the Project Officer and Contracting Officer at regular intervals, either in person or via teleconference, to review protocols, data, the status of approved projects, and to discuss any matters relevant to the scientific and financial administration of the contract and future activities. The schedule for those meetings will be established by the Project Officer and Contracting Officer after Task Order award. Prepare and submit the agenda and meeting materials to the Project Officer for review and approval 5 calendar days prior to the meeting, distribute the agenda and background materials to all meeting participants at least 2 calendar days in advance of the meeting, prepare and provide a summary of all meetings and teleconferences to the Project Officer within 7 calendar days of the conclusion of the meeting/teleconference, and include each summary in the Semi-Annual Progress Reports.

3) Site Visit(s)

Arrange for and conduct site visits for NIAID contract and program staff to review and discuss: 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 Principal Investigator, the Contractor's business representative, and all key personnel. The Contractor shall be responsible for:

- a. Working with the Project Officer on the agenda;
- b. Developing written and oral presentation materials;
- c. Arranging for the logistics associated with the site visits and for travel costs for all non-Government site visit attendees; and
- d. Preparing and submitting site visit materials including presented materials to the Project Officer and Contracting Officer within 30 calendar days of completion of each site visit.

7. Final Transition

The Contractor shall ensure an orderly, secure, and efficient transition of contract-related materials and activities to the successor contractor or to the Government. A description of transition activities, timelines, and assigned staff shall be provided in Draft and Final Transition Plans, which will be reviewed and approved by the Project Officer and Contracting Officer. The Draft Transition Plan shall be submitted to the Project Officer 4 months prior to the completion date of the contract, and the Final Transition Plan (as approved by the Project Officer and Contracting Officer) shall be submitted 2 months prior to the completion date of the contract. The final transition to a successor contractor or to the Government shall be fully completed by the expiration date of the contract.

PART A, STATEMENT OF WORK: SMALL ANIMAL MODELS

Part A provides for the development and use of a variety of small animal models for routine screening and early efficacy testing for products against a wide range of pathogens. For the purposes of this contract, small animals are defined as traditional small laboratory animal species such as mice, rats, guinea pigs, hamsters, ferrets, chinchillas and rabbits. While all pathogens are within scope and may be the subject of post-award task order solicitations, particular pathogens of interest are:

- Respiratory
 - viruses (influenza, RSV, human metapneumovirus, rhinoviruses, and coronaviruses, including SARS-CoV, parainfluenza)
 - bacteria (including but not limited to *Streptococcus pneumoniae*, *haemophilus* spp.)
 - Mycobacterial pathogens (*Mycobacterium tuberculosis*, non-tuberculous mycobacteria, and also *Mycobacterium leprae* and other pathogenic mycobacteria);
- invasive aspergillosis
- Non-biodefense viruses: Hepatitis B and C viruses, Herpesviruses (HSV 1 and 2, CMV, VZV); papillomaviruses; polio; adenovirus; prion disease
- Biodefense
 - viruses: orthopoxviruses, VEE, WEE, WNV, Punta Toro, Pichinde, YFV, dengue, filoviruses, Junin virus
 - bacteria: *Burkholderia mallei* and *pseudomallei*; *Francisella tularensis*; *Rickettsia prowazekii*; *Yersinia pestis*, antimicrobial-resistant bacteria
 - toxins: Botulinum toxins
- Sexually transmitted infections of viral or bacterial etiology (such as *Chlamydia trachomatis*, herpes simplex virus).

Design, develop and execute studies using small animal models, as directed in the Task Order Statement of Work, including the following:

- Studies to screen products for efficacy to provide proof-of-concept data.
- Studies to further evaluate features of a product, such as time-to-protection, testing additional strains, novel dosing or delivery strategies, combination studies, etc.
- New animal model development, which may include:

1. comparisons of disease between species of animals and/or strains of pathogen
 2. median lethal dose or median infectious dose determinations
 3. natural history of disease, including pathology
 4. aerosol deposition studies
 5. innate and adaptive immune responses
 6. comparison of challenge routes.
- Refinement of existing animal models.
 - Development and/or characterization of reagents requiring animals or required to support animal models.
 - Studies to evaluate the capability of strategies to prevent infection at a local and/or mucosal surface.
 - Development of diagnostic or immunologic assays and reagents necessary to support robust animal model development in a product-neutral manner.

Assays and reagents that become integral features of the small animal model shall be Deliverables of the Task Order award.

PART B, STATEMENT OF WORK: GLP SMALL ANIMAL MODELS

Part B provides for the refinement and use of existing small animal models for GLP efficacy testing for products against a wide range of pathogens. For the purposes of this contract, small animals are defined as traditional small laboratory animal species such as mice, rats, guinea pigs, hamsters, ferrets, chinchillas and rabbits. While all pathogens are within scope and may be the subject of post-award task order solicitations, particular pathogens of interest are:

- Respiratory
 - viruses (influenza, RSV, human metapneumovirus, rhinoviruses, and coronaviruses, including SARS-CoV, parainfluenza)
 - bacteria (including but not limited to *Streptococcus pneumoniae*, *haemophilus* spp.)
 - Mycobacterial pathogens (*Mycobacterium tuberculosis*, non-tuberculous mycobacteria, and also *Mycobacterium leprae* and other pathogenic mycobacteria);
- invasive aspergillosis
- Non-biodefense viruses: Hepatitis B and C viruses
- Biodefense
 - viruses: orthopoxviruses, VEE, WEE, WNV, Punta Toro, Pichinde, YFV, dengue, filoviruses, Junin virus, hantaviruses, rabies
 - bacteria: *Burkholderia mallei* and *pseudomallei*; *Francisella tularensis*; *Rickettsia prowazekii*; *Yersinia pestis*, *Bacillus anthracis*, antimicrobial-resistant bacteria
 - toxins: Botulinum toxins

Part B requires the Contractor provide for the conduct of studies according to the FDA GLP Regulations, as codified in 21 CFR Part 58:

(<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=>

58). Supporting assays considered to be pivotal shall be validated if required and specified in the Task Order Statement of Work.

Design, develop and execute studies using small animal models, as directed in the Task Order Statement of Work, including the following:

- Refinement of existing animal models.
- Studies to evaluate vaccination in both general and post-exposure prophylaxis indications.
- Studies that demonstrate immunological correlates of protection in animal models and delineation of correlate markers of protection for vaccine candidates.
- Further characterization of immune responses including humoral and cell mediated immune responses and evaluation of how these findings correlate with protection.
- Animal efficacy studies on vaccine candidates to support licensure (BLA).
- Immunogenicity studies in vaccine candidates to support licensure (BLA).
- Development of therapeutic models for the assessment of treatment efficacy, alone or in combination with vaccines or other therapeutics.
- Efficacy studies to support the treatment and/or post-exposure indications for various therapeutic candidates, to support licensure (NDA or BLA).
- Studies to evaluate the capability of strategies to prevent infection at a local and/or mucosal surface.
- Production and/or characterization of reagents requiring animals or required to support animal models.
- Development of diagnostic or immunologic assays and reagents necessary to support robust animal model development in a product-neutral manner.

Assays and reagents that become integral features of the small animal model shall be Deliverables of the Task Order award.

PART C, STATEMENT OF WORK: NON-HUMAN PRIMATE MODELS

Part C provides for the development, refinement and use of non-human primate (NHP) models for efficacy testing for products against a wide range of pathogens. Some studies will require testing to be conducted under GLP, as specified in the Task Order Statement of Work. While all pathogens are within scope and may be the subject of post-award task order solicitations, particular pathogens of interest are:

- Respiratory
 - viruses (influenza, and SARS-CoV)
 - Mycobacterial pathogens (*Mycobacterium tuberculosis*, non-tuberculous mycobacteria, and also *Mycobacterium leprae* and other pathogenic mycobacteria);
- Biodefense
 - viruses: orthopoxviruses, filoviruses, Junin virus, Dengue, Nipah

- bacteria: *Burkholderia mallei* and *pseudomallei*; *Francisella tularensis*; *Rickettsia prowazekii*; *Yersinia pestis*, *Bacillus anthracis*
- toxins: Botulinum toxins

Part C requires that the Contractor provide for the conduct of some studies according to the FDA GLP Regulations, as codified in 21 CFR Part 58: (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=58>). Supporting assays considered to be pivotal shall be validated if required and specified in the Task Order Statement of Work.

Design, develop and execute studies using non-human primates, as directed in the Task Order Statement of Work. Examples of NHP studies that, as specified in the Task Order Statement of Work may require testing to be conducted under GLP, include the following:

- New animal model development, which may include:
 1. comparisons of disease between species of animals and/or strains of pathogen
 2. median lethal dose or median infectious dose determinations
 3. natural history of disease, including pathology
 4. aerosol deposition studies
 5. innate and adaptive immune responses
 6. comparison of challenge routes.
- Refinement of existing animal models.
- Studies to evaluate vaccination in both general and post-exposure prophylaxis indications.
- Studies that demonstrate immunological correlates of protection in animal models and delineation of correlate markers of protection for vaccine candidates.
- Further characterization of immune responses including humoral and cell mediated immune responses and evaluation of how these findings correlate with protection.
- Animal efficacy studies on vaccine candidates to support licensure (BLA).
- Immunogenicity studies in vaccine candidates to support licensure (BLA).
- Development of therapeutic models for the assessment of treatment efficacy, alone or in combination with vaccines or other therapeutics.
- Efficacy studies to support the treatment and/or post-exposure indications for various therapeutic candidates to support licensure (NDA or BLA).
- Studies to evaluate the capability of strategies to prevent infection at a local and/or mucosal surface.
- Development, production and/or characterization of reagents requiring animals or required to support animal models.
- Development, qualification and/or validation of diagnostic or immunologic assays and reagents necessary to support robust animal model development in a product-neutral manner.

Assays and reagents that become integral features of the NHP animal model shall be Deliverables of the Task Order award.

PART D, STATEMENT OF WORK: NONTRADITIONAL ANIMAL MODELS

Part D provides for the development, refinement and use of nontraditional animal models to better understand human disease and for efficacy testing for products against a wide range of pathogens, and for production of biological research resources. Some studies will require testing to be conducted under GLP, as specified in the Task Order Statement of Work. A nontraditional animal is defined as a specialty laboratory animal species not covered in Small Animal (Part A) or Non-Human Primate (Part C), which may have requirements not met in typical biomedical laboratory animal facilities, such as armadillos, woodchucks, snails and other invertebrates, goats, swine, horses, cattle, etc.

While all pathogens are within scope and may be the subject of post-award task order solicitations, particular pathogens of interest are:

- Neglected tropical diseases (for example, filariasis, trachoma, schistosomiasis, leprosy)
- surrogate pathogens, such as woodchuck hepatitis virus, as a model for hepatitis B virus
- dengue

Part D requires that the Contractor provide for the conduct of some studies according to the FDA GLP Regulations, as codified in 21 CFR Part 58: (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=58>). Supporting assays considered to be pivotal shall be validated if required and specified in the Task Order Statement of Work.

Design, develop and execute studies using nontraditional animal models, as directed in the Task Order Statement of Work. Examples of studies that, as specified in the Task Order Statement of Work, may require testing be conducted under GLP, include the following:

- New animal model development, which may include:
 1. comparisons of disease between species of animals and/or strains of pathogen
 2. median lethal dose or median infectious dose determinations
 3. natural history of disease, including pathology
 4. aerosol deposition studies
 5. innate and adaptive immune responses
 6. comparison of challenge routes.
- Refinement of existing animal models.
- Studies to screen products for efficacy to provide proof-of-concept data.
- Studies to further evaluate features of a product, such as time-to-protection, testing additional strains, novel dosing or delivery strategies, combination studies, etc.
- Studies to evaluate vaccination in both general and post-exposure prophylaxis indications.

- Studies that demonstrate immunological correlates of protection in animal models and delineation of correlate markers of protection for vaccine candidates.
- Further characterization of immune responses including humoral and cell mediated immune responses and evaluation of how these findings correlate with protection.
- Animal efficacy studies on vaccine candidates to support licensure (BLA).
- Immunogenicity studies in vaccine candidates to support licensure (BLA).
- Development of therapeutic models for the assessment of treatment efficacy, alone or in combination with vaccines or other therapeutics.
- Efficacy studies to support the treatment and/or post-exposure indications for various therapeutic candidates, to support licensure (NDA or BLA).
- Studies to evaluate the capability of strategies to prevent infection at a local and/or mucosal surface.
- Development, production and characterization of pathogens or reagents requiring animals or required to support animal models.
- Development, qualification and/or validation of diagnostic or immunologic assays and reagents necessary to support robust animal model development in a product-neutral manner.

Assays and reagents that become integral features of the nontraditional animal model will be Deliverables of the Task Order award.

**ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS,
FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS**

**ANIMAL MODELS OF INFECTIOUS DISEASES
RFP-NIH-NIAID-DMID-AI2008041**

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 RFP and provide specific instructions and formatting for the Technical Proposal. While Section L.2.b. of the RFP 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 RFP 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 are reminded that the total page limitation for the entire Technical Proposal is 200 pages including all appendices and attachments. Any pages in excess of this limit will be expunged from the proposal and will not be considered in the technical review.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

GENERAL NOTES

Offerors may propose in response to one or more Part(s) of their choosing, and are not expected to respond to all Parts. Offerors are also not expected to be responsible for all pathogens of interest or within scope for these contracts. Offerors responding to multiple Parts must provide separate Technical and Business Proposals for each Part. Proposals for each Part will be reviewed independently.

- A. The Technical Proposal should address all elements in the General Statement of Work and in addition provide a detailed plan to address one of the Sample Task Orders for the Part. The Sample Task Orders for Parts A-D are contained in Section 7 of these Additional Technical Proposal Instructions.
- B. The Technical Proposal should incorporate general approaches that are common to many pathogens.

- C. If an Offeror wishes to propose multiple animal models within a Part, a summary of all models in abbreviated or tabular form should be provided in the Proposal. See the Annual Report in Article C - Reporting Requirements for guidance on preparing the summary information for multiple animal models.
- D. The total page limit for Technical Proposals for each Part is 200 pages.
- E. GLP compliance is necessary for Part B and may be required for Task Orders in Parts C and D. Offerors responding to these Parts should indicate clearly in the Technical Proposal whether they are able to perform studies in compliance with GLP. Offerors capable of performing GLP studies should document their capability in detail, as detailed in Section 3.A.5 below.
- F. The Sample Task Orders included in this solicitation are:
 - 1. Part A, DEVELOPMENT OF SMALL ANIMAL MODEL AND METHODS
 - 2. Part A, SMALL ANIMAL MODEL PRODUCT SCREENING
 - 3. Part B, GLP SMALL ANIMAL MODEL
 - 4. Part C, DEVELOPMENT OF A NON-HUMAN PRIMATE MODEL
 - 5. Part C, NON-HUMAN PRIMATE GLP EFFICACY TESTING
 - 6. Part D, PRODUCTION OF PATHOGENS AND/OR REAGENTS FROM INFECTED ANIMALS
 - 7. Part D, DEVELOPMENT AND USE OF A NONTRADITIONAL ANIMAL AS MODEL OF INFECTION

SECTION 1:

- 1) PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.
- 2) GOVERNMENT NOTICE FOR HANDLING PROPOSALS
- 3) PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)
- 4) TABLE OF CONTENTS

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

Provide a brief description of the proposed project, including:

- 1) A summary describing the animal model(s) the offeror is proposing to advance and the scope of activities proposed.
- 2) A description of the activities to be performed by the offeror and those that shall be provided by any proposed subcontractor, including the identification of the proposed subcontractors and a list of key personnel of the offeror and the proposed subcontractors with degrees and titles.
- 3) A brief description of the facilities and other resources to be made available by the offeror and any proposed subcontractors.

SECTION 3: TECHNICAL PLAN / APPROACH

A. PERFORM ANIMAL STUDIES (SOW ITEM 1)

- 1. Provide a general species- and pathogen-independent overview describing the approach to, and experience with provision of animal models and

refinement of existing models, support for new animal model development, protocol development, testing of products in animal models and assay development. Examples include procedures to challenge animals by various routes, pathological analyses, immunological analyses, pharmacological analysis, clinical analyses, and statistical analyses of median infective or lethal dose data.

2. Provide a detailed description of specific approaches to individual animal models (individual species, route and pathogen combinations). Specific approaches apply to animal models that have already been developed, and should include information such as the rationale for the challenge dose and route, detail on endpoints to be assessed, and evidence that the model is appropriate for the intended product efficacy studies. Specific models that the Offeror proposes to develop or refine should be described clearly, including information on existing models and the rationale for the proposed model or refinement. Assays specific to proposed pathogens or models should also be described in detail, including the development, qualification, and/or validation status. Include a discussion of the problems likely to occur with the conduct of animal studies and proposed approaches for overcoming the problems.
3. Provide a detailed technical plan, not to exceed 25 pages and included within the 200 page limit, to address one of the Sample Task Orders (see Section 7) for the Part proposed. The Sample Task Order is not an actual Task Order, but is a sample included for evaluation purposes. Offerors must respond with a technical approach directed toward a pathogen of their own choosing. While all pathogens are within scope, pathogens of interest to NIAID are listed in the Part Statements of Work.
4. Discuss procedures for securing a reliable source, and sufficient numbers of animals to carry out the proposed studies. Discuss the species available and experience with the species. For non-human primates, indicate which species of non-human primates you will have access to (through breeding colonies or purchase) and describe your experience in housing the various species.
5. For Offerors responding to Parts B – D, clearly indicate whether you are capable of performing studies under GLP. Include information to document institutional capabilities and resources in the following areas:
 - a. Personnel, including a description of management, availability of trained Study Directors, the size and experience of Quality Assurance personnel and their reporting structure.
 - b. Facilities, including a description of animal facility and laboratory areas that are GLP compliant, facilities for handling test and control articles, specimen and data storage areas, and record storage areas.
 - c. Equipment, including the type of equipment available for GLP studies and a description of calibration and maintenance.
 - d. Operations, including an overview of documentation practices, general areas covered by SOPs, and findings during inspections and corrective actions

B. PRODUCTION AND CHARACTERIZATION OF PATHOGEN(S) AND REAGENTS (SOW ITEM 2)

Provide a clear description of the microbiological approaches including all the pathogens proposed, the approach to propagate the proposed pathogen(s), including strain(s) and history, and methods. Describe in detail the characterization tests to be performed, prior to use in animal studies. Tabular presentation is acceptable when proposing multiple pathogens.

SECTION 4: PERSONNEL AND PROJECT MANAGEMENT

A. 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. 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 proposal subcontractors. Clearly identify who is to be assigned as Key Personnel. Limit CVs to 2-3 pages [to be included in the total page limitations], provide selected references for publications relevant to the scope of the RFP, and include experience with projects of similar scope, size and complexity carried out by the offeror and any proposed subcontractors over the past 5 years.

1. **Principal Investigator (PI):** include the experience and qualifications of the PI to plan, manage, and direct the activities to be carried out under this contract. The experience described should be specific to the conduct of the animal models proposed.
2. **Scientific and Technical Personnel:**
Document the training and availability of all personnel experienced in and dedicated to performance of the general technical approaches, such as laboratory animal studies, pathology, statistics, immunology, etc.
Document the training and availability of all personnel with specific areas of expertise key to the particular animal models proposed. Include the number of available lab animal technicians certified at various AALAS levels (http://www.aalas.org/Certification/tech_cert.asp). Include a description of the number of available personnel trained at each Biocontainment Safety Level and plans for additional personnel if proposed.

B. PROJECT MANAGEMENT (SOW ITEM 6)

1. Provide a plan for project organization, staffing, and management in relation to 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. For Offeror institutions proposing multiple animal models, clearly describe the administrative structure for the management of multiple Task Orders and/or multiple animal models, to include the process of resource

allocation and oversight for multiple projects. If consultants and/or subcontractors are proposed, include a plan to manage, coordinate, and oversee the work performed by consultants and/or subcontractor(s). Include a chart of the proposed organizational/management structure for the project.

2. Describe the project management systems that will be used to track activities and to keep multiple activities on time and budget. The plan must include a description of the quality control methods that will be used to ensure the effective and efficient initiation, implementation, management, and oversight of contract requirements.
3. Outline how the PI (or Project Manager) will communicate with the Project Officer and Contracting Officer and how the PI (or Project Manager) will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

C. SHARING RESEARCH RESOURCES (SOW ITEM 4)

1. Describe plans for the development and oversight of Technology Transfer Packages. Include a description of experience with the transfer, both incoming and outgoing, of animal models, assays, reagents and pathogens. Include a draft Technology Transfer Package for the transfer of an animal model or an assay.
2. Describe procedures to ensure that reagents and pathogens generated under the contract are deposited in a repository. Provide an outline of documentation to be submitted along with reagents and/or pathogens. Describe experience submitting pathogens and reagents to NIAID or other repositories, including actual documentation.
3. Describe plans for annual meeting participation, including experience with similar meetings and the titles of presentations given.

SECTION 5: FACILITIES, EQUIPMENT AND OTHER RESOURCES (SOW ITEMS 3, 5 & 1G)

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

1. Location and features of facilities including a floor plan and a list of equipment and resources dedicated to the project for the prime contractor and any proposed subcontractors (lease or ownership information should be provided).
2. A clear description of biocontainment space, including laboratory and animal areas, biocontainment level, and numbers of animals for all species that could be housed in that space. For example, “xx square feet of BSL-X laboratory space, xx square feet of BSL-X animal space which can house a total of xx mice AND/OR xx rats AND/OR xx rabbits AND/OR xx non-human primates, etc.” Include a description of the Institutional Biosafety Office and name the Responsible Official.

3. Identification and description of ALL support resources (including Information Technology systems) which will be required to effectively complete the SOW.
4. Capabilities in data management, including software programs currently in use. Provide examples of data queries planned or currently being conducted. Provide a description of the oversight and staffing of data management and a plan for communication with technical staff.
5. Procedures for receiving, storing, shipping, and inventory of products, specimens, materials, and reagents in accordance with applicable safety and other regulatory guidelines and standards.

SECTION 6: OTHER CONSIDERATIONS

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) Care of Live Vertebrate Animals

Section L of the RFP specifies the minimum documentation requirements for Animal Welfare compliance. All related documentation should be included in the proposal in a clearly marked section. The Technical Proposal should document all information necessary to evaluate Animal Welfare issues.

2) Biological Agents or Toxins

The Technical Proposal should include a plan for biohazard safety and security requirements.

3) 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.

4) 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.

5) Sharing of Model Organisms for Biomedical Research (Plan)

Section L of the RFP specifies the minimum documentation requirements for Model Organism sharing. All related documentation should be included in the

proposal in this clearly marked section. The Technical Proposal should include a plan for sharing Model Organisms as required by this RFP.

6) 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.

SECTION 7: SAMPLE TASK ORDERS

PART A, SAMPLE TASK ORDER, A-01 DEVELOPMENT OF SMALL ANIMAL MODEL AND METHODS

The activity to be supported under this Sample Task Order is the development of a challenge model in small animals, for possible future refinement into a well characterized model suitable for development of products using the FDA "Animal Rule". As such, all efforts should be well documented and animal endpoints should be relevant to human disease and endpoints. The intent of this Task Order is to provide a better understanding of disease in small animal models and the effects of challenge routes, infectious agent strain and host strain on the course of disease. Offerors must respond with a technical approach directed toward one pathogen of their own choosing, preferably from the list of pathogens in the Statement of Work for Part A.

Develop a small animal model for a specific pathogen of the Offeror's choosing. Provide a justification for the model proposed. The Offeror should propose an appropriate model development program for the pathogen of their choice, using the subtasks listed below as possible guidelines.

Subtask 1. Comparison of disease between species of animals and/or strains of pathogen.

Propose experiments to evaluate disease using appropriate host species/pathogen strain combinations, including median infectious and/or lethal dose and time-to-disease and/or death determinations. Evaluations may include deposition, natural history, innate and adaptive immune response, gross and histopathology and tissue distribution of pathogen, using one route of challenge. Evaluation of mutant strains of pathogen and/or animal may be required.

Subtask 2. Comparison of routes of challenge in animals, when multiple challenge routes are known or suspected in human disease.

Evaluate the disease comparing multiple challenge routes, using one or more informative species/strains as determined in Subtask 1. Determine an appropriate challenge dose that most closely manifests the disease commonly seen in humans. Perform the same evaluations as in Subtask 1.

Subtask 3. Evaluate the suitability of the model selected from Subtasks 1 & 2 to determine the efficacy of products. Assume that the Contractor shall acquire commercially available products for use as a control where possible.

Subtask 4. Prepare a technology transfer package for the model, suitable for replicating the model in another contractor's facility, summarizing the

development and including all the components (assays, protocols, procedures, reagents, etc.) necessary to support future refinement and/or use of the model under GLP.

PART A, SAMPLE TASK ORDER, A-02 SMALL ANIMAL MODEL PRODUCT SCREENING

The activity to be supported under this Sample Task Order is the development and/or utilization of an appropriate small animal challenge model(s) to screen potential candidate products for early efficacy. Studies will be well documented and animal endpoints should be relevant to human disease and endpoints. The intent of this Sample Task Order is to provide a resource to rapidly evaluate new products using standardized small animal models. Assume that products will be provided to the Contractor by the Project Officer or a third party after Project Officer approval. Offerors must respond with a technical approach directed toward at least one specific pathogen of their own choosing, preferably from the list of pathogens in the Statement of Work for Part A.

Provide a well characterized small animal model for the pathogen. Provide a justification for the model proposed for screening the initial efficacy of products against the pathogen.

Describe the throughput for product screening in the proposed model. Assume 10-20 products per year will be tested, which may vary based upon the pathogen being used. Assume data reports will be generated for each product source documenting methods, characterization of challenge material, raw and summary data, and statistical analysis. Assume an annual summary of all products tested and results reported will be a deliverable. Provide a database with all information (provide a description of in-house database) or deposit information into NIAID sponsored database as directed.

Part B, SAMPLE TASK ORDER, B-01 GLP SMALL ANIMAL MODEL

The activity supported under this Sample Task Order is to provide a challenge model and completion of associated animal studies to support use of new products. Offerors must respond with a technical approach directed toward a specific pathogen of their own choosing, preferably from the list of pathogens in the Statement of Work for Part B. Documentation for this project must include final study protocols, raw data, histology data, and final report detailing all findings. Assume that the Project Officer will provide the vaccines and/or therapeutics. Specific studies will be performed in accordance with Good Laboratory Practices (GLP) regulations (21 CFR 58).

Design, develop and execute 5 challenge studies conducted under GLP, using small animal models to support the desired indication for vaccines and/or therapeutics. Provide a justification for the model proposed. The Offeror should propose an appropriate model development program for the pathogen of their choice. Examples of studies include the following:

- Studies to evaluate vaccination in both general and post-exposure prophylaxis indications.

- Studies that demonstrate immunological correlates of protection in animal models and delineation of surrogate markers of protection for vaccine candidates.
- Further characterization of immune responses including CMI responses and evaluation of how these findings correlate with protection.
- Animal efficacy studies on vaccine candidates to support a BLA submission.
- Immunogenicity studies in vaccine candidates to support a BLA submission.
- Development of therapeutic models for the assessment of treatment efficacy, alone or in combination with vaccines or other therapeutics.
- Efficacy studies to support the treatment and/or post-exposure indications for various therapeutic candidates, in support of NDA submission.
- Development, qualification and/or validation of diagnostic or immunologic assays and reagents necessary to support robust animal model development in a product-neutral manner.

Assume that assays and reagents that become integral features of the animal model will be deliverables.

Part C, SAMPLE TASK ORDER C-01 DEVELOPMENT OF A NON-HUMAN PRIMATE MODEL

The activity to be supported under this Sample Task Order is the development of a challenge model in non-human primates, for possible future refinement into a well characterized model suitable for development of products using the FDA “Animal Rule”. As such, all efforts should be well documented and animal endpoints should be relevant to human disease and endpoints. The intent of this Task Order is to provide a better understanding of disease in non-human primates and the effects of challenge routes and species on the course of disease. Offerors must respond with a technical approach directed toward a specific pathogen of their own choosing, preferably from the list of pathogens in the Statement of Work for Part C.

Develop a non-human primate model for a specific pathogen of the Offeror's choosing. Provide a justification for the model proposed. The Offeror should propose an appropriate model development program for the pathogen of their choice, using the subtasks listed below as possible guidelines.

Subtask 1. Comparison of disease between species of non-human primates.
Conduct experiments to evaluate disease in appropriate species of non-human primates, including median infectious and/or lethal dose and time-to-disease and/or death determinations. Evaluations should include deposition, natural history, innate immune response, gross and histopathology and tissue distribution of the pathogen, using one route of challenge.

Subtask 2. Comparison of routes of challenge in animals.
Evaluate the disease comparing multiple challenge routes, using one or more informative species as determined in Subtask 1. Determine an appropriate challenge dose that most closely represents the disease in humans. Perform the same evaluations as in Subtask 1.

Subtask 3. Evaluate the suitability of the model selected from Subtasks 1 & 2 to determine the efficacy of products.

Subtask 4. Prepare a technology transfer package for the model, suitable for replicating the model in another contractor's facility and summarizing the development and including all the components (assays, protocols, procedures, reagents, etc.) necessary to support future refinement and/or use of the model under GLP.

Part C, SAMPLE TASK ORDER, C-02 NON-HUMAN PRIMATE GLP EFFICACY TESTING

The activity to be supported under this Sample Task Order is to provide a non-human primate challenge model and to complete associated studies under GLP to support the use of products. Studies will be well documented and animal endpoints should be relevant to human disease and endpoints. Assume that the Project Officer will provide the candidate products. Offerors must respond with a technical approach directed toward a specific pathogen of their own choosing, preferably from the list of pathogens in the Statement of Work for Part C, and must demonstrate how studies will be performed in accordance with GLP.

Provide a well characterized non-human primate model for the pathogen. Provide a justification for the model proposed for testing efficacy of products.

1) Design, develop and execute 5 challenge studies conducted under GLP using non-human primate models to support the desired indication for vaccines and/or therapeutics. Examples of these studies include, but are not limited to, the following:

- Studies to evaluate vaccination in both general and post-exposure prophylaxis indications.
- Studies that demonstrate immunological correlates of protection in animal models and delineation of surrogate markers of protection for vaccine candidates.
- Further characterization of immune responses including CMI responses and evaluation of how these findings correlate with protection.
- Animal efficacy studies on vaccine candidates to support a BLA submission.
- Immunogenicity studies in vaccine candidates to support a BLA submission.
- Development of therapeutic models for the assessment of treatment efficacy, alone or in combination with vaccines or other therapeutics.
- Efficacy studies to support the treatment and/or post-exposure indications for various therapeutic candidates, in support of NDA submission.
- Development, qualification and/or validation of diagnostic or immunologic assays and reagents necessary to support robust animal model development in a product-neutral manner.

Assume that assays and reagents that become integral features of the animal model will be deliverables.

Part D, SAMPLE TASK ORDER D-01
PRODUCTION OF PATHOGENS AND/OR REAGENTS FROM INFECTED ANIMALS

The activity to be supported under this Sample Task Order is to provide infected animals for the production of microbiological, immunological, genetic, and other reagents required to study a pathogen. Offerors must respond with a technical approach directed toward a specific pathogen of their own choosing, preferably from the list of pathogens in the Statement of Work for Part D. Studies will be well documented in order to support the deposit and distribution of research materials through a centralized repository. All orders for materials will be coordinated through the NIAID repository; live materials will be shipped directly from the producer to the requester, while all other materials possible will be deposited in the central repository for further distribution.

Provide a well characterized animal model for the pathogen. Provide a justification for the model proposed and for the pathogen/reagents produced.

1. Provide master and working banks of pathogens. Characterize the identity, purity, concentration, infectivity, and other critical properties of the infectious agent.
2. As appropriate, maintain various life cycle stages of infectious agent.
3. Infect animals and collect tissues and fluids as required to produce the reagents.
4. Ship products appropriately as follows:
 - a. infected tissues or live pathogens directly to requester
 - b. infected tissues to third party or NIAID repository for further processing
 - c. fully characterized product to NIAID repository for further distribution

Part D, SAMPLE TASK ORDER D-02
DEVELOPMENT AND USE OF A NONTRADITIONAL ANIMAL AS MODEL OF INFECTION

The activity to be supported under this Sample Task Order is to develop and provide an animal model of human disease by infecting nontraditional animals, for the purpose of evaluating candidate products. Studies will be well documented and animal endpoints should be relevant to human disease and endpoints. The intent of this Task Order is to provide a resource to rapidly evaluate new products using standardized animal models. Assume that the Project Officer will provide the candidate products. Offerors must respond with a technical approach directed toward a specific pathogen of their own choosing.

Provide a well characterized animal model for the pathogen. Provide a justification for the model proposed for screening initial efficacy of products the pathogen. Assume five products will be provided each year. Assume data reports will be generated for each product source documenting methods, characterization of challenge material, raw and summary data, and statistical analysis. Assume an annual summary of all products tested and results reported will be a deliverable. Provide a database with all information (provide a description of in-house database) or deposit information into NIAID sponsored database as directed.

**ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS
AND UNIFORM COST ASSUMPTIONS**

**ANIMAL MODELS OF INFECTIOUS DISEASES
RFP-NIH-NIAID-DMID-AI2008041**

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)

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 the proposal in a clearly marked section.

SECTION 3 – UNIFORM COST ASSUMPTIONS

1) Technical Cost Assumptions

The business proposal should be based on the detailed approach to the Sample Task Order proposed, using the numbers of animals proposed and following the guidelines in the Sample Task Order requirements.

Contract Value:

Each contract will have a Minimum Guaranteed Award and a Maximum Potential Value based on Parts awarded, as specified in the table below. The Maximum Potential Value is not guaranteed, but represents the fair opportunity to compete for additional funding through task order awards within the contract pool during the period of performance, up to the Maximum Potential Value.

	Minimum Guaranteed Award	Maximum Potential Value	Full Time Equivalent FTE's
Part A	\$50,000	\$20,000,000	4.85
Part B	\$100,000	\$40,000,000	5.75
Part C	\$150,000	\$60,000,000	7.75
Part D	\$25,000	\$10,000,000	2.15
ALL PARTS	\$325,000	\$130,000,000	20.5

2) Travel

Annual Contractor Meeting: Assume annual meetings in Bethesda, Maryland to present data to other contractors. Assume that this meeting will require a two-night stay and shall be attended by all of the Contractor's key personnel.

General Scientific Meetings: Offerors shall propose a total of \$3,750 annually for the Principal Investigator and selected Contractor staff for travel to general scientific meetings for presentations of work conducted under this contract.

3) Special Shipping and Packaging

Offerors should include a uniform cost assumption of 10 pathogens/reagents per year to be labeled, packaged and shipped.

Offerors should include a uniform assumption of 9 domestic shipments per year. Offerors should include a uniform assumption of 1 international shipment per year.

4) Storage

Offerors should include a uniform assumption of 500 new study specimens to be stored and inventoried each year.

5) Government Furnished Equipment (GFE)

The purchase of Government Furnished Equipment will not be authorized as a direct charge under this contract.

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.

ADDITIONAL RFP SPECIFIC MATERIALS

The below RFP-Specific Materials are applicable to this solicitation.

CURRENT DMID ANIMAL MODEL PROGRAMS

- Aspergillosis:** [RFP-NIH-NIAID-DMID-03-09](#): New Animal Models for: Part A Tuberculosis (TB); and Part B Invasive Aspergillosis (IA)
- Filiariasis:** <http://www.filariasiscenter.org/>: Filariasis Research Resource Center
- Hepatitis:** <http://www.niaid.nih.gov/contract/archive/rfp0512.pdf>: Animal Models for the Prevention and Treatment of Hepatitis B and Hepatitis C
[RFP-NIH-NIAID-DMID-99-19](#): Hepatitis Animal Model Network
- Leprosy** <http://www.niaid.nih.gov/contract/archive/rfp0214.pdf>
Leprosy Research Support and Maintenance of an Armadillo Colony
- Schistosomiasis:** <http://www.schisto-resource.org/>: Schistosomiasis Research Reagent Resource Center
- Sexually Transmitted Infections:** <http://www.niaid.nih.gov/contract/archive/rfp0718.pdf>: Topical Microbicide Safety and Efficacy Evaluation in Non-Human Primates
- Tuberculosis:** [RFP-NIH-NIAID-DMID-04-21](#): Tuberculosis Vaccine Testing and Research Materials
[RFP-NIH-NIAID-DMID-03-09](#): New Animal Models for: Part A Tuberculosis (TB); and Part B Invasive Aspergillosis (IA)
- Viral Diseases:** <http://www.niaid.nih.gov/contract/archive/rfp0103.pdf>: Animal Models of Human Viral Infections for Evaluation of Experimental Therapies
- Biodefense And Emerging Infectious Diseases:** [RFP-NIH-NIAID-DMID-03-39](#), [RFP-NIH-NIAID-DMID-04-40](#): *In Vitro* and Animal Models for Emerging Infectious Diseases and Biodefense

SAMPLE NIAID NON-CLINICAL EVALUATION AGREEMENT

<Insert Submitter's name>, referred to in this Agreement as "Submitter" has requested to participate in one or more of the anti-infective or other non-clinical evaluation programs funded by the Division of Acquired Immunodeficiency Syndrome (DAIDS), the Division of Allergy, Immunology and Transplantation (DAIT), and the Division of Microbiology and Infectious Diseases (DMID), all part of the National Institute of Allergy and Infectious Diseases ("NIAID"), an institute of the National Institutes of Health (NIH), which is a component of the Department of Health and Human Services (HHS), an agency of the U.S. Government. Submitter may request to submit without charge patented or unpatented drugs, compounds or other products ("Material") to NIAID. Through its contract testing laboratories or contract coordinating facilities ("Contractors") and according to the terms and conditions below NIAID may evaluate Material for possible activity against infectious organisms or perform other non-clinical evaluations ("Evaluations"). NIAID and Submitter therefore agree as follows:

1. Submission of Material

- 1.1 NIAID represents that the contracts between NIAID and its Contractors are consistent with the terms of this Agreement.
- 1.2 While Submitter may not select the Contractors to be used, Submitter has the right to decline the use of particular Contractors conducting Evaluations. NIAID has the right to decline to conduct Evaluations of any Material. Submitter understands that not all Evaluations offered by NIAID are available at all times.
- 1.3 With respect to each of the proposed Evaluations, Submitter must complete Appendix A attached to this Agreement which must be mutually agreed to by NIAID and Submitter before such agreed Evaluations will be conducted. Appendix A must include a description of Material to be submitted to NIAID and the specific Evaluations requested by Submitter.
- 1.4 Following concurrence by NIAID, Submitter will forward to Contractors, in accordance with NIAID's directions, Material for Evaluations as listed in Appendix A. In addition Submitter will forward data sheets for each Material which will contain pertinent data as to chemical composition, purity, solubility, toxicity, previous biological efficacy and any precautions that need to be followed in the handling, storing, or shipping of Material.
- 1.5 At Submitter's request and with the prior approval of NIAID, Material to be evaluated may be submitted to Contractors under code. NIAID must be provided with the key to the code and the chemical structures of the encoded material to prevent duplication of evaluations.

2. Evaluations of Material

- 2.1 Protocols used for Evaluations will be approved jointly by NIAID and Submitter.
- 2.2 NIAID will work in conjunction with Contractors to ensure rapid ongoing communication of data and results generated from the Evaluations ("Results") to Submitter, and Submitter will in turn use reasonable efforts to keep NIAID informed of Submitter's own concurrent studies with Material including, but not limited to those that may affect Evaluations, Results or duplication of efforts.

- 2.3 Material will be used by Contractors only for Evaluations as mutually agreed to by Submitter and NIAID and for no other purpose. In addition, the Material will not be chemically modified, replicated, derived or reverse engineered. Upon completion of Evaluations all unused Material will be returned to Submitter, destroyed or otherwise disposed of as directed by Submitter.

3. Confidentiality

- 3.1 Submitter may provide to NIAID or Contractors scientific, business or financial information relevant to Material that Submitter deems to be its proprietary and confidential information ("Confidential Information"). Submitter must identify Confidential Information in writing as confidential. NIAID represents that Contractors are required by the NIAID contracts to protect such Confidential Information in accordance with this Section 3.
- 3.2 To the extent permitted by law, Confidential Information disclosed to NIAID or Contractors will remain confidential for three (3) years from the effective date of this Agreement unless the information:
- a) Is known by the public or becomes known by the public through no fault of the recipient;
 - b) Was obtained by the recipient, without restriction, from a third party having no confidentiality obligation to Submitter;
 - c) Was made available to the recipient by Submitter without a confidentiality obligation, or with prior written authorization for its disclosure;
 - d) Has been independently developed by the recipient without reference to Submitter's information; or
 - e) Is required to be disclosed by law, regulation or court order provided that Submitter has been notified and the recipient has taken reasonable efforts to minimize the extent of the required disclosure.
- 3.3 NIAID will ensure that Confidential Information is kept in restricted-access files. Only personnel directly involved in the Evaluations will have access to the files containing Confidential Information. Submitter acknowledges that Results are not Submitter's Confidential Information and may be disclosed by NIAID and Contractors in accordance with Section 4 below.

4. Publications

- 4.1 NIAID and the Contractors may publish or otherwise publicly disclose Results after a period of four (4) months from the date of transfer of Results to Submitter. This delay in disclosure is intended to allow Submitter time to file patent applications if desired.
- 4.2 Publication of Results earlier than the four (4) month period by NIAID or Contractors will require Submitter's prior written consent, which will not be unreasonably withheld.
- 4.3 Before Submitter or NIAID submit a paper or abstract for publication or otherwise intend to publicly disclose information about Evaluations or Results related to Submitter's Material, such as a press release, NIAID and Submitter will provide the other Party fourteen (14) days to review and comment on the proposed disclosure.
- 4.4 Submitter will not be identified in NIAID or Contractor's publications as the source of Material without Submitter's prior written approval.
- 4.5 Submitter will not construe the involvement of NIAID in Evaluations as an endorsement of Material by the U.S. Government or any of its agencies, employees or

Contractors. Submitter will give appropriate credit for the Evaluations to NIAID, and/or the Contractors.

5. Intellectual Property

- 5.1 Subject to applicable law, Submitter will retain all of Submitter's existing intellectual property rights to Material.
- 5.2 NIAID represents that the contracts between NIAID and the Contractors require the Contractors to assign to Submitter all right, title and interest in and to any new invention made during the Evaluations that contain in whole or in part the Submitter's Material or relate to a new method of use of the Material.

6. No Warranty

Material is experimental in nature. **Submitter makes no representations and extends no warranty of any kind, either expressed or implied, including any warranty of merchantability or fitness for a particular purpose, or warranty that the use of Material will not infringe any patent, copyright, trademark or other proprietary right.**

7. Liability and Indemnification

- 7.1 Submitter disclaims all liability for claims, damages, or liability resulting from its activities under this agreement, unless caused by Submitter's gross negligence or willful misconduct.
- 7.2 No indemnification is provided by either Party under this Agreement. NIAID is prohibited under statute, the Anti-Deficiency Act, 31 U.S.C. § 1341, from indemnifying any party, absent other specific statutory authorization.

8. Governing Law

The construction, validity, performance and effect of this Agreement will be governed by Federal law, as applied by the Federal Courts in the District of Columbia. Federal law and regulations will preempt any conflicting or inconsistent provisions in this Agreement.

9. Duration of Agreement

This Agreement will be in effect for three (3) years from the date of the last signature below.

10. Amendments.

- 10.1 If NIAID or Submitter desires an extension of, or other modification to, this Agreement they will, upon reasonable notice to the other, confer in good faith to determine the desirability of the modification. No modification is effective until a written amendment is signed by authorized representatives of NIAID and Submitter.
- 10.2 If Submitter desires to add Material or Evaluations not originally listed in Appendix A, prior written approval from NIAID is required. All other terms and conditions of this Agreement will remain in full force and effect.

11. Termination

Either NIAID or Submitter may terminate this Agreement at any time by giving written notice at least thirty (30) days prior to the desired termination date.

12. Severability

The illegality or invalidity of any provisions of this Agreement will not impair, affect, or invalidate the other provisions of this Agreement.

13. Survivability

The provisions of Articles 3, 4, 5, 6, 7, 8, 12 and 13 will survive the termination or expiration of this Agreement.

SIGNATURES BEGIN ON NEXT PAGE

Accepted and agreed by the Parties through their duly authorized representatives as of the last date of signature below.

FOR NIAID:

Director, DMID, NIAID, NIH
Ph: _____
Fax: _____
Date: _____

FOR SUBMITTER:

Name: _____
Title: _____
Organization: _____
Address: _____
Phone/Fax: _____
Date: _____

SUBMITTER POINTS OF CONTACT:

Submitter Agreement POC

Name: _____
Title: _____
Organization: _____
Street/Bldg: _____
City: _____ State: _____ Zip: _____
Phone: _____
Fax: _____
Email: _____

Submitter Scientific POC

Name: _____
Title: _____
Organization: _____
Street/Bldg: _____
City: _____ State: _____ Zip: _____
Phone: _____
Fax: _____
Email: _____