

U.S. Department of Health and Human Services  
National Institutes of Health  
National Institute of Allergy and Infectious Diseases (NIAID)

**RFP-NIH-NIAID-DAIDS-08-09**

**“NON-HUMAN PRIMATE MODELS TO EVALUATE THERAPEUTIC STRATEGIES AND TOPICAL MICROBICIDES FOR HIV”**

OMB Control Number 0990-0115

1. <b>OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.</b> <a href="http://www.fedbizopps.gov/">http://www.fedbizopps.gov/</a>		
2. <b>SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1</b> <b>NOTE: The issuance of this solicitation does not commit the government to an award.</b>		
3. <b>Issue Date:</b>  May 10, 2007	4. <b>Due Date:</b> July 30, 2007  <b>Time:</b> 4:00 P.M., Local Time	5. <b>Small Bus. Set-Aside:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <b>8(a) Set-Aside:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <b>NAICS: 541710</b> (See Part IV, Section L.)
6. <b>Just In Time:</b> <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes (See Part IV, Section L.)		
7. <b>Number of Awards:</b> <input type="checkbox"/> Only 1 Award <input checked="" type="checkbox"/> Multiple Awards		
8. <b>Technical Proposal Page Limits:</b> <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes (See Section J, Attachment 1, Packaging and Delivery of Proposal)		
9. <b>Issued By:</b> Anita Hughes Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612		
10. <input checked="" type="checkbox"/> NIAID reserves the right to make awards without discussion.		
11. <b>Options:</b> <input type="checkbox"/> No <input checked="" type="checkbox"/> Yes (See Part IV, Section L.)		
12. <b>Period of Performance:</b> <input checked="" type="checkbox"/> March 28, 2008 – March 27, 2013, with two one- year option periods		
13. <b>Primary Point of Contact:</b> <b>Name :</b> Anita Hughes <b>Phone:</b> 301- 496-0612 <b>Fax:</b> 301-402-0972 <b>E-Mail:</b> <a href="mailto:anhughes@niaid.nih.gov">anhughes@niaid.nih.gov</a>	14. <b>Secondary Point of Contact:</b> <b>Name:</b> Eileen Webster-Cissel <b>Phone:</b> 301-496-0612 <b>Fax:</b> 301-402-0972 <b>E-Mail:</b> <a href="mailto:webstere@niaid.nih.gov">webstere@niaid.nih.gov</a>	15. <b>Protest Officer:</b> Charles Grewe Director, OA <b>Address (see Block 9.)</b>
16. COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.		
17. <b>Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled “Proposal Summary and Data Record, NIH-2043” (See Part III, SECTION J – Attachments)</b>		
<b>18. DELIVERY ADDRESS INFORMATION</b>		
19. <b>Hand Delivery or Overnight Service:</b> Anita Hughes, Contract Specialist Office of Acquisitions DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817		20. U.S. Postal Service or an Express Delivery Service Anita Hughes, Contract Specialist Office of Acquisitions DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612
21. The <b>Official Point of Receipt</b> for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with FAR 15.208 entitled "Submission, Modification, Revision, and Withdrawal of Proposals." <b>FACSIMILE AND E-MAIL SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.</b>		

Updated thru FAC 2005-14 (11/22/2006)

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## PART I - THE SCHEDULE

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 purpose of this contract is to provide the scientific expertise, materials, equipment, and housing facilities in order to evaluate therapeutic agents/strategies for the treatment of HIV/AIDS and evaluate topical microbicides for the prevention of HIV/AIDS using SIV/SHIV macaque animal models.

#### 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.

##### a. Confidentiality of Information

Information and data provided to or generated by the Contractor under this contract shall be treated confidentially and protected by an Advance Understanding to be included in the resulting contract and worded as follows:

"Because there is a likelihood that the Contractor will be utilizing and evaluating materials provided to the Government by a third party Provider, it is essential to include provisions that will protect the proprietary rights of the Provider. These materials generally are supplied to the Government as proprietary and confidential. The Contractor shall be bound by the same terms and conditions as the Government in these agreements, with respect to the proprietary and confidential nature of the information provided by the Provider.

All information provided by the Provider or Project Officer shall be assumed to be confidential unless specifically identified as non-confidential in writing by the Project Officer. Confidential information may not be revealed without written permission. All materials supplied to the Contractor and all test results similarly are to be considered confidential. All materials supplied to the Contractor shall be utilized solely for contract-related research purposes and no unauthorized use or distribution of these materials will be permitted.

Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted for review and written approval by the Project Officer before submission for public presentation or publication. Contract support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information. The Project Officer will review all manuscripts/abstracts in a period of time not to exceed 20 calendar days from receipt, and will either grant clearance for publication/disclosure, recommend changes or, as applicable, refer the document to the Provider of the drug substance for their review. When the Provider does not consent to publication of the manuscript or abstract, the Project Officer shall withhold approval to publish in accordance with the terms and conditions of any existing Evaluation Agreement or Material Transfer Agreement between NIAID and the Provider. NIAID will use its best efforts to assist and expedite the review and approval process by the Provider."

**b. Intellectual Property**

Contractors acknowledge that:

\* If needed for the project, Contractor is solely responsible for the timely acquisition of any proprietary rights, including intellectual property rights, and all materials appropriate for Contractor to perform the project;

\* Contractor acknowledges that prior to, during, and subsequent to the award, the U.S. Government is not required to obtain for Contractor any proprietary rights, including intellectual property rights, or any materials needed by Contractor to perform the project;

\* Contractor acknowledges the requirement to report to the U.S. Government all inventions made in the performance of the project, as specified at 35 U.S.C. Sect. 202 (Bayh-Dole Act).

Contractor is encouraged to reach early consensus with any proposed partners regarding any appropriate intellectual property or other legal issues that may arise during the project. In addition, Contractors are expected to exercise their Bayh-Dole rights in a manner that does not conflict with the goals of this award or the intent of the Bayh-Dole Act to promote the utilization, commercialization and availability of U.S. Government-funded inventions for public benefit. Finally, Contractor is expected to make new information and materials known to the research community in a timely manner through publications, web announcements, and reports to the NIAID or other mechanisms consistent with laws, regulations, and NIH policies.

Shall patents arise from this contract, they will be subject to laws governing federally funded inventions. The Government retains, for government purposes, a non-exclusive, irrevocable, paid-up license to federally funded inventions.

## **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 3/14/2007, attached hereto and made a part of this Solicitation (See SECTION J - List of Attachments).

### **ARTICLE C.2. REPORTING REQUIREMENTS**

a. **Technical Progress Reports**

1. In addition to the required reports set forth elsewhere in the Technical Report Delivery 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.

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

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

(b) Format of Cover Page: All reports, unless otherwise indicated shall include a Cover Page prepared in accordance with the following format:

- Contract Number and Project Title
- Contractor's Name and Address
- Author(s)
- Date of Submission
- Delivery Address
- Reporting Period
- Summary

## 1. **Annual Progress Report**

The Annual Progress Report shall describe in detail the work conducted during one calendar year and the activities planned for the ensuing reporting period. Reports are due seven (7) calendar days before the anniversary date of the contract. The Annual Progress Report shall include the following sections:

- a. **Cover page:** Format for the cover page is provided at paragraph a.1.(b) above.
- b. **Table of Contents**
- c. **Studies in Progress:** For each ongoing study this shall include the final version of the Study Design, a list of changes/modifications that occurred during the conduct of the study that differ from the Study Design, and a display of data in table and figure form, as appropriate.
- d. **Studies Planned:** For each study in the planning stage this shall include the latest version of the Study Design.
- e. **Technical and Administrative Problems Encountered:** This section shall describe all technical and administrative problems encountered over the past year and their resolution or proposed corrective action.
- f. **Cumulative List of Drugs/Therapies and Topical Microbicides Studied:** For each drug/therapy and topical microbicide studied, the list shall include the study identification number and title, the dates the study was conducted, the name(s) of the drug/therapy and/or topical microbicide evaluated, and a description of the study in no more than 150 words.
- g. **Cumulative List of Published Articles, Oral, and Abstract Presentations:** For each publication the list shall include the study identification number, the study title and abstract section, if available, and the publication reference.

## 2. **Study Report**

After the completion of each study a Study Report shall be prepared that describes the completed study in detail. The Study Report shall be submitted to the Project Officer 60 calendar days after completion of the study for approval. The Study Report shall be written in the format of a scientific paper and shall include the following sections:

- a. **Cover Page:** This section shall list the contract number and title, the study identification number and title, start and completion dates of the study, and the submission date of the report.
- b. **Table of Contents**
- c. **Abstract**
- d. **Introduction**
- e. **Materials and Methods**
- f. **Results**
- g. **Discussion**
- h. **Supplemental Material**

### 3. **Monthly Animal Inventory Report**

The Animal Inventory Report shall describe the status of every animal supported by the contract and shall be submitted to the Project Officer on the last business day of each month. The Animal Inventory Report shall include:

- a. The study identification number, if applicable, and the animal identification number for each animal
- b. Species, date of purchase, origin, sex, current age, and current weight for each animal
- c. Infection status, the strain of SIV/SHIV used, the route of infection, and the date of infection, when applicable
- d. Health status of each animal in less than 20 words

### 4. **Subcontractor/Consultant Report**

In the event contract-supported activities are subcontracted to a third party or the Contractor utilizes the services of a consultant, the Contractor shall provide the Project Officer with the original subcontractor/consultant reports within seven (7) calendar days after the Contractor receives the report(s).

### 5. **Final Report**

The Final Report shall summarize all work performed and results obtained for the entire contract period of performance. The Final Report is due 30 calendar days prior to the completion date of the contract performance period. This Report shall include:

- a. **Cover Page:** This section shall list the contract number and title, period of performance being reported, Contractor's name and address, author(s), date of submission, and delivery address.
- b. **Table of Contents**
- c. **Studies Completed:** This section shall include a list of the study identification numbers and titles of all completed studies.
- d. **Studies Ongoing:** This section shall include a list of the study identification numbers and titles for all ongoing studies. For each ongoing study it shall include the final version of the Study Design and a display of summary data in table and figure form, if applicable.
- e. **Cumulative List of Drugs/Therapies and Topical Microbicides Studied:** The list shall include for each drug/therapy and topical microbicide studied, the study identification number and title, the dates the study was conducted, the name(s) of the drug/therapy and/or topical microbicide evaluated, and a description of the study in no more than 150 words.
- f. **Cumulative List of Published Articles, Oral, and Abstract Presentations:** The list shall include, for each publication, the study identification number, the study title and abstract section, if available, and the publication reference.

### 6. **Summary of Salient Results**

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

**b. Other Reports/Deliverables**

In addition to the above reports, other reports and deliverables are identified in the Statement of Work (see Attachment 3). A listing is included in Article F.2., Deliveries.

- (1) Study Design (see Statement of Work (SOW), paragraph 3.)
- (2) Initial and Final Transition Plan (see SOW, paragraphs 16.a. and b.)
- (3) Draft and Final Transition Plan (see SOW, paragraph 16.b.)
- (4) Standard Operating Procedures (SOPs) and Experimental Protocols (see SOW, paragraph 9.)
- (5) Presentations at Scientific Meetings (see SOW, paragraph 10.c.)
- (6) Manuscripts (see SOW, paragraph 10.d.)
- (7) Data Collection, Management, and Quality Control (see SOW, paragraphs 11.a. and b.)
- (8) Summary of Action Items (see SOW, paragraph 15.b.)
- (9) Animal, Procurement, Testing, and Maintenance (see SOW, paragraph 1.)
- (10) Receipt, Storage, Shipment, and Inventory of Contract Resources (see SOW, paragraph 12.)

**ARTICLE C.3. INVENTION REPORTING REQUIREMENT**

All reports and documentation required by [FAR Clause 52.227-11/FAR Clause 52.227-11 (Deviation)/FAR Clause 52.227-13] 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(a)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be due on or before \_\_\_\_\_. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer  
Office of Acquisitions  
Division of Extramural Activities (DEA)  
National Institute of Allergy and Infectious Diseases (NIAID)  
National Institutes of Health (NIH)  
6700-B Rockledge Drive, Room 3214, MSC 7612  
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 the National Institute of Allergies and Infectious Diseases, NIH, Bethesda, Maryland.
- 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 **52.246-5, Inspection of Research and Development (Short Form)** (April 1984).

**SECTION F - DELIVERIES OR PERFORMANCE**

**ARTICLE F.1. PERIOD OF PERFORMANCE**

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

<b>Option</b>	<b>Option Period</b>
1	March 28, 2013 through March 27, 2014
2	March 28, 2014 through March 27, 2015

**ARTICLE F. 2. DELIVERIES**

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Article C.1. of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

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

<b>Item</b>	<b>Type of Report</b>	<b>Delivery Schedule</b>	<b>Recipient &amp; Number of Electronic and Hard Copies</b>
1.	Annual Progress Report	Annually, 7 calendar days before anniversary date of the contract	1 electronic copy to PO 1 hard copy to CO
2.	Study Report	As required, 60 calendar days after the completion of a study	1 electronic copy to PO
3.	Monthly Animal Inventory Report	Monthly, on the last business day of each month	1 electronic copy to PO
4.	Subcontractor/Consultant Report	As required, 7 calendar days after the report is submitted by the subcontractor/consultant to the Contractor	1 electronic copy to PO
5.	Final Report	30 calendar days prior to the completion date of the contract	1 electronic copy to PO 1 hard copy to CO
6.	Summary of Salient Results	The Summary of Salient Results shall be submitted with the Final Report.	1 electronic copy to PO and CO; 1 hard copy to CO

b. Other Reports and Deliverables

<b>Item</b>	<b>Type of Report</b>	<b>SOW Reference</b>	<b>Delivery Schedule</b>	<b>Recipient &amp; Number of Hard &amp; Electronic Copies</b>
1.	Study Design	Paragraph 3.	15 calendar days after PO's request	1 electronic copy to PO
2.	Initial Transition Plan	Paragraph 16.a.	14 calendar days after contract award	1 electronic copy to PO
3.	DRAFT Final Transition Plan	Paragraph 16.b.	6 months before the expiration date of the contract	1 electronic copy to PO
4.	Final Transition Plan	Paragraph 16.b.	2 months before the expiration date of the contract	1 electronic copy to PO and CO
5.	Standard Operating Procedures and Experimental Protocols	Paragraph 9.	7 calendar days after PO's request	1 electronic copy to the PO
6.	Presentations at Scientific Meetings	Paragraph 10.c.	7 calendar days before the submission date of a scientific meeting (abstracts) and 7 calendar days before the first day of the conference (slide presentations and posters)	1 electronic copy to the PO
7.	Manuscripts	Paragraph 10.d.	90 calendar days after PO's request	1 electronic copy to the PO
8.	Data Collection, Management, and Quality Control	Paragraph 11.a. and 11.b.	7 calendar days after PO's request	1 electronic copy to the PO
9.	Summary of Action Items	Paragraph 15.b.	48 hrs. after weekly teleconferences and site visit	1 electronic copy to the PO
10.	Animal Procurement, Testing, and Maintenance	Paragraph 1.	As requested by the PO. To be specified 30 calendar days prior to contract completion	The Government or its designee
11.	Receipt, Storage, Shipment, and Inventory of Contract Resources	Paragraph 12.	To be specified 30 calendar days prior to contract completion	The Government or its designee

c. The above items shall be addressed and delivered to:

<b>Addressee</b>	<b>Deliverable Item No.</b>	<b>Quantity</b>
Contracting Officer Office of Acquisitions (OA) Division of Extramural Activities (DEA) National Institute of Allergy and Infectious Diseases (NIAID) National Institute of Health (NIH) 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612 Email: To be determined at time of contract award	See above delivery schedule	See above delivery schedule

Project Officer Targeted Interventions Branch, Basic Sciences Program Division of Acquired Immunodeficiency Syndrome (DAIDS) National Institute of Allergy and Infectious Diseases (NIAID) National Institute of Health (NIH) 6700-B Rockledge Drive, Room 4155, MSC 7626 Bethesda, Maryland 20892-7626 Email: To be determined at time of contract award	See above delivery schedule	See above delivery schedule
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- d. Unless otherwise specified, deliveries shall be made to the Delivery Point specified above Mondays through Fridays (excluding Federal Holidays) between the hours of 8:30 a.m. and 5:00 p.m. EST only. Supplies or services scheduled for delivery on a Federal holiday shall be made the following day.

**ARTICLE F.3. 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 prior to award]

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**

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

NAME	TITLE
[To be specified prior to award]	

**ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST**

a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

(1) Invoices/financing requests shall be submitted as follows:

(a) To be considered a "proper" invoice in accordance with FAR 32.9, Prompt Payment, each invoice shall clearly identify the two contract numbers that appear on the face page of the contract as follows:

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN261200411000C.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand corner of the SF-26, i.e. N01-CO-41234.)

(b) An original and two copies to the following designated billing office:

Contracting Officer  
Office of Acquisitions (OA)  
Division of Extramural Activities (DEA)  
National Institute of Allergies and Infectious Diseases, NIAID  
National Institutes of Health (NIH)  
6700-B Rockledge Drive, Room 3214, MSC 7612  
Bethesda, MD 20892-7612

(2) Inquiries regarding payment of invoices should be directed to the designated billing office, (301) 496-0612.

**ARTICLE G.4. INDIRECT COST RATES** *(applies to contracts with commercial organizations only)*

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.5. 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.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

### **a. Contractor Performance Evaluations**

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with 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 performed.

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 GeneTransfer 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 May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules ( <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.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](http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836))

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

- a. Pursuant to Public Law(s) cited in paragraph b. , below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used 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.

- b. **Public Law and Section No.**                      **Fiscal Year**                      **Period Covered**

[Applicable information to be included at award]

### ARTICLE H.4. NEEDLE EXCHANGE

- a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

- b. **Public Law and Section No.**                      **Fiscal Year**                      **Period Covered**

[Applicable information to be included at award]

### ARTICLE H.5. PRESS RELEASES

- a. Pursuant to Public Law(s) cited in paragraph b., below, 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.

- b. **Public Law and Section No.**                      **Fiscal Year**                      **Period Covered**

[Applicable information to be included at award]

### ARTICLE H.6. ANTI-LOBBYING

- a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.
- b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c. **Public Law and Section No.**                      **Fiscal Year**                      **Period Covered**

[Applicable information to be included at award]

**ARTICLE H.7. 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.8. 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.9. OPTION PROVISION**

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to clause 52.217-\_\_ set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost plus fixed fee Article in SECTION B of this contract.

**ARTICLE H.10. SUBCONTRACTING PROVISIONS**

**a. Small Business Subcontracting Plan**

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

**b. Subcontracting Reports**

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

- (1) Individual Subcontract Reports (ISR)

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

April 30th  
October 30th

- (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 30<sup>th</sup>

For both the Individual and Summary Subcontract Reports, the [Contracting Officer/Contract Specialist/or title of alternate designee] shall be included as a contact for notification purposes at the following e-mail address:

[e-mail address of Contracting Officer/Contract Specialist will be provided upon award]

#### ARTICLE H.11. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. 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 per year 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. Public Law and Section No.*	Fiscal Year*	Dollar Amount of Salary Limitation*
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[\*Applicable information to be included at award]

c. Payment of direct salaries is limited to the Executive Level rate which was in effect on the date(s) the expense was incurred.

#### ARTICLE H.12. 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. \_\_\_\_\_."

#### ARTICLE H.13. 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](mailto: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.14. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

The Policy requests that beginning May 2, 2005, NIH-funded investigators 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://publicaccess.nih.gov> .

## **ARTICLE H.15. 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.

## **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:

#### **General Clauses for a Cost-Reimbursement Research and Development Contract and Education Institutions**

The complete listing of these clauses may be accessed at:  
<http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clauses.jsp>

#### **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:

ARTICLE I.1. of this SECTION is hereby modified as follows:

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.

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.

Alternate II (October 2001) of FAR Clause 52.219-9, Small Business Subcontracting Plan (September 2006) is added.

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 this contract 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 52.217-2, Cancellation Under Multiyear Contracts (July 1996).

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

"(a) The Government may extend the term of this contract by written notice to the Contractor within [INSERT THE PERIOD OF TIME WITHIN WHICH THE CONTRACTING OFFICER MAY EXERCISE THE OPTION]; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least \_\_\_ days [60 days unless a different number of days is inserted] before the contract expires. The preliminary notice does not commit the Government to an extension."

(b) The total duration of this contract, including the exercise of any options under this clause, shall not exceed \_\_\_ [MONTHS/YEARS]."

(3) 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."

(4) FAR Clause 52.219-25, Small Disadvantaged Business Participation Program—Disadvantaged Status and Reporting (October 1999).

(5) FAR Clause 52.227-14, Rights in Data - General (June 1987).

(6) Alternate V (June 1987), FAR Clause 52.227-14, Rights in Data--General (June 1987). Specific data items that are not subject to paragraph (j) include

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

(8) FAR Clause 52.227-17, Rights in Data--Special Works (June 1987).

(9) FAR Clause 52.230-2, Cost Accounting Standards (April 1998).

(11) FAR Clause 52.230-3, Disclosure and Consistency of Cost Accounting Practices (April 1998).

(12) FAR Clause 52.230-5, Cost Accounting Standards – Educational Institution (August 1992).

(13) FAR Clause 52.230-6, Administration of Cost Accounting Standards (April 2005).

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

(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.

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

(1) HHSAR Clause 352.224-70, Confidentiality of Information (January 2006).

(2) HHSAR Clause 352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities (January 2001).

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 52.222-39, 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.nlr.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 20210, 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.

## PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

### SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 1	Packaging and Delivery of Proposal	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	Material Evaluation Agreement	See Attachment Section at the end of the RFP

**TECHNICAL PROPOSAL ATTACHMENTS:** (The following attachments must be completed, where applicable, and submitted with the Technical Proposal. They can be found at the electronic weblinks provided below and are, therefore not included as Attachments to the RFP.)

<b>Title</b>	<b>Location</b>
Technical Proposal Cost Summary	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Summary of Related Activities	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Government Notice for Handling Proposals	<a href="http://www.niaid.nih.gov/contract/forms/form7.pdf">http://www.niaid.nih.gov/contract/forms/form7.pdf</a>
Project Objectives, NIH 1688-1	<a href="http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf">http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf</a>

**BUSINESS PROPOSAL ATTACHMENTS:** (The following attachments must be completed, where applicable, and submitted with the Business Proposal. They can be found at the electronic weblinks provided below and are, therefore not included as Attachments to this RFP.)

<b>Title</b>	<b>Location</b>
Proposal Summary and Data Record, NIH-2043	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Small Business Subcontracting Plan	<a href="http://rcb.cancer.gov/rcb-internet/forms/forms.htm">http://rcb.cancer.gov/rcb-internet/forms/forms.htm</a>
Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	<a href="http://oamp.od.nih.gov/contracts/BUSCOST.HTM">http://oamp.od.nih.gov/contracts/BUSCOST.HTM</a> <a href="http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls">http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls</a>
Offeror's Points of Contact	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="http://rcb.cancer.gov/rcb-internet/forms/forms.htm">http://rcb.cancer.gov/rcb-internet/forms/forms.htm</a>

**INFORMATIONAL ATTACHMENTS:** (The following Attachments and Reports will become part of any contract resulting from this RFP and will be required during contract performance. They can be found at the electronic weblinks provided below and are, therefore not included as Attachments to this RFP.)

<b>Title</b>	<b>Location</b>
Invoice/Financing Request Instructions--Cost-Reimbursement, NIH(RC)-1	<a href="http://rcb.cancer.gov/rcb-internet/forms/forms.htm">http://rcb.cancer.gov/rcb-internet/forms/forms.htm</a>
Procurement of Certain Equipment, NIH(RC)-7	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>

## 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 2004)]

(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. **"JUST IN TIME"**

This RFP contains special procedures for the submission of business management proposals. These special procedures are designed to reduce the administrative burden on offerors without compromising the information during the initial evaluation of proposals. Certain documents will not longer be required to be submitted with initial proposals, but will be requested at a later stage in the competitive process. Specifically, the travel policy, the annual financial statement, the total compensation plan, the subcontracting plan, and certain types of cost/pricing information will only be required to be submitted from those offerors included in the competitive range, or the apparent successful offeror. The special procedures for submission of this documentation are set forth in detail below:

**Travel Policy.** The offeror's (and any proposed subcontractor's) written travel policy shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a travel policy as a part of their final proposal revision.

**Annual Report.** The offeror's most recent annual report shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required submit a copy of their most recent annual report as a part of their final proposal revision.

**Total Compensation Plan.** The offeror's total compensation plan shall **not** be submitted with the initial business proposal. All offerors included in the competitive range will be required to submit a total compensation plan as a part of their final proposal revision.

**Subcontracting Plan.** The offeror's Small Business Subcontracting Plan shall **not** be submitted with the initial business proposal. Only those offerors included in the competitive range will be required to submit **an acceptable** subcontracting plan.

**Cost/Pricing Information.** The offeror's business proposal shall include the basic cost /pricing information specified in Section L.2.c.(1) of this RFP. In addition, the Government may require offerors included in the competitive range to submit additional information substantiating their proposed costs or prices. This additional cost/pricing information will be requested after establishment of the competitive range, and potentially includes payroll documentation, vendor quotes, invoice prices, and/or any other information deemed necessary by the contracting officer to evaluate the reasonableness of the price or to determine cost realism.

**c. NAICS CODE AND SIZE STANDARD**

Note: The following information is to be used by the offeror in preparing its Representations and Certifications (See Section K of this 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 54170.
- (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 (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.**

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

It is anticipated that 1 to 2 awards will be made from this solicitation and that the award(s) will be made on/about March 28, 2008.

It is anticipated that the award(s) from this solicitation will be a multiple-year cost reimbursement type contract, completion with a term of five years and two, one year option periods, and that incremental funding will be used (see Section L.2.c. Business Proposal Instructions).

**e. ESTIMATE OF EFFORT**

It is expected that a completion type contract 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 seven (7) full time equivalents. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

**f. COMMITMENT OF PUBLIC FUNDS**

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

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

h. **RELEASE OF INFORMATION**

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

i. **COMPARATIVE IMPORTANCE OF PROPOSALS**

You are advised that paramount consideration shall be given to the evaluation of technical proposals. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. The relative importance of the evaluation factors are specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

j. **PREPARATION COSTS**

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

k. **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:

Charles Grewe  
Director, Office of Acquisitions  
Division of Extramural Activities  
National Institute of Allergies and Infectious Diseases, NIH  
6700-B Rockledge Drive, Room 3214, 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)

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

#### (2) **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, 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 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) **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 procurement, 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.

(8) **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 General Accounting 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.

(9) **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. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.
- 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.

(10) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

**EACH INSTITUTION MUST:**

- (a) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.
- (b) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.
- (c) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children):
  - (i) that would reasonably appear to be affected by the research for which the NIH funding is sought;
  - and (ii) in entities whose financial interests would reasonably appear to be affected by the research.All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.
- (d) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.
- (e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.
- (f) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.
- (g) Certify, in each application/proposal for funding to which the regulations applies, that:
  - 1) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;
  - 2) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;
  - 3) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and
  - 4) the Institution will otherwise comply with the regulations.

## **Institutional Management of Conflicting Interests**

- (a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **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.**

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

- (i) public disclosure of significant financial interests;
  - (ii) monitoring of research by independent reviewers;
  - (iii) modification of the research plan;
  - (iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
  - (v) divestiture of significant financial interests; or
  - (vi) severance of relationships that create actual or potential conflicts of interests.
- (b) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

### **(11) 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.

### **(12) Past Performance Information**

- a) Offerors shall submit the following information as part of their [business/technical] proposal.

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

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement

6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial 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.

(13) **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 Clause 52.204-6 (October 2003).
- b) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997)
- c) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- d) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).\

**b. TECHNICAL PROPOSAL INSTRUCTIONS**

**NOTE: Offerors are advised to also refer to the information included in Attachment 4, "Additional Technical Proposal Instructions" when preparing their Technical Proposal.**

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.

**1. Technical Discussions**

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

**a) Project Objectives, NIH-1688-1**

The offeror shall insert a completed NIH Form 1688-1, Project Objective, as provided in Section J, Attachments, behind the Title Page of each copy of the proposal, along with the "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

- For an **Institution of Higher Education**: The form MUST be completed in its entirety.
- For **OTHER** than an Institution of Higher Education: The starred items (Department, Service, Laboratory or Equivalent, and Major Subdivision) should be left blank.

The information required under the "Summary of Objectives" portion of the form MUST meet the requirements set forth in the section of the form entitled, "**INSTRUCTIONS:**"

b) **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

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.

c) **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. Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in SECTION M - Evaluation Factors for Award of this solicitation.

**3. Additional Technical Proposal Information**

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

**4. 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.

**5. Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)**

Recombinant DNA Molecules are either 1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or 2) DNA molecules that result from the replication of those described in 1).

The NIH Guidelines for Research Involving Recombinant DNA Molecules at: (<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html> and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules at: (<http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html> )

and any subsequent revisions to the Guide Notice) 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 NIH 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 NIH funding for any work related to Recombinant DNA Research or a requirement for the contracting officer's prior approval of any or all Recombinant DNA projects under any contract awarded from this solicitation. 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, at: ([http://www4.od.nih.gov/oba/rac/guidelines\\_02/Appendix\\_M.htm#\\_Toc7255836](http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836) ).

**6. 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)

- 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.

**c. BUSINESS PROPOSAL INSTRUCTIONS**

**NOTE: Offerors are also advised to also refer to the information included in Attachment 5, "Additional Business Proposal Instructions and Uniform Budget Assumptions" when preparing their Business Proposal.**

**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.

***This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.***

### **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 rational 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 \$650,000, 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 proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

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 2007

Offerors are advised that pursuant to P.L. 110-005\*\*, no NIH Fiscal Year 2006 (October 1, 2006 - September 30, 2007) 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. 110-005\*\* applies only to Fiscal Year 2007 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. 110-005\*\* 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/oaca/07tables/html/ex.asp>

**\*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 2007 Executive Level I Salary rates.

*\*\*Public Law 110-005, Revised Continuing Appropriations Resolution, 2007, extends the legislative provisions provided in the FY 2006 Appropriations Act (Public Law 109-149) through the end of FY 2007. Therefore, the provision that restricts the amount of direct salary to Executive Level I of the Federal Executive Pay Scale continues through FY 2007. The Executive Level I annual salary rate was \$183,500 for the period January 1 through December 31, 2006. Effective January 1, 2007, the Executive Level I salary rate increased to \$186,600.*

## 6) Small Business Subcontracting Plan

***This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.***

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 (SF 294 and SF 295) 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 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.

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**

***This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.***

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

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

***This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.***

**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 will submit, as a part of their business proposal, 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) 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.

**11) Other Administrative Data**

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:

- (a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.
- (b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

(2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.

(3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

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.

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.*

**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**

***NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.***

All offerors included in the competitive range will be required to submit a copy of the organization's most recent annual financial report.

**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**

***NOTE: This document is INCLUDED in the "Just In Time" procedures. Specific instructions for the submission of this document are outlined in SECTION L.1. of this RFP.***

All offerors included within the competitive range will be required to submit one copy of their written travel policy. A written travel policy for any proposed subcontractors shall also be submitted at that time. If an offeror (or any proposed subcontractor) does not have a written travel policy, the offeror shall so state.

## SECTION M - EVALUATION FACTORS FOR AWARD

### A. 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 or price. In any case, 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.

### B. EVALUATION OF OPTIONS

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

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

### C. 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. The information under each evaluation criteria is of equal importance.

#### TECHNICAL EVALUATION CRITERIA

#### WEIGHT

##### **CRITERION 1: PERSONNEL**

**40 points**

a. Principal Investigator (20 points)

Appropriateness, adequacy, and relevance of the documented experience, education, expertise, training, availability, and leadership in:

- 1) Planning, directing, and coordinating the conduct of SIV/SHIV macaque studies
- 2) The conduct, analysis, and interpretation of immunology and virology assays required to perform the Statement of Work
- 3) Performance of *in vitro* assays for efficacy and cytotoxicity in human and appropriate non-human primate PBMC
- 4) Providing technical assistance to, and oversight of, technical personnel engaged in the conduct of studies

b. Veterinarian/Clinical and Anatomic Pathologist (15 points)

Appropriateness, adequacy, and relevance of the documented experience, education, expertise, training, availability, and leadership in:

- 1) The care of uninfected and SIV/SHIV-infected macaques

- 2) The monitoring and evaluation of the clinical status of animals required to perform the Statement of Work
  - 3) Performing pathology/histopathology evaluations
  - 4) Performing intra-vaginal, intra-rectal, and intravenous challenges with SIV/SHIV, and surgical procedures such as vaginal and rectal pinch biopsies, lymph node biopsies, and post-mortem evaluations
  - 5) Providing technical assistance to, and oversight of, veterinary technical personnel engaged in the conduct of studies
- c. Other Scientific and Technical Personnel (5 points)
- Appropriateness, adequacy, and relevance of the documented experience, education, expertise, availability, and training of other proposed scientific and technical personnel of the Offeror and all proposed subcontractors in:
- 1) The conduct of SIV/SHIV macaque studies
  - 2) The immunology and virology assays required to perform the Statement of Work
  - 3) The care of uninfected and SIV/SHIV infected macaques
  - 4) The monitoring of the clinical status of animals related to performing the requirements of the Statement of Work

**CRITERION 2: TECHNICAL APPROACH**

**40 points**

- a. Immunology and Virology Assays (15 points)
- Soundness, adequacy, and strength of the proposed methodologies, technical approaches and procedures, and technical understanding required to perform, analyze, and interpret the immunology and virology assays required for:
- 1) The evaluation of therapeutic agents/strategies and topical microbicides in the SIV/SHIV macaque animal models
  - 2) The development of novel and improvement of existing SIV/SHIV macaque animal models
  - 3) The *in vitro* evaluation of efficacy and cytotoxicity of therapeutic agents and microbicides in human and non-human PBMCs
- b. Animal Procurement, Testing, Maintenance; Animal Challenge and Treatment (15 points)
- Soundness, adequacy, and strength of the proposed methodologies, technical approaches and procedures, and technical understanding required to:
- 1) Perform animal testing and maintenance
  - 2) Perform animal challenge with SIV/SHIV by different routes
  - 3) Perform animal treatment with drugs and therapies by different routes
  - 4) Perform application of vaginal and rectal microbicides
  - 5) Procure non-human primates free of TB, STLV, ARV, and SIV

**c. Animal Care and Monitoring/Clinical Observations (10 points)**

Soundness, adequacy, and strength of the proposed methodologies, technical approaches and procedures, and technical understanding required to provide animal care, and monitoring and technical understanding required to perform, analyze, and interpret clinical observations of, and toxicities in animals as they relate to:

- 1) Novel therapeutic agents/strategies
- 2) Anti-retroviral agents
- 3) Topical microbicides
- 4) SIV/macaque and SHIV/macaque animal model development
- 5) Performance of pathology/histopathology evaluations

**CRITERION 3: PROJECT MANAGEMENT; DATA COLLECTION, MANAGEMENT AND QUALITY CONTROL 10 points**

- a. Adequacy, thoroughness, and appropriateness of the proposed overall project organization and staffing; and plans and procedures for monitoring, tracking, coordination, and management of all contract activities.
- b. Appropriateness and feasibility of the plan for communication with the Project Officer and Contracting Officer to ensure the efficient planning, initiation, implementation, monitoring, and management of all projects carried out under contract, including projects carried out by subcontractors and consultants.
- c. Adequacy of plans for maintenance of data integrity during transfer; maintenance of confidentiality; and quality control of data generated during the contract.

**CRITERION 4: FACILITIES, EQUIPMENT, SAFETY, AND TRAINING 10 points**

- a. Availability, adequacy, and suitability of equipment and facilities to quarantine, house, care, and maintain uninfected and SIV/SHIV-infected rhesus macaques in compliance with AAALAC and OLAW guidelines and regulations.
- b. Adequacy of the biocontainment procedures and training programs for the safe handling of SIV/SHIV-infected animals, pathogenic viruses, and infectious specimens.
- c. Availability and adequacy of equipment and facilities to perform immunology and virology assays required in the Statement of Work.
- d. Availability and adequacy of equipment and facilities to perform animal challenges with SIV/SHIV, treat animals with drugs and therapies, apply vaginal and rectal microbicides, conduct animal necropsies, and perform pathology/histopathology evaluations.

**TOTAL POINTS 100 points**

**D. PAST PERFORMANCE FACTOR**

An evaluation of offerors' past performance information will be conducted 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 judgement 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.

#### **E. 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.

## **SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP**

The following pages include Attachments applicable to this RFP as specified in SECTION J -  
List of Attachments

**ATTACHMENT 1  
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-DAIDS-08-09  
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"**

**B. PAPER COPIES and CD-Rom to:**

<b>If Hand Delivery or Express Service</b>	<b>If using U.S. Postal Service</b>
Anita Hughes Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Anita Hughes 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 (NOV 1986).

**C. NUMBER OF COPIES:**

**TOTAL PAGE COUNT DOES NOT INCLUDE:** Title 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.

**Documents submitted using Adobe .pdf shall 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. It is requested that the Technical Proposal be submitted as one document.

**Note:** We would prefer that multiple files not be submitted. However, if multiple files are submitted for either proposal, please include the name of the section in the file name.

**EXAMPLE:** XYX Company-08-09-Technical-Approach-6-16-07

3. CDs should be named using the following format:

**Technical Proposal: Company name-RFP number-technical-date**

**Business Proposal: Company name-RFP number-business-date**

**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	<b>PAPER</b> One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES  <b>ELECTRONIC FILES ON CD</b> Two (2) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)	Not to Exceed 200 pages (inclusive of all Attachments and Appendices)
Business Proposal	<b>PAPER</b> One (1) unbound SIGNED ORIGINAL. Two (2) unbound COPIES  <b>ELECTRONIC FILES ON CD</b> Two (2) 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 <a href="#">Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet</a> to access the Excel Workbook.	N/A

**ATTACHMENT 2**  
**PROPOSAL INTENT RESPONSE SHEET**  
**RFP No.: NIH-NIAID-DAIDS-08-09**  
**RFP Title: Non-human Primate Models to Evaluate Therapeutic Strategies**  
**and Topical Microbicides for HIV**

Please review the attached Request for Proposal. Furnish the information requested below and return this Proposal Intent Response Sheet by mail, FAX or email to Anita Hughes by **June 10, 2007**. 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 FOR NOT SUBMITTING:

**Company/Institution Name (print):** \_\_\_\_\_  
**Address (print):** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

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

**Names of Other Key Personnel:**  
**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:  
Anita Hughes, Contract Specialist  
OA, DEA, NIAID, NIH  
6700-B Rockledge Drive, Room 3214, MSC 7612  
Bethesda, MD 20892-7612  
RFP-NIH-NIAID-DAIDS-08-09  
FAX# (301) 402-0972  
Email: [anhughes@niaid.nih.gov](mailto:anhughes@niaid.nih.gov)

**ATTACHMENT 3  
STATEMENT OF WORK**

**NON-HUMAN PRIMATE MODELS TO EVALUATE THERAPEUTIC STRATEGIES  
AND TOPICAL MICROBICIDES FOR HIV  
RFP NIH-NIAID-DAIDS-08-09**

**BACKGROUND and INTRODUCTION:**

The mission of the Division of Acquired Immunodeficiency Syndrome (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID) is to ensure an end to the human immunodeficiency virus/acquired immunodeficiency syndrome (HIV/AIDS) epidemic by supporting research that can lead to the development of therapies, vaccines, and prevention strategies. Since the mid-1980's animal models of HIV infection have played an important role in the Institute's efforts to achieve its mission. The NIAID awarded two contracts in 2001 to support the pre-clinical evaluation of therapeutic interventions and topical microbicides in the simian immunodeficiency virus (SIV) and simian/human immunodeficiency virus (SHIV) non-human primate animal models. The purpose of this contract is to continue the requirement for a non-human primate model resource to support pre-clinical evaluation of therapeutic agents/strategies and topical microbicides for HIV.

Since the non-human primate contracts were awarded in 2001 over 30 studies have been completed. Products for pre-clinical evaluation have been supplied from pharmaceutical and biotechnology companies, and academic investigators. Examples of strategies evaluated include therapeutic vaccines, vaginal and rectal microbicides, gene transfer approaches, and immune-based therapies. In addition, these contract resources have supported non-human primate animal model development and provided valuable services and reagents to the scientific community.

The objective of this contract is to provide a resource to evaluate therapeutic agents/strategies and topical microbicides in SIV/SHIV macaque animal models. Study products for evaluation will be provided to the Contractor by the sponsor of the study product or through the NIAID. The Project Officer will select the studies to be performed, to include:

- Confirmation of efficacy of candidates/interventions that have proved promising in other animal models
- Proof-of-concept studies with the potential to advance development of an agent or strategy
- Evaluations that cannot be done in other animal models of HIV infection
- Development of new and improved SIV/SHIV macaque animal models
- *In vitro* assessment of efficacy and toxicity of therapeutic agents and microbicides in non-human primate and human cells

The Contractor shall provide:

- Animals, appropriate housing facilities, and veterinary services required for the care and monitoring of animals to successfully conduct the contract objectives
- Scientific expertise required in the evaluation of therapeutic agents/strategies and topical microbicides, in the development of new and improved SIV/SHIV macaque animal models, and in the assessment of efficacy and toxicity of agents *in vitro* using non-human primate and human cells
- State-of-the-art technologies in immunology and virology to accomplish the contract objectives

**SCOPE:**

The scope of the work to be performed includes:

- Evaluation of therapeutic agents/strategies for the treatment of HIV/AIDS using SIV/SHIV macaque animal models
- Evaluation of topical microbicides for the prevention of HIV/AIDS using SIV/SHIV macaque animal models
- Development of novel and improvement of existing SIV/SHIV macaque animal models
- *In vitro* assessment of efficacy and toxicity of therapeutic agents and microbicides in non-human primate and human cells
- Options to extend the contract to continue the services required during the base period for up to an additional two years

The Contractor shall use state-of-the-art technologies to accomplish the contract objectives and shall incorporate new and improved technologies into contract activities when appropriate.

## **TECHNICAL REQUIREMENTS (BASE PERIOD):**

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

### **1. Animal Procurement, Testing, and Maintenance**

- a. Procure up to 60 macaques per year, including Chinese and Indian rhesus macaques (*Macaca mulatta*), cynomolgous macaques (*Macaca fascicularis*), and pig-tail macaques (*Macaca nemestrina*) for studies to be conducted under this contract. Baboons and chimpanzees shall not be used for any study. The decision of which non-human primate species to be used for a study will be made jointly by the Project Officer, the sponsor of the study product, and the Contractor, with the Project Officer having the final approval authority.
- b. House and maintain the animals in well-equipped and Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC)-accredited facilities. House up to 150 animals at any one time, in appropriate biohazard containment facilities, using required biosafety procedures to care for and handle SIV/SHIV infected animals.
- c. Quarantine animals upon arrival at the Contractor's facility and assure that they are tuberculosis (TB)-free, as well as free of simian T cell lymphotropic virus (STLV), simian type D retrovirus (SRV), and SIV. Test animals for TB on a quarterly basis and euthanize those with a positive TB test immediately. Notify the Project Officer by e-mail and in writing within 48 hrs of a positive TB test.
- d. At the termination of a study, the end of the contract, or when requested by the Project Officer, move animals onto another study, transfer animals to other facilities, or euthanize animals according to humane procedures approved by the Contractor's Institutional Animal Care and Use Committee (IACUC). Shipment of any SIV/SHIV-infected animal shall be conducted using appropriate biocontainment practices and shall conform to applicable regulations for intra-state or interstate transport.
- e. Provide and maintain in working condition, a 24-hours per day, seven days a week, security system to prevent unauthorized entry into the animal care facility.

### **2. Animal Care and Monitoring/Clinical Observations**

- a. Provide animal care in compliance with the Office of Laboratory Animal Welfare (OLAW) regulations, <http://grants.nih.gov/grants/olaw>. Provide veterinary care for the animals on a 24-hour per day, seven days a week (on-call) basis. Provide, at a minimum, daily observation of the health status of each animal, including weekends and holidays.
- b. Provide clinical laboratory testing for the animals such as complete blood counts (CBC), serum chemistry evaluations, parasite and bacterial testing, and simian herpes B virus testing.
- c. Perform CD4 and CD8 T cell counts and total lymphocyte counts of blood samples according to the approved study design.
- d. Monitor animals for toxicities.
- e. 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.
- f. Euthanize animals according to humane procedures approved by the Contractor's IACUC. Notify the Project Officer by e-mail and in writing within 48 hrs when an animal is sufficiently ill for the veterinarian to recommend euthanasia.
- g. For animals that have died or have been euthanized, provide a detailed clinical history, gross pathological observations, and properly preserved tissue samples to a veterinarian, board-certified in clinical and anatomic pathology, for disease diagnosis.

### 3. Study Design

Within 15 calendar days of receiving a request from the Project Officer develop, in conjunction with the Project Officer, other NIAID staff, and the sponsor of the study product, a Study Design that outlines and describes the study to be performed. Submit the Study Design for Project Officer approval. Written approval by the Project Officer of the final Study Design shall be required prior to study initiation. Once a study has been initiated, the study design shall only be amended after concurrence with the Project Officer. The Study Design shall contain the following sections:

- a. **Cover Page:** Contract number and title, study identification number and study title, and date of submission.
- b. **Table of Contents**
- c. **Study Outline:** Overall summary of the study that includes justification for the number, species, and sex of animals to be used; description of interventions, therapies, and viral challenge; and description of study groups and of positive and negative controls to be used. Describe which elements of the study will be analyzed statistically (e.g. randomization of animals, comparison of viral load data between study groups).
- d. **Animals:** Information about the animals to be used in the study including animal species, sex, weight, age, and infection status.
- e. **Viruses:** A description of the virus strain(s) to be used and rationale for selecting the strain(s), virus titer and titration method(s), dose and route of virus administration.
- f. **Drugs and Therapies:** A description of all interventions, therapies, and treatments to be used including drug formulation and reconstitution, description of placebos, and dose and route of administration.
- g. **Time Schedule:** A timeline for blood collection, immunizations/therapies and interventions, tissue specimen collection, and viral challenge.
- h. **Assays to be Performed:** For every assay to be performed, the experimental protocols and SOPs that will be utilized. Include a description of the positive and negative controls for each assay.
- i. **Necropsy and Clinical Pathology/Histopathology:** The criteria to be used in deciding on euthanasia and the clinical information the clinical and anatomic pathologist will require in making pathology/histopathology evaluations.

All studies shall be performed at the initiation of the Project Officer. The Contractor shall not initiate or conduct studies under the contract without Project Officer approval.

### 4. Virus Stocks

- a. Propagate virus stocks *in vitro* and *in vivo* as specified by the approved study design.
- b. Determine the *in vitro* and/or *in vivo* titers of virus stocks as specified by the approved study design.

### 5. Animal Challenge and Treatment

- a. Conduct intra-vaginal, intra-rectal, and intravenous SIV/SHIV challenge of macaques using established SOPs.
- b. Treat macaques with single and/or combinations of anti-retroviral drug regimens.
- c. Immunize/treat animals with therapeutic modalities and/or microbicides as specified by the approved study design.
- d. Collect blood, sera, plasma, mucosal (nasal, vaginal, rectal) lavages, tissues, and peripheral blood mononuclear cells (PBMC) according to established SOPs and the approved study design.
- e. Conduct vaginal and rectal pinch biopsies as well as lymph node biopsies according to established SOPs and the approved study design.

## **6. *In Vitro* Efficacy and Toxicity Studies**

- a. Evaluate therapeutic agents and microbicides for efficacy against SIV/SHIV using human PBMC, and PBMC derived from the appropriate non-human primate species, as specified by the approved study design.
- b. Evaluate potential cytotoxicities of therapeutic agents and microbicides in non-human primate PBMC and commercially available human PBMC, as specified by the approved study design.

## **7. Immunology and Virology Assays**

- a. Perform immunological analyses of specimens according to established SOPs and the approved study design (e.g. intracellular cytokine staining).
- b. Perform virological analyses of specimens according to established SOPs and the approved study design (e.g. detection of plasma virus RNA, infectious titer determinations, etc.).

## **8. Model Development**

Develop novel and improve existing SIV/macaque and SHIV/macaque animal models that include:

- a. Intra-vaginal challenge of Depo Provera-treated macaques with SIV/SHIV
- b. Repeated low dose SIV/SHIV intra-vaginal challenge of macaques
- c. Oral and intranasal SIV/SHIV challenge of macaques

## **9. SOPs and Experimental Protocols**

SOPs and experimental protocols shall include quality control and assurance steps for all procedures supported by the contract. Provide e-mail copies of the SOPs and experimental protocols to the Project Officer, as requested. Update SOPs and experimental protocols on a regular basis and submit revised versions to the Project Officer when changes are made.

## **10. Data Analysis and Reporting**

- a. Perform statistical analyses of data collected according to the approved study design.
- b. Within 60 calendar days of completion of a study, prepare and submit to the Project Officer for review and approval, a Study Report that describes the work performed. All Study Reports shall be written in the format of a scientific paper and include:
  - 1) Cover Page - contract number and title, study identification number and title, start and completion dates of the study, and the submission date of the report.
  - 2) Table of Contents
  - 3) Abstract
  - 4) Introduction
  - 5) Materials and Methods
  - 6) Results
  - 7) Discussion
  - 8) Supplemental Material
- c. Presentations at Scientific Meetings:
  - 1) Provide the Project Officer with an e-mail copy of the abstract to be presented at scientific meetings in final form 7 calendar days prior to the submission date, for the Project Officer's approval. The material shall be revised by the Contractor, if necessary, before submission.
  - 2) Provide the Project Officer with an e-mail copy of the poster and slide presentation to be presented at scientific meetings in final form 7 calendar days before the first day of the scientific conference, for the Project Officer's approval. The material shall be revised by the Contractor, if necessary, before presentation.

The Contractor shall not present any information or data generated by performance of the contract at scientific meetings without prior written approval of the Project Officer.

d. Manuscripts:

Provide the Project Officer, for approval, an e-mail copy of the scientific material to be published in final form, within 90 calendar days of the Project Officer's request. The material shall be revised by the Contractor, if necessary, before publication. **The Contractor shall not publish any material developed through the contract without prior written approval from the Project Officer.**

## 11. Data Collection, Management, and Quality Control

- a. Maintain electronic records of scientific data and provide e-mail copies to the Project Officer, as requested.
- b. Transfer electronic records of scientific data to the Project Officer upon request, in a format to be specified by the Program Officer.
- c. Ensure integrity of scientific data during electronic transfer between different computer programs and software, databases, etc.
- d. Provide quality control procedures for all data generated under the contract such as scientific data, Contractor and subcontractor/consultant reports, etc.
- e. Store all confidential data related to the study products and testing results in files that are accessible only to the Contractor's Principal Investigator and involved staff.

## 12. Receipt, Storage, Shipment, and Inventory of Contract Resources

- a. Receive, store, and maintain study products according to specifications provided by the supplier.
- b. Receive, store, and maintain virus stocks.
- c. Store, track, and maintain animal specimens collected during the course of the studies conducted under this contract. Store animal specimens as specified by the approved study design.
- d. Provide for appropriate storage and 24-hours a day/seven days a week monitoring of refrigerator/freezer conditions by automatic temperature alarm to guarantee continuous proper storage of virus stocks, study products, specimens, and other material.
- e. Maintain locked storage container, refrigerator, or freezer with access only to authorized personnel in accordance with appropriate biosafety level requirements.
- f. Ship infectious and non-infectious materials using shipping conditions appropriate for preserving the materials to be shipped including virus stocks, drugs, therapies, microbicides, placebos, and fresh, frozen, and preserved biological samples. Use biocontainment shipping procedures and containers that comply with International Air Transport Association (IATA) Dangerous Goods Regulations ([www.iata.org](http://www.iata.org)) for shipment by air transportation or with Department of Transportation (DOT) regulations for shipment by ground transportation.
- g. Establish an inventory control system in which study products, virus stocks, reagents, drugs and therapies, animal specimens, etc., are tracked and inventoried so that product use and disposition can be monitored.

## 13. Safety and Training

- a. Conduct work in accordance with the most recent Guidelines for Biosafety in Microbiological and Biomedical Laboratories (<http://bmbi.od.nih.gov>).
- b. Provide staff with the required training, experience, and expertise to operate the facilities and conduct the studies in accordance with appropriate Biosafety Guidelines for working with potentially hazardous pathogens, specimens, and non-human primates (see also <http://bmbi.od.nih.gov>).

- c. Provide adequate and appropriate training, protective garments, equipment, and monitoring for all involved personnel to assure safe handling and transport of potentially hazardous pathogens, specimens, and non-human primates.

#### 14. Number of Studies

- a. For studies that utilize non-human primates the Contractor shall conduct 2-3 studies per year maximum, as determined by the Project Officer, with up to a total of 60 animals.
- b. For *in vitro* efficacy and toxicity studies, the Contractor shall conduct up to 3 studies per year, as determined by the Project Officer.

#### 15. Project Management

- a. Provide the scientific, technical, and administrative infrastructure to ensure the efficient planning, initiation, implementation, and management of all activities carried out under this contract. Infrastructure at the Contractor's site shall include a PI with responsibility for overall project management and communications, tracking, monitoring, and reporting on project status and progress. This infrastructure shall also include administrative staff with responsibility for financial management and financial reporting on all activities conducted by the Contractor and all subcontractors.
- b. Assure effective communications with the Project Officer and Contracting Officer. This shall involve weekly teleconferences for the purpose of updating the Project Officer on the status of ongoing and planned studies and other issues related to the contract. Submit a summary of action items to the Project Officer within 48 hours of completion of each weekly teleconference.
- c. Organize one or more site visits per year as requested by the Project Officer, at the Contractor's facility(s). The site visits shall include the Project Officer and other NIAID staff, as well as all key personnel supported by the contract. The site visits are to be arranged and coordinated by the Contractor. Submit a summary of action items to the Project Officer within 48 hours of completion of the site visit.

#### 16. Initial and Final Transition

##### a. Initial Transition

In the event a new contractor assumes the requirements of the contract:

- 1) Within 5 calendar days of the effective date of the contract, the Project Officer will provide the Contractor with a copy of the incumbent contractor's Final Transition Plan, which will specify transition requirements and processes. The transition will require the transfer of contract-related materials and data that include:
  - a) Animals
  - b) Reagents such as drugs, therapies, viral stocks, etc.
  - c) Biological samples, fresh, frozen, and preserved
  - d) Scientific data, reports, and SOPs
  - e) Government furnished property such as computers, software, etc.
- 2) Within 14 calendar days of the effective date of the contract, the Contractor shall submit to the Project Officer and Contracting Officer for approval, an Initial Transition Plan and timeline for the transition of activities and contract-related materials from the current contractor, and the activities required for having the Contractor's facility ready for study initiation.
- 3) Upon Project Officer and Contracting Officer approval of the Initial Transition Plan, implement and complete the transition within the first 45 calendar days following the effective date of the contract.

##### b. Final Transition

Provide a Final Transition Plan for the orderly, safe, and efficient transition of contract-related materials, data, and activities, to a successor contractor or the Government, if other than the incumbent is awarded a follow-up contract. This plan shall be subject to written approval by the Project Officer and Contracting Officer.

- 1) The Draft Final Transition Plan shall be submitted to the Project Officer and Contracting Officer 6 months prior to the completion date of the contract, for review and comment. Upon receipt of the Project Officer's and Contracting Officer's comments, the Contractor shall revise the Draft Final Transition Plan as necessary.
- 2) The Final Transition Plan shall be submitted for written approval to the Project Officer and Contracting Officer 2 months prior to the completion date of the contract. The Contractor shall implement and complete the Transition Plan by the completion date of the contract.
- 3) The transition process will require the transfer of contract-related material to include:
  - a) Animals
  - b) Equipment
  - c) Reagents such as drugs, therapies, viral stocks, etc.
  - d) Biological samples, fresh, frozen, and preserved
  - e) Scientific data and reports
  - f) Government-furnished property such as computers, software, etc.

#### **17. Options to Extend the Period of Performance**

In addition to the services to be provided for the basic requirement outlined above, the Government may exercise two (2) options to extend the contract for a period of one (1) year each. If and to the extent the options are exercised, the services required will be of the same scope as outlined for the basic requirement.

***[END OF STATEMENT OF WORK]***

**ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS  
FORMAT FOR TECHNICAL PROPOSAL**

**NON-HUMAN PRIMATE MODELS TO EVALUATE THERAPEUTIC STRATEGIES AND TOPICAL MICROBICIDES  
FOR HIV  
RFP NIH-NIAID-DAIDS-08-09**

**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. 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 in this Appendix.

Offerors are advised to give careful consideration to the Statement of Work, all reference materials, appendices 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.** Proposals shall NOT include links to Internet Web site addresses (URLs) or direct readers to alternate sources of information.

**TECHNICAL PROPOSAL – TABLE OF CONTENTS**

**GENERAL**

NIAID anticipates making one to two awards under this RFP for a base period of five years with an Option to extend the contract two additional years through the exercise of up to two 1-year Options.

The Government recognizes that it may be necessary for the Contractor to subcontract a portion of the work. When a specific subcontractor(s) is proposed, similar technical information as that required of the Offeror shall be provided by the subcontractor.

**SECTION 1**

- I. 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.
- II. PROJECT OBJECTIVES (NIH FORM 1688-1)
- III. GOVERNMENT NOTICE FOR HANDLING PROPOSALS
- IV. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)
- V. TABLE OF CONTENTS

**SECTION 2: TECHNICAL PROPOSAL OVERVIEW** (suggested limit of 3 pages)

- a. Provide a brief description of the activities to be performed by the Offeror and those that shall be provided by all proposed subcontractors, including the identification of the proposed subcontractors.
- b. Provide a list of key personnel of the Offeror and the proposed subcontractors with degrees and titles.

- c. Provide a brief description of the facilities, equipment, and other resources to be made available by the Offeror and all proposed subcontractors.

### **SECTION 3: 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.

- a. Principal Investigator (PI)
  - 1) Describe the formal education and training of the proposed PI and the percentage of total time the PI will be committed to the project. Include a CV (2-3 pages) and provide selected references of publications relevant to the scope of the RFP.
  - 2) Describe the experience and qualifications of the proposed PI to provide leadership in the planning, directing, and coordinating the conduct of SIV/SHIV macaque studies; and the ability to provide technical assistance and oversight of technical personnel.
  - 3) Discuss the experience and technical understanding of the proposed PI regarding the immunology and virology assays required for the evaluation of therapeutic agents/strategies and microbicides.
  - 4) Discuss the experience and technical understanding of the proposed PI regarding the in vitro assays required for the evaluation of efficacy and cytotoxicity in human and non-human primate PBMCs.
- b. Veterinarian/Clinical and Anatomic Pathologist
  - 1) Describe the formal education, experience, and training of the proposed veterinarian and the percentage of total time she/he will be committed to the project. Include a CV (2-3 pages) and provide selected references of publications relevant to the scope of the RFP.
  - 2) Describe the experience and qualifications of the proposed veterinarian to provide leadership in the care of uninfected and SIV/SHIV-infected macaques, and in evaluating animal clinical observations and toxicities as they relate to standard animal care and to the treatment of animals with novel therapeutic agents/strategies, anti-retroviral agents, and microbicides.
  - 3) Describe the qualifications of the proposed veterinarian to perform pathology/histopathology evaluations.
  - 4) Describe the experience and qualifications of the proposed veterinarian to perform intra-vaginal, intra-rectal, and intravenous challenges with SIV/SHIV, and to perform surgical procedures such as vaginal and rectal pinch biopsies, lymph node biopsies, and post-mortem examinations.
- c. Other Scientific and Technical Personnel
  - 1) Describe the formal education, training, experience, and qualifications of senior scientific and technical personnel in the conduct of SIV/SHIV macaque studies. Include the percentage of total time each will be committed to the project. Include CVs (2-3 pages) and selected references of publications relevant to the scope of the RFP. This applies to staff of the Offeror and all proposed subcontractors and consultants.
  - 2) Describe the formal education, training, experience, and qualifications, and the role of other personnel as needed to address the requirements of the Statement of Work.

### **SECTION 4: TECHNICAL APPROACH**

- a. Immunology and Virology Assays
  - 1) Describe the immunology assays in place to evaluate the efficacy and potential toxicities of a therapeutic agent and/or strategy.
  - 2) Describe the immunology assays in place to evaluate the protective efficacy and potential toxicities of a vaginal and a rectal microbicide.

- 3) Describe the virology assays in place to evaluate therapeutic agents/strategies and topical microbicides.
  - 4) Describe the steps required to scale up two immunology and two virology assays from the initial pilot phase to the final phase of assaying samples from 20 animals. Describe problems that might occur during the process of scale up and ways to overcome them.
  - 5) Describe the *in vitro* assays in place to evaluate the potential efficacy of a therapeutic agent and microbicide.
  - 6) Describe the *in vitro* assays in place to evaluate potential cytotoxicities of a therapeutic agent and microbicide.
  - 7) Describe how you would improve the repeated low dose non-human primate animal model to enhance its usefulness in the evaluation of therapies or topical microbicides.
- b. Animal Procurement, Testing, and Maintenance
- 1) Describe the procedures for procuring non-human primates (Rhesus, cynomolgus, or pig-tail macaques) and assuring that they are free of TB, STLV, SRV, and SIV. Identify the facilities from which they will be purchased. Indicate which species of primates you will have access to and discuss any problems you foresee with procuring the number and kind of animals described in the Statement of Work.
  - 2) Provide documentation on the number of animals, species, sex, age, and origin that the Offeror procured in the last 2-3 years.
  - 3) Describe the animal quarantine procedure.
  - 4) Estimate the length of time that might elapse between placing an order for animals and the initiation of a study.
  - 5) The Statement of Work requires that the macaques purchased shall be TB-free. Describe the procedure for TB testing from the time an animal arrives at the Offeror's facility to euthanasia or death of the animal. Describe the steps to be taken if an animal(s) tests positive for TB.
- c. Animal Challenge and Treatment
- 1) Describe the procedures used for intra-vaginal and intra-rectal challenge of macaques with SIV/SHIV. Describe how tissue injury is avoided.
  - 2) Describe procedures for, and experience in, the treatment of macaques with anti-retroviral drug therapies administered by different routes.
- d. Animal Care and Monitoring/Clinical Observations
- 1) Describe the clinical care and monitoring of uninfected and SIV/SHIV-infected animals and the criteria for euthanasia at the Offeror's facility. Describe animal care during weekends and holidays and how an animal will be handled if found dead in its cage. Estimate the longest period of time animals will be left unattended and describe potential pitfalls and solutions.
  - 2) Describe the clinical information (e.g. CBCs, chemistries, etc.) that will be required by a veterinarian to make pathology evaluations. Describe the histopathology procedures that will be used and the Offeror's experience with pathology/histopathology evaluations and provide supporting documentation.
  - 3) Describe the monitoring of toxicities in uninfected and SIV/SHIV-infected animals as they relate to standard animal care and to the therapeutic agents/strategies, anti-retroviral agents, and microbicides that might be used in studies. Provide examples of potential toxicities and describe steps that would be undertaken to address such toxicities.

## **SECTION 5: PROJECT MANAGEMENT; DATA COLLECTION, MANAGEMENT, AND QUALITY CONTROL**

- a. 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, and an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel. Include a chart of the proposed organizational/management structure for the project.

- b. Describe the project management systems that will be used to track activities and to keep multiple activities on time and budget. The plan should 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.
- c. Outline how the PI will communicate with the Project Officer and Contracting Officer and how the PI will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).
- d. Describe how the integrity of scientific data will be maintained during transfer between computer programs and software, databases, etc.
- e. Describe how quality control of the data generated under the contract (e.g. scientific data, Contractor and subcontractor/consultant reports etc.) will be achieved.
- f. Provide a plan for maintaining confidentiality of data collected during the execution of the responsibilities of this contract.

#### **SECTION 6: FACILITIES, EQUIPMENT, SAFETY, and TRAINING**

- a. Describe and provide documentation for the bio-containment procedures and required training used at your facility for the housing and care of uninfected and SIV/SHIV-infected macaques.
- b. Provide documentation to describe compliance with the OLAW animal care policy, and of AAALAC accreditation; describe the OLAW assurance, AAALAC accreditation, and IACUC approval procedures at your institution.
- c. Describe the safe practices and procedures to assure a safe working environment for all personnel handling or in contact with pathogens, specimens, and infected non-human primates.
- d. Provide the location and features of facilities to be utilized for contract work, including a floor plan and a list of equipment and resources dedicated to the project, for the Offeror and any proposed subcontractors (lease or ownership information should be provided).
- e. Identify and describe ALL support resources (including Information Technology systems) which will be required to effectively complete the Statement of Work.

#### **SECTION 7: TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION**

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 that is in addition to the minimum requirements identified in Section L.

##### **I) Animal Welfare**

Section L of the RFP specifies the minimum documentation requirement 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.

##### **II) Biohazard Safety**

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

##### **III) Information Technology (IT) Systems Security**

The IT System Security Plan (SSP) details the overall security infrastructure for the systems. It includes details of the system, the various controls of the system, the information security policies of the organization, and any connections that the system has to other systems internal and external to the organization. The National Institute for Standards and Technology (NIST) has developed a Special Publication NIST SP-800-18 Revision 1 Guide for Developing Security Plans for Federal Information Systems, (<http://www.csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>). The vendor can use this document as a guideline for developing the SSP. The SSP should be provided to the Project Officer in electronic and paper format within 60 days of contract award.

## ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

### NON-HUMAN PRIMATE MODELS TO EVALUATE THERAPEUTIC STRATEGIES AND TOPICAL MICROBICIDES FOR HIV RFP NIH-NIAID-DAIDS-08-09

**In addition to the format requirements for the Business Proposal that are contained in Section L of the solicitation, the information provided in this Appendix 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 appendices and attachments, the Technical Evaluation Criteria, and, the RFP as a whole, in the development of your Business 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 in this Appendix, as well as **any other** information which will benefit the proposal.

#### **BUSINESS PROPOSAL – TABLE OF CONTENTS**

**SECTION 1 – PROPOSAL COVERSHEET** (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**

Assume that 10 SIV/SHIV infected animals and 10 uninfected animals will be transferred to a different facility during the duration of the contract.

Assume that 60 animals will be purchased each year of the contract. The number of non-human primates to be housed at any given time shall not exceed 150. For studies that will utilize non-human primates, assume 2 studies per year will be conducted, for a total of 60 animals. For *in vitro* efficacy and toxicity studies, assume 2 studies per year.

For budgetary purposes assume that 60 animals will be infected with SIV/SHIV per year. Plasma, serum, and lymphocytes will be collected and processed two times before viral challenge, six times in the first month following viral challenge, twice monthly for the next 6 months, and monthly for the duration of the study (12 months). Viral load determinations will be performed following viral challenge and concurrently with lymphocyte collection. Assume six lymph node, six vaginal, and six rectal biopsies per year.

For budgetary purposes assume that CBC and serum chemistry evaluations will be performed monthly, and parasite and bacterial testing will be performed 6 times per year. Assume that 30 animals per year will be euthanized and 15 will require pathology/histopathology evaluations.

For budgetary purposes, assume that one *in vitro* study will include one dose-response assay of a therapeutic agent or microbicide, appropriate positive and negative controls, and one cytotoxicity assay at each point in the dose-response curve.

##### **2) Special Shipping and Packaging**

Offerors should include a uniform assumption of 20 domestic blood shipments per year.

##### **3) Storage**

Offerors should include a uniform assumption of 200 specimens to be transferred from the previous contract.

Offerors should include a uniform assumption of 1500 new, in 1 ml volume, specimens to be stored each year.

**4) Site Visits**

Offerors should include a uniform assumption of one site visit per year.

**8) Travel**

Offerors should include a uniform cost assumption of \$2000 annually for the Principal Investigator to attend general scientific meetings for presentations of work conducted under this contract.

**SECTION 4 – OPTIONS** (If and to the extent exercised)

Offerors shall price each of the two (2) 1-year expansion options separately. Offerors shall assume that the base contract period of performance requirements will continue during the Option periods of performance.

**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 submitted 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 submitted 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 submitted with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

**DIVISION OF ACQUIRED IMMUNODEFICIENCY SYNDROME  
NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES  
MATERIAL EVALUATION AGREEMENT**

**This Material Evaluation Agreement is made and entered into between the Division of Acquired Immunodeficiency Syndrome (“DAIDS”) of the National Institute of Allergy and Infectious Diseases (“NIAID”), located at 6700B Rockledge Drive, Bethesda, Maryland 20892, and <insert company>, having its principal place of business located at <insert company’s address> (“PROVIDER”). DAIDS funds a comprehensive portfolio of contracts to discover and develop novel agents for the prevention and treatment of infections caused by human immunodeficiency virus (HIV), opportunistic infections associated with AIDS, hepatitis C, and tuberculosis. PROVIDER requests to voluntarily participate in one or more of the evaluation programs (e.g., in vitro, animal model, drug development) funded by DAIDS and submits for evaluation patented or unpatented drugs, compounds, or other products (“Material”) to DAIDS. Without cost to the PROVIDER, DAIDS may evaluate the submitted Material through its Contractors. DAIDS shall determine which programs shall be utilized to evaluate PROVIDER’s Material and the extent of the evaluation. PROVIDER shall have the right to request limitations on the scope and extent of evaluation of the Material by DAIDS.**

DAIDS and PROVIDER therefore agree as follows:

**1. Definitions.**

- 1.1 “Confidential Information” is scientific, business, or financial information the PROVIDER or DAIDS deem to be proprietary or confidential and which information is identified as “Confidential” in writing. Confidential written information shall be marked “Confidential.” Oral disclosures must be reduced to writing, marked “Confidential,” and sent to the other Party’s Point of Contact listed in Section 11 within 10 business days after disclosure to be considered Confidential Information.
- 1.2 “Contractors” are DAIDS approved non-profit and for-profit testing laboratories with contractual obligations to DAIDS.
- 1.3 “DAIDS” is a division within the 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.
- 1.4 “Evaluations” will include the testing of the Materials in the manner described below.
  - a. <DAIDS to provide description of evaluations – use terms from “MEA examples list”>
- 1.5 “Invention” means any invention or discovery which is or may be patentable or otherwise protected under Title 35, United States Code (“U.S.C.”), or any novel variety or plant which is or may be protectable under the Plant Variety Protection Act (7 U.S.C. §§ 2321 et seq.).
- 1.6 “Material” means:
  - a. <DAIDS & PROVIDER to negotiate Description of Material - use terms from “MEA examples list” >
- 1.7 “Results” means all recorded data, results, and technical information produced from the Evaluations of the Material under this Agreement and not previously disclosed by the PROVIDER.

**2. Submission and Evaluations of Material.**

- 2.1 DAIDS represents that the contracts between DAIDS and the Contractors are consistent with the terms of this Agreement.
- 2.2 DAIDS has the right to decline to conduct Evaluations of any Material or to limit the scope of such Evaluations. PROVIDER understands that not all Evaluations offered by DAIDS are available at all times. Evaluations must be mutually agreed to by DAIDS and PROVIDER prior to commencement of Evaluations and are delineated in Section 1.4 above. After initiation of Evaluations listed in Section 1.4, PROVIDER and/or DAIDS may request additional or advanced Evaluations. Such Evaluations are contingent upon data meeting DAIDS criteria for such Evaluations and shall be mutually agreed upon in writing and attached hereto as an Appendix.

- 2.3 While PROVIDER may not select the Contractors, PROVIDER has the right to decline the use of particular Contractors conducting Evaluations prior to the communication of any Material to such Contractors.
- 2.4 Under the direction of DAIDS, PROVIDER will forward to Contractors the Material to be tested together with a Material Safety Data sheet for each Material which contains pertinent available data as to chemical composition, purity, solubility, toxicity, and any precautions that need to be followed in handling, storing, and shipping the Material.
- 2.5 Material is to be used by Contractors for Evaluations under this Agreement only and for no other purpose. In addition, Material will not be chemically modified, replicated, derived or reverse engineered unless specifically necessary for the performance of the Evaluations. Such modification would require PROVIDER approval. As mutually agreed upon by the Parties, upon completion of Evaluations, all unused Material will be returned to PROVIDER or destroyed.
- 2.6 DAIDS will use reasonable efforts to ensure rapid ongoing communication of Results to the PROVIDER, and PROVIDER will in turn use reasonable efforts to keep DAIDS informed of PROVIDER's own concurrent studies with the Material that may affect Evaluations or Results.

### **3. Confidentiality.**

- 3.1 PROVIDER may provide Confidential Information relevant to the Evaluation of the Material to DAIDS and the Contractors. DAIDS represents that the Contractors are required by their DAIDS contracts to protect such Confidential Information with reasonable efforts as specified in 3.3 below.
  - a. To the extent permitted by law, Confidential Information disclosed to DAIDS or the Contractors will remain confidential for five (5) years after the effective date of this Agreement unless the information:
    - b. Is known by the public or becomes known by the public through no fault of DAIDS or the Contractors;
    - c. Was obtained by DAIDS or the Contractors, without restriction, from a third party having no confidentiality obligation to the PROVIDER;
    - d. Has been independently developed by DAIDS or the Contractors without reference to the PROVIDER's Confidential information; or
    - e. Is required to be disclosed by law, regulation, or court order provided that PROVIDER has been notified and DAIDS or the Contractors have taken reasonable efforts to minimize the extent of the required disclosure.
- 3.2 No data about the Material, Evaluations, or Results will be kept in files open to the public either by DAIDS or the Contractors. Only personnel directly involved in the Evaluations will have access to the files containing Confidential Information.
- 3.3 PROVIDER acknowledges that Results are not Confidential Information as defined in section 1.1, and may be disclosed by DAIDS and the Contractors only in accordance with Article 4 below.

### **4. Disclosure of Results.**

- 4.1 DAIDS and the Contractors may publish or otherwise publicly disclose Results after a period of six (6) months from the date of transfer of Results to PROVIDER. The six-month delay in disclosure is intended to allow PROVIDER time to file patent applications if desired.
- 4.2 Publication of Results earlier than the six (6) month period by DAIDS or Contractors will require PROVIDER's prior written consent, which will not be unreasonably withheld.
- 4.3 PROVIDER is encouraged to pursue publication of Results in conjunction with or separately from DAIDS and the Contractors. Before PROVIDER or DAIDS submit a paper or abstract for publication or otherwise intend to publicly disclose information about Evaluations or Results related to PROVIDER's Material, such as a press release, DAIDS and PROVIDER will provide the other Party fourteen (14) days to review and comment on the

proposed disclosure. DAIDS will require the Contractors to consult with PROVIDER, whenever the Contractor intends to include Results in any publication or other public disclosure such as a press release.

- 4.4 PROVIDER will not be identified in DAIDS or Contractor publications as the source of Material without PROVIDER's prior written approval.
- 4.5 PROVIDER will not construe the involvement of DAIDS in Evaluations as an endorsement of Material by the U.S. Government or any of its agencies, employees, or Contractors.
- 4.6 PROVIDER will include acknowledgement of DAIDS/NIAID/NIH and the contract number(s) providing support in any public disclosure (e.g., publication, press release, poster at a meeting).

## 5. Intellectual Property.

- 5.1 Subject to applicable law, PROVIDER shall retain all of PROVIDER's existing intellectual property rights to Material. DAIDS acknowledges that this Agreement may not be construed as a grant by the PROVIDER of a license or any other right or interest to the Material beyond those expressly set forth herein.
- 5.2 PROVIDER acknowledges that the Contractors have the right to elect to retain title to any new Invention(s) made under DAIDS sponsored contracts [37 CFR 401.14(b)]. However, Contractors have agreed to an "Intellectual Property Option" as part of their contracts with DAIDS. Under the Intellectual Property Option the Contractors are required to:
  - a. Promptly notify DAIDS and the PROVIDER of any new Invention(s) made by the Contractors in the performance of the Evaluations under this Agreement;
  - b. Grant PROVIDER a paid-up, nonexclusive, nontransferable, royalty-free, world-wide license to all such new Invention(s) for research purposes only; and
  - c. Grant PROVIDER a time-limited first option to negotiate an exclusive, worldwide royalty-bearing license to Contractor's interest in all such new Invention(s) for all commercial purposes, including the right to grant sub-licenses, on terms to be negotiated in good faith by PROVIDER and the Contractor.

## 6. Warranty and Limitation of Liability.

- 6.1 DAIDS acknowledges and agrees that the Material is experimental in nature. **PROVIDER 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.**
- 6.2 PROVIDER disclaims all liability for any claims, damages, or liability resulting from its activities under this agreement, unless caused by PROVIDER's gross negligence or willful misconduct. DAIDS shall be liable for any loss, claim, damage, or liability that DAIDS incurs as a result of its activities under this Agreement, except that DAIDS, as part of an agency of the United States, assumes liability only to the extent provided under the Federal Tort Claims Act, 28 U.S.C. §§ 2671 et seq.
- 6.3 No indemnification for any loss, claim, damage, or liability is intended or provided by DAIDS under this Agreement. DAIDS is prohibited under statute, the Anti-Deficiency Act 31 U.S.C. §1341, from indemnifying any party, absent other specific statutory authorization.

## 7. Term and Termination.

- 7.1 This Agreement will be in effect for five (5) years from the date of the last signature below.
- 7.2 DAIDS may terminate evaluations of Material based on demonstrated lack of efficacy, unanticipated toxicity, technical difficulties in performing Evaluations, lack of contract funds, or unavailability of resources. DAIDS shall notify PROVIDER in writing within five (5) business days of such a decision.

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

**8. Amendments.**

8.1 If DAIDS or PROVIDER 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 DAIDS and PROVIDER.

8.2 If PROVIDER desires to add Material or Evaluations not originally agreed to, prior approval from DAIDS is required and an amendment to this Agreement must be made. All terms and conditions of this Agreement will remain in full force and effect.

**9. Governing Law.**

The construction, validity, performance, and effect of this Agreement shall 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. The illegality or invalidity of any provisions of this Agreement shall not impair, affect, or invalidate the other provisions of this Agreement.

**10. Survivability.**

The provisions of Articles 3, 4, 5, 6, 9 and 10 will survive the termination or expiration of this Agreement.

**11. Points of Contact.**

**For DAIDS**

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

**For PROVIDER**

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

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

**The Division of AIDS (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH)**  
6700B Rockledge Drive  
Bethesda, MD 20892

**Insert PROVIDER Name**  
**Insert Address**

Authorized Signature:

Authorized Signature:

\_\_\_\_\_  
Carl W. Dieffenbach, Ph.D.  
Acting Director, DAIDS, NIAID

\_\_\_\_\_  
Name: \_\_\_\_\_

Date: \_\_\_\_\_

Title: \_\_\_\_\_  
Date: \_\_\_\_\_

## **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 the Article pertaining to the Intellectual Property Option to the Provider, 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 the 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 (1).

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.

### **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)**<sup>1</sup> 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 cause to be assigned to the Provider 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.**"

### **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.

<sup>1</sup>35 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.