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

RFP NIH-NIAID-DMID-07-18
Topical Microbicide Safety and Efficacy Evaluation in Nonhuman Primates

OMB control number 0990-0115

1. **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.** http://www.fedbizopps.gov/

2. **SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1**
NOTE: The issuance of this solicitation does not commit the government to an award.

3. **Issue Date:**	4. **Due Date:** **July 6, 2006** **Time:** 4**:00 p.m., EDT**	5. **Small Bus. Set-Aside:** [ ]Yes [X] No **8(a) Set-Aside:** [ ]Yes [X] No **NAICS #:** 541710 (See Part I, Section L.)
March 06, 2006		

6. **Just In Time:**	7. **Number of Awards:**	8. **Technical Proposal Page Limits:**
[X] No [ ] Yes (See Part IV, Section L.)	[X] Only 1 Award [ ] Multiple Awards	Number of Copies: See Part III, Section J (Packaging and Delivery of Proposal) Page Limits: See Appendix A.

9. **Issued By:**
Liem Nguyen, Contracting Officer
Office of Acquisitions, DEA
NIH, NIAID
6700-B Rockledge Drive
Room 3214, MSC 7612
Bethesda, MD 20892-7612

10. [X] **NIAID reserves the right to make awards without discussion.**

11. **Options:**
[X] No
[ ] Yes (See Part IV, Section L.)

12. **Period of Performance:**
7 years beginning on or about April 2, 2007

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : Suzanne L. Dawkins **Phone: 301-451-3698** **Fax: 301-480-4675** E-Mail: **sd33r@nih.gov**	**Name: Liem Nguyen** **Phone: 301-451-3687** **Fax: 301-402-0972** **E-Mail: lnguyen@niaid.nih.gov**	Charles W. Grewe Director, OA **Address (See block 9.)**

16. **COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.**

17. **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)**

18. **DELIVERY ADDRESS INFORMATION**

19. **Hand Delivery or Overnight Service:**	20. **U.S. Postal Service or an Express Delivery Service**
Suzanne L. Dawkins Office of Acquisitions, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Suzanne L. Dawkins Office of Acquisitions, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

21. **The Official Point of Receipt 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 HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.**

DETAILED TABLE OF RFP CONTENTS

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 PROPOSED CONTRACT DOCUMENT. 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. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR 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 solicitation is to re-compete the "Sexually Transmitted Diseases Prevention-Primate Unit" to further the development of topical microbicides aimed at the prevention and control of sexually transmitted infections through pre-clinical safety and efficacy testing in nonhuman primates.

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.

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 January 10, 2006, attached hereto and made a part of this Solicitation (See Section J - List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

(See RFP Attachment 5)

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.

As stated in the Statement of Work (Attachment 4), ship specimens (microbiological samples, plasma, serum, cells, etc.) to investigators as designated by the NIAID Project Officer or as designated in the approved protocol

using shipping conditions appropriate for preserving the specimens. Use biocontainment containers that comply with domestic postal regulations, and pertinent International Code Counsel (ICC) (www.iccsafe.orgwww.iccsafe.org) regulations. The shipping containers must provide the refrigeration levels needed for specific materials; this may include, ice, dry ice, etc. Shipments of sera, cells, blood and other tissues from nonhuman primates shall be made in accordance with proper biocontainment shipping procedures. Provide International Air Transport Association Dangerous Goods (www.iata.orgwww.iata.org) Regulations training for the shipping of hazardous materials.

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 (named upon award) is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at:

DMID, NIAID, NIH
6610 Rockledge Drive
Bethesda, MD 20892-6604

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

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

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. DELIVERIES

a. Satisfactory performance of this contract shall be deemed to occur upon performance of the work described in Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the [services/supplies/items] specified in the Delivery Schedule which are described in SECTION C of this contract.

b. Deliveries required by the contractor shall be made F.O.B. destination as set forth in FAR Clause 52.247-35, F.O.B. Destination, Within consignees Premises (April 1984) [and any specifications stated in SECTION D, PACKAGING AND MARKING AND SHIPPING, of this contract] to the address/addressee listed below:

DELIVERY POINT:

National Institutes of Health
National Institute of Allergy and Infectious Diseases
Building 6700-B, Room 3214
BETHESDA MD 20892- 7612

c. 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 5:30 p.m. EST only. Supplies or services scheduled for delivery on a Federal holiday shall be made the following day.

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

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. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

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

Any contract awarded from this RFP will contain the following:

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 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

Pursuant to the Key Personnel clause incorporated in this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

NAME TITLE

[To be specified prior to award]

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

a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The 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.

These instructions also provide for the submission of financial and personnel reporting required by HHSAR 342.7002.

(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. HHSN2662007XXXXXC.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand corner of the SF-26, i.e. N01-AI-7XXXX.)

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

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

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

OR

ARTICLE G.4 . LETTER OF CREDIT PAYMENT INFORMATION

a. Advance payments will be provided under Letter of Credit Number _____ in accordance with Alternate V, Advance Payments Without Special Bank Account, of FAR Clause 52.232-12, Advance Payments. This clause is provided in full text in Article I.4. of this contract.

The contractor shall withdraw funds pursuant to Department of Treasury Circular 1075 (31 CFR Part 205, http://www.access.gpo.gov/nara/cfr/waisidx_00/31cfr205_00.html).

ARTICLE G.5. CONTRACT FINANCIAL REPORT

a. Financial reports on the attached Form NIH 2706, Financial Report of Individual Project/Contract, shall be submitted by the Contractor in accordance with the Instructions for Completing Form NIH 2706, which accompany the form, in an original and two copies, not later than the 30th working day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories) which shall be reported within the total contract are listed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

b. Unless otherwise stated in that part of the Instructions for Completing Form NIH 2706, entitled "**PREPARATION INSTRUCTIONS**," all columns A through J, shall be completed for each report submitted.

c. The first financial report shall cover the period consisting of the first full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

e. The following is a listing of expenditure categories to be reported (specific elements will be determined prior to award):

Expenditure Category A	**Percentage of Effort/Hours Expended**
(1) Direct Labor	
(a) Principal Investigator	
(b) Co-Principal Investigator	
(c) Key Personnel	
(i)	
(ii)	
(iii)	
(2) Other Professional Personnel	
(3) Personnel - Other	

(4) Fringe Benefits
(5) Accountable Personal Property
(6) Materials/Supplies
(7) Patient Care Costs
(8) Travel
(9) Consultant Costs
(10) Premium Pay
(11) Computer Costs
(12) Subcontract Costs
(13) Other Direct Costs
(14) Indirect Costs
(15) G&A Expense
(16) Total Cost
(17) Fee
(18) Total Cost Plus Fixed Fee

f. The Government may unilaterally revise the NIH 2706 to reflect the allotment of additional funds.

ARTICLE G.6. INDIRECT COST RATES

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

Director, Division of Financial Advisory Services
Office of Contracts Management
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC 7540
BETHESDA MD 20892-7540

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

ARTICLE G.7. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the DHHS Publication (OS) 686, entitled, **Contractor's Guide for Control of Government Property**, which can be found at:

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

ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on 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 evaluations may be prepared every two years to coincide with the anniversary date of the contract. Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted 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. 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 46.208(a)(2) 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.3. 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.4. 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.5. 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.6. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

(1) The Small Business Subcontracting Plan, dated TBD 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), SF-294

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), SF-295

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

October 30th

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

sd33r@nih.gov
Contract Specialist, OA, DEA, NIAID

ARTICLE H.7. 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 Aindirect costs@ or Afacilities and administrative (F&A) costs@). Direct salary has the same meaning as the term Ainstitutional 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 No.**	**Fiscal Year**	**Dollar Amount of Salary Limitation***
	P.L. 109-149	[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.

For the period 10/1/05 - 12/31/05, the Executive Level rate is $180,100. Effective January 1, 2006, the Executive Level I rate increased to $183,500 and will remain at that rate until it is revised. See the web site listed below for the Executive Schedule rates of pay:

FOR FY-06 EXECUTIVE LEVEL SALARIES EFFECTIVE JANUARY 1, 2006:
http://www.opm.gov/oca/06tables/html/ex.asp
(Note: This site shows the FY-06 rates. For previous years, click on "salaries and wages" and then scroll down to the bottom of the page and click on the year to locate the desired Executive Level salary rates.)

ARTICLE H.8. INFORMATION SECURITY

The Statement of Work (SOW) requires the contractor to develop or access Federal automated information systems; therefore, the contractor shall comply with the ADHHS Information Security Program PolicyA (http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc) as set forth below. The contractor shall include this provision in any subcontract awarded under this contract.

a. Information Type

******** ***(NOTE: The resultant contract will include the Information Type, however for the purposes of this RFP, the Information Type is specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.)*** ********

[X] Administrative, Management and Support Information:

[X] Mission Based Information:

b. Security Categories and Levels

******** ***(NOTE: The resultant contract will include the Security Categories and Levels, however for the purposes of this RFP, the Security Categories and Levels are specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.)*** ********

Confidentiality	Level:	**[ ]** Low	**[X]** Moderate	**[ ]** High
Integrity	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Availability	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Overall	**Level:**	**[X] Low**	**[ ] Moderate**	**[ ] High**

c. Position Sensitivity Designations

(1) The following position sensitivity designations and associated clearance and investigation requirements apply under this contract:

******** ***(NOTE: The resultant contract will include the Position Sensitivity Designations, however for***

the purposes of this RFP, the Position Sensitivity Designations applicable to this RFP are specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.) ****

[ ] Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI). Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

[ ] Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

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

(2) The contractor shall submit a roster, by name, position and responsibility, of all IT staff working under the contract. The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 days of the effective date of the contract. Any revisions to the Roster as a result of staffing changes shall be submitted within fifteen (15) calendar days of the change. The Contracting Officer shall notify the contractor of the appropriate level of suitability investigations to be performed. An electronic template, ARoster of Employees Requiring Suitability Investigations,@ is available for contractor use at:
http://ais.nci.nih.gov/forms/Suitability-roster.xls

Upon receipt of the Government=s notification of applicable Suitability Investigation required, the contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the ANIAID Information Technology Security Policies, Background Investigation Process@ website: http://ais.nci.nih.gov.

(NOTE: The website listed at http://ais.nci.nih.gov provides information about IT Security Policies and the background investigation process. NCI points of contact do not apply to this acquisition. Contact your NIAID contract specialist for applicable contact information.)

Contractor employees who have had a background investigation conducted by the U.S. Office of Personnel Management (OPM) within the last five years may only require an updated or upgraded investigation.

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

Levels 5 and 1: Contractor employees may begin work under the contract after the contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c.(2) above.
Level 6: In special circumstances the Project Officer may request a waiver of the preappointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the contractor employee to work under the contract.

d. Systems Security Plan

The contractor shall protect Federal automated information systems that are developed or accessed by the contractor. System security shall be accomplished in accordance with the contractor=s System Security Plan dated (upon award). The plan must:

(1) Include a detailed plan of present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. The contractor shall use the **NIH Systems Security Plan Template** (detailed) at http://irm.cit.nih.gov/security/secplantemp.doc or **NIH Systems Security Plan Outline** (outline only) at http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc.

OR *(To be determined during negotiations)*

(1) Include a plan of present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed include, but are not limited to administrative, technical, and physical security as follows:

(i) Security Awareness Training
(ii) Logical Access Control
-Network (ex: firewall)
-System (ex: network OS, tcp wrappers, SSH)
-Application (ex: S-LDAP, SSL)
-Remote Access (ex: VPN)
-Monitoring and support (ex: IDS, pager, NOC)
(iii) Protection against data loss
-OS security (ex: patch management, configuration)
-Application security (ex: patch management)
-Database security
-Back-up and recovery
-Fault tolerance, high availability
(iv) Malicious Code Protection (ex: Antivirus, filtering of e-mail attachments, etc)
(v) Physical Security
-Access control (ex: locks, guards)
-Power conditioning and/or UPS
-Air conditioning
-Fire protection

Include an acknowledgment of its understanding of the security requirements.

Provide similar information for any proposed subcontractor developing or accessing an AIS.

e. Rules of Behavior

The contractor shall comply with the **NIH Information Technology General Rules of Behavior** at: http://irm.cit.nih.gov/security/nihitrob.html.

f. Information Security Training

Each contractor employee shall complete the NIH Computer Security Awareness Training (http://irtsectraining.nih.gov/) prior to performing any contract work, and on an annual basis thereafter, during the period of performance of this contract.

The contractor shall maintain a listing by name and title of each individual working under this contract that has completed the NIH required training. Any additional security training completed by contractor staff shall be included on this listing.

Contractor staff shall complete the following additional training prior to performing any work under this contract:
******* Additional courses will be listed here in the resultant contract, if applicable. *******

g. Personnel Security Responsibilities

The contractor shall perform and document the actions identified in the AEmployee Separation Checklist@, attached and made a part of this contract, when a contractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request

h. Commitment to Protect Departmental Information Systems and Data

(1) Contractor Agreement
The Contractor shall not release, publish, or disclose sensitive Department information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any

other pertinent laws and regulations governing the confidentiality of sensitive information:

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

(2) Contractor-Employee Non-Disclosure Agreements

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

i. References

1. DHHS Information Security Program Policy: http://www.hhs.gov/ohr/manual/pssh.pdf
2. DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
3. NIST Special Publication 800-16, Information Technology Security Training Requirements: http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
   Appendix A-D: http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf
4. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: http://csrc.nist.gov/publications/nistpubs/index.html
5. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf
6. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf
7. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle: http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf
8. NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/
9. Roster of Employees Requiring Suitability Investigations: http://ais.nci.nih.gov/forms/Suitability-roster.xls
10. NIAID Information Technology Security Policies, Background Investigation Process: http://ais.nci.nih.gov/
11. NIH Systems Security Plan Template (detailed): http://irm.cit.nih.gov/security/secplantemp.doc
12. NIH Systems Security Plan Outline (outline only): http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc
13. NIH Information Technology General Rules of Behavior: http://irm.cit.nih.gov/security/nihitrob.html
14. Commitment To Protect Non-Public Information - Contractor Agreement: http://irm.cit.nih.gov/security/Nondisclosure.pdf

ARTICLE H.9. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

****** (Select the appropriate phrase within the brackets below and complete if necessary.) ******

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) all Electronic and Information Technology (EIT) developed, procured, maintained and/or used under this contract shall be in compliance with the AElectronic and Information Technology Accessibility Standards@ set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the AAccess Board@) in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at: http://www.access-board.gov/.

The standards applicable to this requirement are identified in the Statement of Work.

ARTICLE H.10. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR 352.224-70, Confidentiality of Information (MARCH 2005):

ARTICLE H.11 . CONSTITUTION DAY

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

ARTICLE H.12. PUBLICATION AND PUBLICITY

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. (number provided upon award).

ARTICLE H.13. 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.14. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

ARTICLE H.15. 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.16. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

a. Sharing of Model Organisms for Biomedical Research

The contractor=s data sharing plan, dated_____, is hereby incorporated by reference. The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

ARTICLE H.17. SHARING RESEARCH DATA

The data sharing plan submitted by the contractor is acceptable. The contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data that must be shared with the public and other researchers. NIH's data sharing policy may be found at the following Web site:

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

NIH recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Privacy Rule at http://www.hhs.gov/ocr/). The rights and privacy of people who participate in NIH-funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

ARTICLE H.18. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

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

For prime or subcontract awards to ***domestic institutions*** that possess, use, and/or transfer Select Agents under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf), as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

For prime or subcontract awards to ***foreign institutions*** that possess, use, and/or transfer Select Agents under this contract, before using NIH funds for any work directly involving the Select Agents, the foreign institution must provide information satisfactory to the NIAID, NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at:
(http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf)

are in place and will be administered on behalf of all Select Agent work sponsored by these funds. The process for making this determination includes inspection of the foreign laboratory facility by an NIAID representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the laboratory facility inspection, and the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf). The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No NIH funds can be used for research involving Select Agents at a foreign institution until NIAID grants this approval.

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

ARTICLE H.19. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

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

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

ARTICLE H.20. 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://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT
FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.arnet.gov/far/.

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Jul 2004	Definitions (Over $100,000)
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Sep 2005	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.204-7	Oct 2003	Central Contractor Registration
52.209-6	Jan 2005	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Oct 2004	Pension Adjustments and Asset Reversions
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other

		than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jul 2005	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-21	Feb 1999	Prohibition of Segregated Facilities
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over $100,000)
52.225-1	Jun 2003	Buy American Act - Supplies
52.225-13	Mar 2005	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims

52.232-25	Oct 2003	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate I (January 2006)
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.244-6	Dec 2004	Subcontracts for Commercial Items
52.245-5	May 2004	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
52.245-9	Aug 2005	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.216-72	Oct 1990	Additional Cost Principles
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publications and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - Rev. 01/2006.

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 clause(s) will be made part of the resultant contract:

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.

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.

FAR Clause **52.216-7, Allowable Cost And Payment** (December 2002), is modified in paragraph (a). The reference to Subpart 31.2 is changed to Subpart 31.3.

Alternate II (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (July 2005) is added.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

(1) FAR Clause **52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns** (July 2005).

"(c) Waiver of evaluation preference.....

[ ] Offeror elects to waive the evaluation preference."

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

(3) **Alternate III** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

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

(5) **Alternate IV** (June 1987), of FAR Clause **52.227-14, Rights In Data--General** (June 1997) (excludes software).

(6) **Alternate V** (June 1987), FAR Clause **52.227-14, Rights in Data--General** (June 1987).

(7) HHSAR Clause **352.223-70, Safety and Health** (January 2001).

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

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

(9) FAR Clause **52.245-1, Property Records** (April 1984).

(10) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).

(11) FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).

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

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

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

(2) HHSAR Clause **352.270-9, Care of Live Vertebrate Animals** (March 2005).

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) (OMB Bulletin 81-16).

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.nlrb.gov.

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

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

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

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

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

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

(4) Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and
(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

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

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

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 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:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	Linked to the Attachment Title
Attachment 2:	Proposal Intent Response Sheet	Linked to the Attachment Title
Attachment 3:	Background	Linked to the Attachment Title
Attachment 4:	Statement of Work	Linked to the Attachment Title
Attachment 5:	Reporting Requirements and Deliverables	Linked to the Attachment Title
Attachment 6:	Appendix A	Linked to the Attachment Title
Attachment 7:	Appendix B	Linked to the Attachment Title

TECHNICAL PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Technical Proposal.)

Attachment No.	Title	Location
Attachment 8:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 9:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 10:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 11:	Project Objectives, NIH 1688-1	http://www.niaid.nih.gov/contract/forms/form1688.doc

BUSINESS PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Business Proposal.)

Attachment No.	Title	Location
Attachment 12:	Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Attachment 13:	Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/sb-subplan-nci.pdf
Attachment 14:	Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://www.niaid.nih.gov/contract/forms.htm http://ocm.od.nih.gov/contracts/spsh/spshexcl.xls
Attachment 15:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Attachment 16:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS: (The following Attachments and Reports will become part of any contract resulting from this RFP and will be required during contract performance.)

Attachment No.	Title	Location
Attachment 17:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 18:	Financial Report of Individual Project/Contract, NIH 2706	http://www.niaid.nih.gov/contract/forms/nih-2706.pdf
Attachment 19:	Instructions for Completing Form NIH 2706	http://www.niaid.nih.gov/contract/forms/instructions2706.pdf
Attachment 20:	Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Attachment 21:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 22:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sfllllin.pdf
Attachment 23:	Commitment To Protect Non-Public Information - Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Attachment 24:	Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Attachment 25:	Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

SECTION K 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.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE SECTION K AND SUBMIT IT AS PART OF YOUR BUSINESS PROPOSAL.

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 legend, specifying the particular portions of the proposal

which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> 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 should mark each page of data it wishes to restrict with the following statement:

> AUse 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 legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(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.

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.

b. **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that one award will be made from this solicitation and that the award will be made on/about April 2, 2007.

It is anticipated that the award from this solicitation will be a multiple-year cost reimbursement type contract with a period of performance of seven years, and that incremental funding will be used (see Section L.2.c. Business Proposal Instructions).

c. **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 2.5 FTEs per annum. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

d. **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.

e. **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.

f. **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.

g. **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.

h. **PREPARATION COSTS**

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

i. **SERVICE OF PROTEST** (AUGUST 1996) - FAR 52.233-2

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

Contracting Officer
Office of Acquisitions

National Institute of Allergy and Infectious Diseases
6700-B Rock;ledge Drive, MSC 7612
Bethesda, MD 20892-7612

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

j. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

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 offers significant cost or technical advantages 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.

k. **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 541710.
(2) The small business size standard is 500 employees.

l. **POTENTIAL AWARD WITHOUT DISCUSSSIONS**

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

m. **ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

n. **SHARING OF MODEL ORGANISMS FOR BIOMEDICAL RESEARCH**

The NIH Research Tools Policy, also referred to as Principles and Guidelines for Recipients of NIH Research Grants and Contracts on Obtaining and Disseminating Biomedical Research Resources: Final Notice, December 1999, supports the concept of timely sharing and distribution of research resources. In accordance with NIH Guide Notice NOT-OD-04-042, dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066, the NIH provides further sharing guidance with particular attention on model organisms

for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

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

- Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) (http://ott.od.nih.gov/NewPages/Rtguide_final.html#sla) for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (http://ott/od/nh/gov/NewPages/UMTA.pdf)

- How will inappropriate Areach-through@ requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?

- How will technologies remain widely available and accessible to the research community, for example, if any intellectual property rights arise for which a patent application may be filed?

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

o. **IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled, AInformation Security.@**

The Statement of Work (SOW) requires the successful offeror to develop or access Federal automated information systems. Pursuant to the DHHS Information Security Program Policy (http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc), the following requirements apply:

(a) Information Type

[X] Administrative, Management and Support Information:

[X] Mission Based Information:

(b) Security Categories and Levels

Confidentiality	Level:	**[ ]** Low	**[X]** Moderate	**[ ]** High
Integrity	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Availability	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Overall	**Level:**	**[X] Low**	**[ ] Moderate**	**[ ] High**

(c) Position Sensitivity Designations

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

[ ] Level 6: Public Trust - High Risk (Requires Suitability Determination with a BI). Contractor employees assigned to a Level 6 position are subject to a Background Investigation (BI).

[ ] Level 5: Public Trust - Moderate Risk (Requires Suitability Determination with NACIC, MBI or LBI). Contractor employees assigned to a Level 5 position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), a Minimum Background Investigation (MBI), or a Limited Background Investigation (LBI).

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

Upon award, the contractor will be required to submit a roster of all IT staff working under the contract. The Government will determine the appropriate level of suitability investigation required for each staff member.

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

(d) Systems Security Plan

The offeror=s proposal must:

(1) Include a detailed plan of its present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. Offerors must use:
NIH Systems Security Plan Template (detailed) at:
http://irm.cit.nih.gov/security/secplantemp.doc; or
NIH Systems Security Plan Outline (outline only) at:
http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc.

OR (to be determined during negotiations)

(1) Include a plan commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed include, but are not limited to administrative, technical, and physical security as follows:

(i) Security Awareness Training
(ii) Logical Access Control
-Network (ex: firewall)
-System (ex: network OS, tcp wrappers, SSH)
-Application (ex: S-LDAP, SSL)
-Remote Access (ex: VPN)
-Monitoring and support (ex: IDS, pager, NOC)
(iii) Protection against data loss
-OS security (ex: patch management, configuration)
-Application security (ex: patch management)
-Database security
-Back-up and recovery
-Fault tolerance, high availability
(iv) Malicious Code Protection (ex: Antivirus, filtering of e-mail attachments, etc)
(v) Physical Security
-Access control (ex: locks, guards)
-Power conditioning and/or UPS
-Air conditioning
-Fire protection

Include an acknowledgment of its understanding of the security requirements.
Provide similar information for any proposed subcontractor developing or accessing an AIS.

The SSP that the offeror must submit with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

(e) Information Systems Security Training

DHHS policy requires contractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor employee has completed the NIH Computer Security Awareness Training course(http://irtsectraining.nih.gov/) prior to performing any contract work, and on an annual basis thereafter, during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

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

p. **REFERENCES**

(1) DHHS Information Security Program Policy: http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc
(2) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(3) NIH Systems Security Plan Template: http://irm.cit.nih.gov/security/secplantemp.doc
(4) NIH Systems Security Plan Outline: http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc
(5) NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/
(6) NIST Special Publication 800-16, Information Technology Security Training Requirements: http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
Appendix A-D: http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf
(7) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: http://csrc.nist.gov/publications/nistpubs/index.html
(8) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf
(9) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf
(10) NIST SP 800-64, Security Considerations in the Information System Development Life Cycle: http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf

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**Error! Bookmark not defined.

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 technical portion of each 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 proposal.

A list of the five most relevant contracts completed during the past three years and all contracts currently in process 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 that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

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. NAICS Code

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as a subcontract **not** over $500,000. .

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

b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. 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.arnet.gov/far/.

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

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 AGovernment 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 ASummary of Objectives@ portion of the form MUST meet the requirements set forth in the section of the form entitled, **AINSTRUCTIONS:@**

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) 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 the Technical Evaluation Criteria (Section M. hereof).

(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) **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 (Revised 1986, Reprinted 2000)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, 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 PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER, OLAW. 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 OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

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

- identification of the species and approximate number of animals to be used;
- rationale for involving animals, and for the appropriateness of the species and numbers used;
- a complete description of the proposed use of the animals;
- a description ofprocedures 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.

(a) **Sharing Research Data**

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

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

(6) **Obtaining and Disseminating Biomedical Research Resources**

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

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

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090]) will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

(7) **Possession, Use and Transfer of Select Biological Agents or Toxins**

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

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

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

9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins (relating to human and animal health, animal health or animal products)

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

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

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

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

Domestic Institutions

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

$ include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.

$ comply with 42 CFR part 73, 7 CFR part 331 and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf, as required, before using NIH funds for research involving Select Agents. No NIH funds can be used for research involving Select Agents if the final registration certificate is denied.

Foreign Institutions

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

$ include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.

$ when requested during negotiations, provide information satisfactory to the NIAID/NIH that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf for U.S. institutions are in place and will be administered on behalf of all Select Agent work under the resulting contract. The process for making this determination includes inspection of the foreign laboratory facility by an NIAID representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents.

An NIAID-chaired committee of U.S. federal employees (including representatives of NIH grants/contracts and scientific program management, CDC , Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the facility inspection, the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at:
http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf.
The committee will provide recommendations to the DEA Director, NIAID. The DEA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No NIH funds can be used for research involving Select Agents at a foreign institution until NIAID grants this approval.

(8) Offerors should submit all technical questions concerning this solicitation in writing to the contract specialist. NIAID should receive all questions no later than 60 calendar days after the RFP release date. NIAID will answer questions which may affect offers in an amendment to the solicitation. NIAID will not reference the source of the questions.

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

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

(2) 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.

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

1. **Direct Labor**

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

2. **Materials**

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

3. **Subcontracted Items**

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

4. **Raw Materials**

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

5. **Purchased Parts**

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

6. **Fringe Benefits**

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

7. **Indirect Costs**

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

8. **Special Equipment**

If direct charge, list any equipment 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.

(3) **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.

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

(b)(1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(3) Cost and Pricing Data, subparagraph b. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(4) **Salary Rate Limitation in Fiscal Year 2006**

Offerors are advised that pursuant to P.L. 109-149, no NIH Fiscal Year 2006 (October 1, 2005 - September 30, 2006) 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. 109-149 applies only to Fiscal Year 2006 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 limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 109-149 states in pertinent part:

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

LINK TO EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/06tables/indexSES.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 2006 Executive Level I Salary rates.*

(5) **Small Business Subcontracting Plan**

Specific instructions for the submission of this document are outlined in SECTION L.1.a. of this RFP.

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the apparent successful 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, Attachment 13 to this RFP is 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 $500,000 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.

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

23% for Small Business; 5% for Small Disadvantaged Business;5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(6) **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.

(7) **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($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 AExtent 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) code, 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 Subsector(s). The applicable authorized NAICS 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 Subsector 223

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

*Note: FAR Subpart 9.6 defines AContractor 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.

(8) **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.

(9) **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)," which can be found at:
http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm

c) **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.

d) **Financial Capacity**

The offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

e) **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 provisions are applicable:

HHSAR 352.232-75, Incremental Funding (January 2001)

(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. 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. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract shall supersede the Limitation of Cost clause found in the General Provisions.

(End of provision)

f) **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.

[ ] 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).

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(10) **Subcontractors**

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

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

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

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

d) Information on their cognizant field audit offices.

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

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

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

(11) **Proposer's Annual Financial Report**

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

(12) **Representations and Certifications**

One copy of the Representations and Certifications attached as Section K shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of the Representations and Certifications shall be submitted from any proposed subcontractor.

(13) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

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

b) **Travel Policy**

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

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost/price, past performance, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, past performance and SDB participation are also important to the overall contract award decision. All evaluation factors, other than cost/price, when combined, are significantly more important than cost or price. In any event, the Government reserves the right to make an award to that Offeror whose proposal provides the best overall value to the Government.

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

2. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the Technical Evaluation Committee when reviewing Technical Proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria listed below are in the order of relative importance with weights assigned for evaluation purposes.

Offerors and reviewers are advised to refer to Appendix A – Additional Technical Proposal Instructions of this solicitation package for guidance and information related to the preparation and format of Technical Proposals**.**

CRITERIA **WEIGHT**

A. TECHNICAL APPROACH AND UNDERSTANDING OF THE PROBLEM **50 Points**

1. Soundness, adequacy, and strength of the Offeror's understanding of the Statement of Work and the proposed methodologies and technical approaches to conduct the tasks of the Statement of Work, with respect to the following: *[30 pts]*

    a) Plans for the acquisition of nonhuman primates, including a description of the proposed source and species of nonhuman primates, any past history of sources previously used; and procedures to assure animals are free of tuberculosis infection.
    b) Procedures for monitoring and care, dosing, treatment, postmortem evaluations, euthanasia, and disposition of nonhuman primates.
    c) Approaches to the development and conduct of protocols;
    d) Methods and approaches for laboratory support; including a sample Laboratory Support SOP;
    e) Procedures and capabilities for storage, including a sample Storage SOP, shipping, and inventory of candidate topical microbicides, pathogen stocks, and animal specimens.
    f) Plans for the orderly transition to another contractor or to the Government upon completion of the contract.

2. Adequacy, feasibility, and innovativeness of experimental design in the two detailed sample protocols, sample SOPs to support the sample protocols, procedure for developing challenge stock of the proposed infectious agent, sample Protocol Completion Reports for Safety and Efficacy, and other described methods used to analyze experimental data and determine the efficacy and toxicity of candidate topical microbicides to prevent STIs. *[20pts]*

B. PERSONNEL **20 Points**

1. Principal Investigator: Adequacy, appropriateness and relevance of experience, education,

and training for the successful performance of the Statement of Work, including:

a) quality of recent work, i.e., number and impact of publications in the last 5 years;
b) ability to conduct *in vivo* and *in vitro* experimental methods and designs;
c) demonstrated scientific capability in the conduct of safety and efficacy evaluations in nonhuman primate models of sexually transmitted infections;
d) experience in housing and caring for nonhuman primates for topical microbicide safety and efficacy studies;
e) availability for the proposed work;
f) participation in similar projects; and
g) experience in managing and coordinating a team effort.

2. Other professional, research, technical and support staff: appropriate spectrum of expertise, qualifications, experience and availability necessary to conduct the proposed studies; and documented capability to conduct the proposed studies including capability for the monitoring and care of nonhuman primates.

C. PROJECT MANAGEMENT

15 Points

Adequacy, thoroughness and appropriateness of the plans and procedures for overseeing, monitoring, and managing a state-of-the art nonhuman primate facility for preclinical testing of topical microbicides with respect to the following:

1. The proposed overall project organization and staffing and plans and procedures for close monitoring, coordination and management of all contract activities.

2. The proposed mix and balance of key personnel in relation to their specific responsibilities and time commitments.

3. Communication with the NIAID Project Officer and NIAID Contracting Officer.

4. A plan for the maintenance of confidentiality for the data.

D. FACILITIES, OTHER RESOURCES, SAFETY and TRAINING **15 Points**

1. Soundness, adequacy and strength of the proposed plan for the provision of appropriate housing for a total of approximately 72 nonhuman primates, including the housing of multiple species.

2. Availability, adequacy, and suitability of facilities, equipment and other resources for the preclinical testing and evaluation of topical microbicides as specified in the Statement of Work, including documentation of capacity for accomplishment of the stated tasks in a timely and efficient manner.

3. Availability and access to required biocontainment laboratories, and an AAALAC-accredited and OLAW-compliant animal facility with necessary biocontainment capabilities.

4. Adequacy of the training programs for the safe handling of pathogenic microorganisms, potentially infectious specimens, and infected nonhuman primates.

5. Adequacy of the security system to ensure 24-hour per day, seven days a week prevention of unauthorized entry into the facility.

TOTAL POSSIBLE POINTS: **100 Points**

Other Factors:

3. EVALUATION OF DATA SHARING PLAN

The Offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy. If your proposal does not include a plan or if the plan in your proposal is considered “unacceptable,” and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government

holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award. The following web site provides guidance on data sharing and additional information on the implementation of this policy: http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm.

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

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

If your proposal does not include a plan, appropriate reasons for restricting sharing, or, if the plan in your proposal is considered "unacceptable," and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan for sharing model organisms during discussions and in your Final Proposal Revision (FPR). If your plan for sharing model organisms is still considered "unacceptable," or your justification for restricting sharing is still considered inappropriate by the Government after discussions, your proposal may not be considered further for award. The following web site provides guidance on sharing model organisms and additional information about this policy: http://grants.nih.gov/grants/policy/model_organism/index.htm.

5. PAST PERFORMANCE FACTOR

An evaluation of each Offeror's 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 judgment by the Government after consideration of relevant information.

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

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

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

6. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

Small Disadvantage Business (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) Complexity and variety of the work SDB concerns are to perform; and
(b) 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

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 IS NOT ACCEPTABLE.

A. EXTERNAL PACKAGE MARKING:

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

"**RFP NO. NIH-NIAID-DMID-07-18**
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. PAPER COPIES and CD-Rom to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Suzanne L. Dawkins Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, Maryland 20817	Suzanne L. Dawkins 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:

TECHNICAL PROPOSAL PAGE LIMITS (see table below).

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

TOTAL PAGE COUNT DOES NOT INCLUDE: 1 Cover and Back Page; 1 Table of Contents; Section Dividers that do not contain information other than title of Section.

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.

The number of copies required of each part of your proposal are as specified below.

Document	Number of Copies	Page Limits
Technical Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Sixteen (16) Compact Disks containing an electronic copy of the Technical Proposal in a Portable Document Format (PDF) [NOTE: 1 file on each disk.]	Limited to not-to-exceed 200 pages **including all appendices.**
Technical Proposal Appendices Any materials not available electronically (i.e. SOPs, Pertinent Manuals, Non-scannable Figures or Data, and Letters of Collaboration/Intent also count in the page limit).	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Sixteen (16) Compact Disks containing an electronic copy of the Appendices in a Portable Document Format (PDF) [NOTE: 1 file on each disk.] If any Appendices are not available electronically, 16 hard copies of each page must be provided.	[NOTE: Included in the 200 total page count.]
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** One (1) Compact Disks containing an electronic copy of the Business Proposal in a Portable Document Form (PDF).	N/A
Breakdown of Proposed Estimated Cost	This Attachment should be submitted also as a separate Excel file on the Business Proposal Compact Disk.	N/A

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-07-18
RFP Title: "**Topical Microbicide Safety and Efficacy Evaluation in Nonhuman Primates**

Please review the attached Request for Proposal. Furnish the information requested below and return this page by June 5, 2006. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

As a reminder, Offerors should submit all technical questions concerning this solicitation in writing to the contract specialist. NIAID should receive all questions no later than 60 calendar days after the RFP release date. NIAID will answer questions which may affect offers in an amendment to the solicitation. NIAID will not reference the source of the questions.

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

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

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

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

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

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____
_____
_____
_____
(Continue list on a separate page if necessary)

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

Attn: Suzanne Dawkins
RFP-NIH-NIAID-DMID-07-18
FAX# (301) 480-4675
Email : sd33r@nih.gov

BACKGROUND

The mission of the Sexually Transmitted Infections (STI) program of the Division of Microbiology and Infectious Diseases (DMID), National Institute of Allergy and Infectious Diseases (NIAID), is to foster, develop, and administer a research program that will contribute to the reproductive health of people and specifically lead to prevention and control of STIs. The broad, public health goals of the research program are:

- Prevention of STIs
- Prevention of Pelvic Inflammatory Disease (PID), adverse outcomes of pregnancy, and infertility
- Prevention of Human Immunodeficiency Virus (HIV) infection
- Prevention of neonatal infections
- Prevention of other chronic STI sequelae

In order to accomplish this mission, new biomedical strategies for primary prevention of STIs, i.e., prevention of infection, must be developed and evaluated. Strategies for prevention of infection/disease include topical microbicides, defined as gels, creams or foams for intravaginal use, and barrier devices.

The nonhuman primate animal models for STIs and Simian Immunodeficiency Virus/Simian-Human Immunodeficiency Virus (SIV/SHIV) infection represent a valuable paradigm for studying infection and disease, prevention strategies, and therapeutic interventions. This crucial, but limited, nonhuman primate model resource is reserved for: (1) studies that cannot be addressed in small animal models (parameters not feasible in small animals for prevention of sexual transmission); (2) topical microbicides or therapeutic prevention approaches where "proof of concept" in a primate model would provide critical information to stimulate further development and evaluation in clinical trials; and/or (3) testing of candidates that have proven most promising in small animal models, or candidates in an advanced stage of development that require further evaluation.

The purpose of this solicitation is to re-compete the “Sexually Transmitted Diseases Prevention – Primate Unit” contract (N01-AI-95388) awarded to the University of Washington in September 1999 and due to expire on May 31, 2007. Under this contract, over 30 topical microbicides have been tested in nonhuman primate models, approximately half for safety alone, and half for safety and efficacy against Chlamydia infection. A highlight of the testing has been that data obtained from the safety evaluation in this nonhuman primate model helped to guide the choice of microbicide gel concentration that is being evaluated in a Phase II/IIb trial conducted in the NIAID-supported HIV Prevention Trials Network (HPTN) (http://www.hptn.org). In addition, the choice of concentration of another microbicide gel being advanced through Phase I clinical trials was made based on results from safety evaluations conducted in these nonhuman primates.

Safety and efficacy evaluation in nonhuman primates of topical microbicides represents one step in the product development pipeline. DMID and the NIAID Division of AIDS (DAIDS) support an integrated product development program with the goal of developing topical microbicides for the prevention of HIV and STIs. Additional information on NIAIDs topical microbicide development program is provided in the following links: NIAID Topical Microbicide Strategic Plan - http://www.niaid.nih.gov/publications/topical_microplan.pdfhttp://www.niaid.nih.gov/publications/topical_microplan.pdf ; DMID/STI website - http://www.niaid.nih.gov/dmid/stds/http://www.niaid.nih.gov/dmid/stds/ ; INTEGRATED

PRECLINICAL/CLINICAL PROGRAM FOR TOPICAL MICROBICIDES - http://grants2.nih.gov/grants/guide/pa-files/PAR-03-137.htmlhttp://grants2.nih.gov/grants/guide/pa-files/PAR-03-137.html .

One (1) award for a term of seven (7) years is expected to be made on or about April 2, 2007. This new contract will expand to include testing for topical microbicide efficacy against Trichomonas vaginalis, SIV/SHIV, and other sexually-transmitted infectious organisms as new animal models are developed and validated. This contract will aid the development of candidate topical microbicides and prepare them for clinical trials and eventual licensesure by the Food and Drug Administration (FDA).

STATEMENT OF WORK

January 10, 2006

INTRODUCTION

The objective of this requirement is to award a contract to further the development of topical microbicides aimed at the prevention and control of sexually transmitted infections (STIs) through pre-clinical testing in nonhuman primates. Candidates to be evaluated through this contract include topical microbicides (defined as gels, creams or foams for intravaginal use) and barrier devices. The contract shall provide a nonhuman primate resource for evaluating the safety and efficacy of topical microbicides for vaginal use in the well-characterized nonhuman primate models. Current nonhuman primate efficacy models supported by NIAID contracts include Chlamydia trachomatis, Trichomonas vaginalis, and Simian Immunodeficiency Virus/Simian-Human Immunodeficiency Virus (SIV/SHIV).

Topical microbicides for evaluation will be provided by or through the NIAID. These products may be the result of work under other NIAID-supported contracts or grants, commercially available products, proprietary compounds, or other sources selected by the NIAID Project Officer. Publication of articles, confidentiality of data, patent rights, intellectual property rights and the protection of proprietary data shall be governed by the paragraphs in the Statement of Work below and applicable clauses contained in the contract document.

SCOPE

The scope of work to be performed includes preclinical testing (safety and efficacy) of topical microbicides, with or without barrier devices, using nonhuman primate models. The existing contract includes efficacy evaluations for the pathogen Chlamydia trachomatis. Advances in model development since the award of the existing contract has lead to an expansion in the scope of efficacy testing to include Trichomonas vaginalis, gonorrhea, syphilis, chancroid, Human Papilloma Virus (HPV) infection, Herpes Simplex Virus (HSV) 1 and HSV 2, SIV/SHIV, organisms associated with Bacterial Vaginosis (BV), and other sexually-transmitted infectious organisms. Efficacy testing against these organisms shall be conducted as well-characterized, appropriate animal models are identified. The Contractor shall use state-of-the-art techniques and technologies in evaluating promising topical microbicides in nonhuman primate models and incorporate new and improved techniques and technologies into the contract activities.

This contract will NOT support the development of new or improved nonhuman primate models for efficacy testing of topical microbicides for the prevention and control of STIs.

TECHNICAL REQUIREMENTS

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

1. Acquisition, Testing, Housing, and Maintenance of Nonhuman Primates

a. Acquire, house and maintain nonhuman primates for protocols to be conducted under this contract. Primary emphasis shall be on rhesus macaques (Macaca mulatta) and pig-tail macaques (Macaca nemestrina). While rhesus macaques (Macaca mulatta) of Indian origin will be emphasized in this contract, because of the continuing shortage of these animals, the Contractor may be requested to house and conduct studies utilizing Chinese-origin macaques, or other nonhuman primate species such as cynomolgus monkeys (Macaca fascicularis), African green monkeys (Cercocebus atys) or

baboons. The decision of which nonhuman primate species to be used for a study will be made jointly by the NIAID Project Officer, the supplier of the topical microbicide, and the Contractor, with the NIAID Project Officer having the final approval authority.

b. Provide nonhuman primates documented to be free of tuberculosis (TB). Testing of all animals maintained under this contract for TB shall be done on a quarterly basis. Animals that test positive for TB shall be euthanized as soon as possible, with timely notification of the NIAID Project Officer. Animals shall be free of other infectious agents as required by the protocol.

c. Quarantine the nonhuman primates as they arrive at the Contractor's facility. While in quarantine, conduct sequential TB testing to confirm TB-free status.

d. Provide well-equipped and maintained AAALAC (Association for the Assessment and Accreditation of Laboratory Animal Care)-accredited facilities, and staff for the maintenance and care of the animals on protocols at appropriate safety levels. House all animals in appropriate biohazard containment facilities and ensure that all personnel are trained in the appropriate biological safety level procedures for the infectious agents under study.

e. Provide technical and veterinary staff for the care of the nonhuman primates, including routine health surveillance, performance of routine procedures, and post-mortem examinations. Provide for (on-call) veterinary coverage for the animal facility 24-hours per day, seven days a week. Provide at least daily observation of the health status of each animal, including weekends and holidays. Record and maintain clinical observations for each animal including the animal's health status, any treatments received, the results of periodic weighing and any other care or procedures required in the experimental design of the protocol. The NIAID Project Officer shall be notified within a week of any untoward findings.

f. At the termination of a protocol, dispose of animals under study as indicated in approved protocols or as specified by the NIAID Project Officer.

g. Provide animal care in compliance with the Office of Laboratory Animal Welfare (OLAW) "The PHS Policy on Humane Care and Use of Laboratory Animals," Amended August, 2002. Other documents that are relevant to PHS Policy include: *Guide for the Care and Use of Laboratory Animals*; United States Government Principles for the Utilization and Care of Vertebrate Animals; Animal Welfare Regulations and Report of the AVMA Panel on Euthanasia. Visit the OLAW website for clarity: http://grants.nih.gov/grants/olaw.

h. Provide and manage a 24-hour per day, seven days a week, security system to prevent unauthorized entry into the animal care facility.

i. Support per diem costs and associated care-related costs for off-site housing of nonhuman primates when agreed upon by the NIAID Project Officer and the Contractor's Principal Investigator (PI). This may include charges paid to a nonhuman primate breeding colony to maintain a breeding group of nonhuman primates intended solely for use by the Contractor; per diem charges paid to a nonhuman primate facility to house nonhuman primates that have been purchased by the Contractor but are too young to use for studies; and per diem costs for animals that have been purchased from breeding facilities or other sources and need to be housed temporarily until space becomes available to move them into the Contractor's facility.

2. Development of Protocols and Standard Operating Procedures

Develop protocols for testing the safety and efficacy of topical microbicides in conjunction with the NIAID Project Officer, other appropriate NIAID staff and other collaborators recognized by the NIAID Project Officer.

a. Within two (2) weeks of receiving a request from the NIAID Project Officer for initiation of protocol development, develop and submit the protocol for approval. Obtain written approval of each study protocol from the NIAID Project Officer before initiation of the study and assign a protocol identification number. The protocol shall consist of:

1) an experimental design;
2) a justification for numbers of animals required and species to be used;
3) a proposed statistical analysis;
4) availability and description of all materials needed;
5) timelines for the work to be completed; and
6) a report format.

b. Protocols for testing safety and efficacy of a microbicide may require the concomitant use of an applicator or barrier device. The use of a specific applicator or device will be based on the microbicide to be tested and will be provided by or through NIAID Project Officer.

c. Amend the protocols during study conduct, as necessary, after concurrence by the NIAID Project Officer.

d. Submit protocols to the Contractor's Institutional Animal Care and Use Committee (IACUC) for approval.

e. Prepare and utilize Standard Operating Procedures (SOPs) for the tasks delineated in approved protocols. Submit SOPs for NIAID Project Officer review and approval at the time of protocol submission. Additional, subsequent SOPs and modifications to current SOPs are to be submitted for NIAID Project Officer review and approval.

3. Development, Evaluation, and Maintenance of Challenge Stock(s) of Infectious Agents for Efficacy Testing

All procedures shall be performed at the initiation of the NIAID Project Officer.

a. Characterize the challenge dose of the infectious agents with respect to strain, concentration and potency (both *in vitro* and *in vivo*). The challenge pathogen stocks may be provided by the Contractor or the Contractor may be requested to obtain the challenge stock from another source, such as the American Type Culture Collection (ATCC), or an NIAID-supported investigator.

b. Maintain and propagate the challenge pathogens in culture or in vivo as needed for a particular pathogen.

c. Conduct approved protocols to determine titrations of pathogen stocks, infectious doses (ID 50 or 80, etc.), route of infection, and other preliminary studies as may be required to carry out carefully characterized challenge studies.

d. Prepare and utilize SOPs for the tasks delineated in approved protocols.

4. Conduct of Studies to Evaluate Candidate Products

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

a. Dose the animals with the candidate product, using the volume, concentrations, schedules and routes indicated in the approved protocols. Record all observations and measurements outlined in the approved protocol. All candidate topical microbicide products will be provided by or through the NIAID Project Officer.

b. Challenge experimental and control animals with one or multiple infectious agents, e.g., Chlamydia or Trichomonas, with a well-characterized inocula of the infectious agent, using doses and routes specified in the approved protocols.

c. Draw blood or obtain other fluids or tissue samples prior to and after administration of candidate product and challenge inocula as specified in the approved protocols. Specimens to be collected shall include: tissue samples of reproductive tract organs, rectal/cervical/vaginal lavages or swabs, blood lymphocytes, cerebrospinal fluid, fecal samples, broncho-alveolar lavages, biopsies of lymph nodes and other organs. Samples shall be processed according to the SOPs specified in the approved protocols; stored at the proper temperature per protocol; and either assayed at the primary facility of the Contractor, shipped at protocol temperature to a laboratory under subcontract to the Contractor, or sent under said temperature requirements to an NIAID contract laboratory or other appropriate laboratory as specified by the study protocol.

d. Determine infection status of animals after challenge with the infectious agent using methods such as pathogen isolation by culture, other microbiological methods, immunological assessment, and other tests or assays as specified in the approved protocol. Conduct in vitro laboratory assays and use this information to: (a) assess the efficacy of a microbicide on the infectious agent by determining the status of challenged animals to confirm protection or infection, and/or (b) assess the responses of the challenged/infected animals; and/or (c) assess gross and histological changes caused by product and record these changes photographically, e.g., colposcopy.

e. Monitor animals for toxicity, including after acute and chronic exposure to product; monitor dosed/challenged animals for general health status (i.e., weight, standard blood and chemistry profiles, opportunistic infections, and other assessments specified in the approved protocol). Perform standardized assays to detect/characterize local and systemic toxicity of products (e.g., renal and liver function tests, colposcopy, and histopathology). Evaluate changes in the vaginal or rectal ecosystem after microbicide use. Conduct necropsies as specified in the approved study protocol.

f. Within thirty (30) calendar days of completion of a topical microbicide testing protocol, prepare and submit to the NIAID Project Officer a Protocol Completion Report for Safety Evaluation and/or a Protocol Completion Report for Safety and Efficacy Evaluation. All reports shall include:

1) Report title (Protocol Completion Report for Safety Evaluation or Protocol Completion Report for Efficacy Evaluation) including the name of the microbicide tested with percent concentration tested

2) The contract number
3) Contract title “Topical Microbicide Safety and Efficacy Evaluation in Nonhuman Primates”
4) Contractor name and address
5) Author name
6) Protocol identification number
7) Protocol title
8) Date of IACUC approval of protocol and approval number
9) Name and source of the microbicide compound under protocol
10) Date of NIAID Project Officer approval of protocol
11) Start and completion date of protocol
12) Date of report submission
13) Summary of available information about the microbicide
14) Protocol design
15) Amendments to protocol, if any
16) Status of adverse effects while under protocol, if any
17) Number, types and identifiers of animals to be used for the protocol
18) Tabular summaries of data on all animals used under study, including current status of animals and any observations of note, e.g., diarrhea, ulcers, lesions, colposcopy photos with key, etc.
19) Experimental results and analysis of safety of treatment
20) Interpretation and brief discussion of the data and recommendations for further development or testing of the microbicide.

The additional information required for efficacy evaluations is as follows:

1) Analysis of efficacy of treatment
2) Disposition of animals, specimens, etc. at study completion

5. <u>Laboratory Support</u>

a. Provide laboratory support, either directly at the Contractor’s facilities, through subcontracts, or through an NIAID contract laboratory, for the conduct of laboratory evaluations as specified in the approved protocols. This shall include:

1) a microbiology laboratory with expertise to conduct microbiological testing;
2) an immunology laboratory with expertise to conduct immunological testing; and
3) a pathology laboratory with expertise to conduct pathology testing.

b. Ensure that all analyses of material obtained after infectious challenge are performed under appropriate biohazard containment by trained personnel.

6. <u>Storage, Shipment, and Inventory of Contract Resources</u>

a. Receive, store, track, and maintain an inventory of candidate topical microbicides, supplied by the NIAID Project Officer.

1) Store candidate topical microbicides at room temperature, four degrees Celsius (4° C), and negative twenty degrees Celsius (-20° C) as specified by the supplier.
2) Provide monitoring of refrigerator/freezer conditions by automatic temperature alarms to guarantee continuous proper storage of candidate topical microbicides.

3) Maintain locked storage container, locker, refrigerator, or freezer with access only to authorized personnel.

b. Store, track, and maintain an inventory of titered pathogen stocks.

1) Store titered pathogen stocks at four degrees Celsius (4° C), negative twenty degrees Celsius (-20°) C, and negative eighty degrees Celsius (-80° C) as specified by the storage SOP.
2) Provide monitoring of refrigerator/freezer conditions by automatic temperature alarms to guarantee continuous proper storage of titered pathogen.
3) Maintain locked storage container, refrigerator or freezer with access only to authorized personnel in accordance with appropriate biosafety level requirements.

c. Label, store, track and maintain an inventory of animal specimens collected during the course of the studies conducted under this contract.

1) Store animal specimens at four degrees Celsius (4°C) negative twenty degrees Celsius (-20° C), and negative eighty degrees Celsius (-80° C) as specified by the animal protocol.
2) Provide monitoring of refrigerator/freezer conditions by automatic temperature alarms to guarantee continuous proper storage of animal specimens.
3) Maintain locked storage container, refrigerator or freezer with access only to authorized personnel in accordance with appropriate biosafety level requirements.
4) Label specimens in the repository allowing for the ability to track by animal protocol, animal history and animal profile.

d. Ship specimens (microbiological samples, plasma, serum, cells, etc.) to investigators as designated by the NIAID Project Officer or as designated in the approved protocol using shipping conditions appropriate for preserving the specimens. Use biocontainment containers that comply with domestic postal regulations, and pertinent International Code Counsel (ICC) (www.iccsafe.org) regulations. The shipping containers must provide the refrigeration levels needed for specific materials; this may include, ice, dry ice, etc. Shipments of sera, cells, blood and other tissues from nonhuman primates shall be made in accordance with proper biocontainment shipping procedures. Provide International Air Transport Association Dangerous Goods (www.iata.org) Regulations training for the shipping of hazardous materials.

e. Establish an inventory control system in which candidate topical microbicides, titered pathogen, and collected animal specimens from protocols are tracked and inventoried so that product use and disposition can be tracked and pathogens and specimens can be archived as needed.

7. Safety and Training

a. Conduct work in accordance with the most recent Guidelines for Biosafety in Microbiological and Biomedical Laboratories (BMBL, Centers for Disease Control and Prevention and the National Institutes of Health, fourth edition, HHS Publication No. [CDC 93-8395, published by the U.S. Government Printing Office, May 1999, Stock Number 017-040-0547-4]).

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 nonhuman primates (see also http://bmbl.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 nonhuman primates.

8. 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. The PI shall be responsible for recommending modifications to project requirements and timelines, including projects undertaken by subcontractors. 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 NIAID Project Officer and the NIAID Contracting Officer. This shall involve meetings with the Contractor's key personnel, including the PI, and the NIAID Project Officer, at periodic intervals to be scheduled after contract award, to review the project status, progress and future plans. These meetings are to be arranged and coordinated by the Contractor.

9. Data Transfer

a. Provide the data from the safety and efficacy testing of candidate microbicides to the NIAID Project Officer and to the product supplier, where appropriate.

b. Provide data and information from the studies to the NIAID Project Officer upon request, and, at the request of the NIAID Project Officer, provide experimental results to the product suppliers and/or to the NIAID Project Officer in a format to be specified by the NIAID Project Officer.

10. Confidentiality of Data

a. Store all confidential data relating to the test products and testing results in files that are accessible only to the Contractor's PI and involved staff.

b. Biomedical test products provided to the Contractor for evaluation under this contract shall be supplied through Material Transfer Agreements (MTAs) between DMID, NIAID and the suppliers.

c. Candidate test products, received only from/through the Government for utilization under this contract, shall be used only for the purposes required by this contract and shall not be released to any other party without approval of the NIAID Project Officer.

11. Publications

a. Submit advance copies of draft manuscripts for publication (including abstracts and public presentations) based on data generated under this contract to the NIAID Project Officer for review and approval no less than thirty (30) calendar days before submission for public

presentation or publication. NIAID contract support shall be acknowledged in all abstracts, presentations and publications.

b. In accordance with NIH policy, the NIAID Project Officer will review all advance copies of draft manuscripts/documents in a period of time not to exceed thirty (30) calendar days from receipt, and will either grant clearance for publication/disclosure, recommend changes, or as applicable, refer the document to the third party supplier of materials utilized under this project for their review. The NIAID will use its best efforts to assist and expedite the review process by the third party suppliers whenever possible. If review by the NIAID Project Officer is not completed in this timeframe, the Contractor may proceed with the publication.

12. **Initial and Final Transition**

a. Initial Transition

In the event a new contractor assumes the requirements of the contract, the Contractor shall carry out the following tasks to provide for an orderly and efficient initial transition:

1) Within ten (10) business days of contract award, develop and submit to the NIAID Project Officer for approval, an Initial Transition Plan and timeline for the transition of activities from the current contractor, and the type and manner of operations required by the Contractor during the transition period. This shall include effective coordination at the start of the new contract period for the safe transfer of contract-related materials, including:

   a) samples and data related to study protocols;
   b) all repository materials, including pathogen stocks, topical microbicides and animal specimens;
   c) contract-related data and associated computer files;
   d) Standard Operating Procedures (SOPs) and manuals; and
   e) Government-furnished property.

2) Upon NIAID Project Officer approval of the Initial Transition Plan, implement and complete the transition within the first thirty (30) calendar days following the effective date of the contract.

b. Final Transition

1) Six (6) months prior to the completion date of this contract, submit, for NIAID Project Officer approval, a Final Transition Plan that details the orderly, efficient, safe and timely transfer of all contract-related materials to a subsequent contractor or the Government, if other than the incumbent.

2) Implement and coordinate the transition of contract resources, including movement of animals, stored specimens, products, data, and all Government-furnished property to a subsequent contractor or to the Government.

3) On or before the completion date of the contract, deliver to the Government or its designee the following items:

   a) all animals, samples, and data related to study protocols;

b) accurate and updated protocols and contract-related database programs and associated computer files;
c) a list of all topical microbicides tested and all test results;
d) all repository materials including pathogen stocks, topical microbicides and animal specimens;
e) all contract-developed manuals and SOPs; and
f) any other contract generated material and data necessary for an orderly transition of this work to a successor contractor or the Government.

REPORTING REQUIREMENTS AND DELIVERABLES

A. **Technical Reports: All Reports must be submitted both electronically and in hard copy.**

1. Technical Progress Reports

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.

For proposal preparation purposes only, it is estimated that 3 copies of these reports will be required as follows:

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

2. Annual Progress Report

This report shall include a summation of the results of the entire contract work for the period covered. An Annual Progress Report will not be required for the period when the Final Report is due.

Thirty (30) days after the end of the contract year, the Contractor shall submit a comprehensive Annual Progress Report to the NIAID Project Officer and to the NIAID Contracting Officer. Annual Progress Reports shall summarize the results of the entire year of contract period of performance. These reports shall include the following: 1) a cover page that identifies the contract number, contract title, Contractor's name and address, period of performance being reported on, report author(s) and date of submission; 2) a concise narrative description of the work performed during the reporting period; 3) chronological listing of evaluation studies performed during the reporting period; 4) accounting for the disposition of animals, specimens, etc. for the year; and 5) discussion of any unanticipated problems encountered and resolution of such problems. Pre-prints and reprints not included previously shall be submitted.

3. Final Report

This report shall consist of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted on or before the last day of the contract performance period. An Annual Progress Report shall not be required for the period when the Final Report is due.

Thirty (30) days before the completion date of the contract, a draft of the Final Report shall be submitted to the NIAID Project Officer and to the NIAID Contracting Officer for review. Fifteen (15) days prior to the completion date of the contract, the Contractor shall receive the revisions to the Final Report. By the completion date of the contract, the Contractor shall submit the corrected Final Report to the NIAID Project Officer and to the NIAID Contracting Officer. This Final Report shall summarize the results of the entire contract period of performance. This Final Report shall be in sufficient detail, outlined in the Annual Progress Report section, to explain comprehensively the

results achieved. Pre-prints and reprints not included previously shall be submitted

4. 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.

5. Invention Reporting Requirement

All reports and documentation required by FAR CLAUSE 52.227-11 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 submitted in accordance with ARTICLE F.1. DELIVERIES of this contract. Thereafter, reports shall be due on or before the 30th day following the reporting period. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract to the following address:

Contracting Officer
National Institutes of Health
National Institute of Allergy and Infectious Diseases, OA
6700-B, Room 3214
Bethesda, Maryland 20892-7612

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

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

6. Source Code and Object Code

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

B. Technical Reports Delivery Schedule

Satisfactory performance of the contract is defined as satisfactorily performing the Statement of Work and delivering the following items:

Item	Type of Deliverable	Initial Report Due	Recipients & Number of Copies	Subsequent Reports Due
1.	Annual Progress Report	30 days after the anniversary date of the contract	Original to Contracting Officer (CO), Electronic & Hard Copy Two (2) Copies to the Project Officer (PO), Electronic & Hard Copy	Annually; submitted 30 days after the anniversary date of the contract. An Annual Progress Report is not due when a Final Report is due.
2.	Final Report Draft	30 days before the expiration date of the contract.	Same as above	
3.	Final Report	On the expiration date of the contract.	Same as above	

C. Other Reports/Deliverables

1. Protocol Completion Reports for Safety Evaluation

This report shall include a description of the activities during the conduct of a safety testing protocol. These reports are due no later than 30 days after the completion of all work in a microbicide testing protocol.

The format shall provide, at a minimum, the following information:

a. Report Title (Protocol Completion Report for Safety Evaluation or Protocol Completion Report for Efficacy Evaluation) including the name of the microbicide tested with percent concentration tested
b. The contract number
c. Contract title "Topical Microbicide Safety and Efficacy Evaluation in Nonhuman Primates"
d. Contractor name and address
e. Author name
f. Protocol Identification Number
g. Protocol title
h. Date of IACUC approval of protocol and approval number
i. Name and source of the microbicide compound under protocol
j. Date of NIAID Project Officer approval of protocol
k. Start and completion date of protocol
l. Date of report submission
m. Summary of available information about the microbicide
n. Protocol design
o. Amendments to protocol, if any
p. Status of adverse effects while under protocol, if any
q. Number, types and identifiers of animals to be used for the protocol

r. Tabular summaries of data on all animals used under study, including current status of animals and any observations of note, e.g., diarrhea, ulcers, lesions, colposcopy photos with key, etc.
s. Experimental results and analysis of safety of treatment
t. Interpretation and brief discussion of the data and recommendations for further development or testing of the microbicide

2. Protocol Completion Report for Safety and Efficacy Evaluation

This report shall include a description of the activities during the conduct of safety and efficacy testing protocols. This report is due no later than 30 days after the completion of all work in a microbicide testing protocol.

The format shall provide, at minimum, the following information:

a. All information in the Topical Microbicide Safety Evaluation Protocol
b. All information in Other Protocols as requested by the Project Officer
c. All information in the Pathogen Challenge Stock Characterization, Maintenance, and Evaluation Protocols
d. All information in the Protocol Completion Report for Safety Evaluation
e. Analysis of efficacy of treatment
f. Disposition of animals, specimens, etc. at study completion

3. Initial and Final Transition Plans:

a. Initial Transition Plan

In the event a new contractor assumes the requirements of the contract, the Contractor shall submit, within ten (10) business days of contract award, an Initial Transition Plan to the NIAID Project Officer for review and approval. The Initial Transition Plan shall include a timeline for the transition of activities from the current contractor, and the type and manner of operations required by the Contractor during the transition period. This shall include effective coordination at the start of the new contract period for the safe transfer of contract-related materials, including: samples and data related to study protocols; all repository materials, including pathogen stocks, topical microbicides and animal specimens; contract-related data and associated computer files; Standard Operating Procedures (SOPs) and manuals; and Government-furnished property.

b. Final Transition Plan

Six (6) months prior to the contract completion date (or earlier as determined by the Contracting Officer, the Contractor shall submit to the NIAID Project Officer a Final Transition Plan for the orderly transition of data and samples to a subsequent contractor or to the Government prior to the contract's completion date. The plan will be subject to the NIAID Project Officer's review and approval and shall include disposition procedures for the following: all animals, samples and data related to study protocols; accurate and updated protocols and contract-related database programs and associated computer files; a list of all topical microbicides tested and all test results; all repository materials including pathogen stocks, topical microbicides and animal specimens; any government-purchased equipment; all contract-developed manuals and SOPs; and any other contract generated material and data necessary for an orderly transition of this

work to a successor contractor or the Government.

4. Data produced and stored under the contract:
On or before the completion date of the contract, deliver to the Government or its designee any and all data produced under this contract.

5. Any data systems developed under contract (IT):
On or before the completion date of the contract, deliver to the Government or its designee any data systems, databases, spreadsheets or programs developed or purchased under this contract.

6. Specimens (samples, plasma, serum, cells):
On or before the completion date of the contract, deliver to the Government or its designee any and all animal specimens collected (tissue samples, plasma, serum, cells, etc.) under this contract.

D. Other Reports, Protocols, and Deliverables Delivery Schedule

Item	Type of Deliverable	SOW Reference	Initial Report Due	Recipients & Number of Copies	Subsequent Reports Due
1.	A Topical Microbicide Safety Evaluation Protocol	Item # 2	Within two (2) weeks of request from the NIAID Project Officer	Original to Contracting Officer (CO), Electronic & Hard Copy Two (2) Copies to the Project Officer (PO), Electronic & Hard Copy	2 weeks after a written request by the NIAID Project Officer
2.	A Topical Microbicide Efficacy Evaluation Protocol	Item # 2	Same as above	Same as above	2 weeks after a written request by the NIAID Project Officer
3.	SOPs Supporting Topical Microbicide Safety and Efficacy Evaluation Protocols	Item # 2	Same as above	Same as above	2 weeks after a written request by the NIAID Project Officer
4.	Other Protocols as Requested by the NIAID Project Officer	Item # 2	Same as above	Same as above	2 weeks after a written request by the NIAID Project Officer

Item	Type of Deliverable	SOW Reference	Initial Report Due	Recipients & Number of Copies	Subsequent Reports Due
5.	Pathogen Challenge Stock Characterization, Maintenance, and Evaluation Protocols and SOPs	Item #3	Same as above	Same as above	2 weeks after a written request by the NIAID Project Officer
6.	Protocol Completion Report for Safety Evaluation	Item # 4, Section f	30 days after Completion of each Microbicide Testing	Original to Contracting Officer (CO), Electronic & Hard Copy Two (2) Copies to the Project Officer (PO), Electronic & Hard Copy	As requested for that particular microbicide
7.	Protocol Completion Report for Safety and Efficacy Evaluation	Item # 4, Section f	30 days after Completion of each Microbicide Testing	Same as above	As requested for that particular microbicide
8.	Initial Transition Report Final Transition Report	Item 12, Section a Item 12, Section b	Within ten (10) business days of contract award Six (6) months prior to the contract completion date	Same as above Same as above	N/A
9.	All data produced under this contract	Item 12, Section b	On or before the completion date of the contract	The Government or its designee (New Contractor)	N/A

Item	Type of Deliverable	SOW Reference	Initial Report Due	Recipients & Number of Copies	Subsequent Reports Due
10.	Any data systems, databases, spreadsheets or programs developed or purchased under this contract	Item 12, Section b	On or before the completion date of the contract	The Government or its designee (New Contractor)	N/A
11.	Any and all animals, animal specimens collected (tissue samples, plasma, serum, cells, etc.)	Item 12, Section b	On or before the completion date of the contract	The Government or its designee (New Contractor)	N/A

F. Copies of reports shall be sent to the following addresses:

1. Project Officer
   Address: To be completed upon award.

2. Contracting Officer
   Address: To be completed upon award.

G. Draft Manuscripts:

Thirty (30) days prior to the submission of any publication or public presentation, a draft of the manuscripts/documents must be submitted to the NIAID Project Officer for review and approval. The NIAID Project Officer shall return the draft with comments no later than 30 days after receipt.

APPENDIX A - ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS
FORMAT FOR TECHNICAL PROPOSAL

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.

The following additional technical proposal instructions reflect the requirements of the RFP and are meant to provide additional instructions as well as a uniform format for technical proposals. The information requested in these instructions should be used as a guide for formatting and preparing the proposal. Offerors should follow the instructions in Section L of the solicitation; include the information requested in this appendix.

Offerors are advised to give careful consideration to the Statement of Work, all reference material, appendices and attachments, the technical evaluation criteria, and, the RFP as a whole, in the development of their proposal.

Offerors who propose 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 between the prime and subcontractor(s), and the expected advantages of such an approach.

Offerors are reminded that the total page limitation for the **entire** technical proposal package is **200** pages inclusive of all appendices.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1

A. 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.

B. PROJECT OBJECTIVES, NIH FORM 1688

C. GOVERNMENT NOTICE FOR HANDLING PROPOSALS

D. TABLE OF CONTENTS

E. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)

SECTION 2 - TECHNICAL PLAN/APPROACH

A. **Acquisition, Testing, Housing, and Maintenance of Nonhuman Primates (SOW Item 1)**

1. Discuss your procedure for securing a reliable source of research quality rhesus macaques (Macaca mulatta) of Indian origin and pig-tail macaques (Macaca nemestrina) documented to be free of tuberculosis and other infectious agents as required by protocol. While primary emphasis will be on rhesus macaques (Macaca mulatta) of Indian origin, because of the continuing shortage of these animals, the Contractor may be requested to house and conduct studies utilizing Chinese-origin macaques, or other nonhuman primate species, such as cynomolgus monkeys (Macaca fascicularis), African green monkeys (Cercocebus atys), or baboons. If you propose to acquire nonhuman primates from outside sources, describe and document your past experience in obtaining nonhuman primate species from proposed sources.

2. Discuss the macaque species available to you and your experience with these species. Indicate which species of nonhuman primates you will have access to through breeding colonies or purchase, and describe your experience in housing the various nonhuman primate species. Discuss plans for, and any relevant issues associated with housing more than one macaque species concurrently in your facility.

3. Describe the testing procedures for assuring that macaques or other nonhuman primate species are free of tuberculosis infection.

4. Describe staff capabilities for the maintenance and care of the macaques or other nonhuman primate species in protocol at appropriate safety levels. Describe your animal husbandry practices, standard procedures for monitoring and care of nonhuman primates, procedures for performance of postmortems, criteria for recommending euthanasia, and procedures for euthanasia. Attach relevant SOPs.

5. Describe staff (Veterinarians, Technicians, and Handlers) capabilities for the care and treatment of the macaques or other nonhuman primate species infected or injured, and for the disposition of animals according to protocols.

6. Provide information describing your experience in housing and caring for nonhuman primates for topical microbicide safety and efficacy studies as specified in the SOW.

B. <u>Development of Protocols and Standard Operating Procedures</u> (SOW Item 2)

1. Provision of Sample Protocols:
   a. Provide two detailed sample protocols; one protocol to outline the test procedure to evaluate the vaginal safety of a candidate microbicide and one protocol to outline the test procedure to evaluate the efficacy of a microbicide against one of the following infectious agents; Chlamydia trachomatis or Trichomonas vaginalis. Included in this should be sample SOPs to support the sample protocol, such as an SOP for the conduct of a nonhuman primate colposcopy.
   b. For purposes of technical evaluation, the two detailed sample protocols to evaluate a topical microbicide should assume that the NIAID Project Officer will provide the test topical microbicides. A full description of the hypothetical test product(s) should be included with the complete protocols; the Offeror may attribute any composition or characteristic to the microbicides and may include the use of a barrier or delivery device, if desired. All aspects of product administration, infection/challenge, collection of samples and laboratory evaluation, including evaluation for local and systemic toxicity, etc. should be addressed.

2. Discuss your proposed approaches to the development of protocols to evaluate topical microbicides. Identify potential risks and obstacles and discuss ways to overcome them.

3. Discuss your proposed approach to the evaluation of the safety and efficacy based on results obtained in the two sample protocols provided.

C. Development, Evaluation, and Maintenance of Challenge Stock(s) of Infectious Agents for Efficacy Testing (SOW Item 3)

Based on the efficacy protocol provided above, outline the procedure to develop the challenge stock of the proposed infectious agent.

D. Conduct of Studies to Evaluate Candidate Products (SOW Item 4)

1. Describe your capacity to perform required testing in a timely and efficient manor with the resources dedicated to the project.

2. Provide sample Protocol Completion Reports for Safety and for Efficacy using the details provided in the Statement of Work, Item 2.f.

E. Laboratory Support (SOW Item 5)

1. Provide one sample SOP for the collection of vaginal/cervical biopsy specimens to be used for microbiological evaluation or *in situ* polymerase chain reaction (PCR) for detecting pathogens in tissues. Provide an SOP describing the microbiological evaluation of the samples including what to test for and how.

2. Discuss your proposed methods and approaches for providing laboratory support to evaluate samples from topical microbicide evaluations. Identify potential risks and obstacles and discuss ways to overcome them.

F. Storage, Shipment, and Inventory of Contract Resources (SOW Item 6)

1. Describe procedures and capabilities for appropriate storage of materials, and for monitoring of storage conditions.

2. Provide a plan to provide and document International Air Transport Association Dangerous Goods Regulations training for the shipping of hazardous materials.

3. Provide one sample SOP for the storage and shipping of vaginal/cervical biopsy specimens to be used for microbiological evaluation or *in situ* polymerase chain reaction (PCR) for detecting pathogens in tissues.

4. Describe the inventory control system for tracking and archiving of candidate topical microbicides, titered pathogen, and collected animal specimens

G. Data Transfer (SOW Item 9)

Describe the reporting system that will be used to provide data and information from the safety and

efficacy testing of candidate microbicides to the NIAID Project Officer and product supplier.

H. Final Transition (SOW Item 12)

Provide a plan for an orderly transition of activities and contract-generated resources to the Government or a successor contractor. Include timelines for the initiation and completion of all transition activities outlined in the Statement of Work and a description of the staffing requirements to execute and orderly, safe and timely transition.

SECTION 3 - PERSONNEL

1. Key Scientific and Technical Personnel: Describe the training, education, experience, and qualifications of the PI and senior scientific and technical personnel proposed, as well as the percentage of the total time each will be committed to the project. This includes scientific and technical staff of the Offeror and any proposed subcontractors. Provide documentation to describe:
    a. Key Scientific and Technical Personnel (limit CVs to 2-3 pages)
    b. Qualifications and relevant training
    c. Experience with projects of similar size and complexity
    d. References to all relevant publications
    e. Availability for the proposed project
    f. Summary of ongoing and completed activities directly related to the requirements of the contract.

2. Other Personnel: Offeror(s) shall demonstrate the related experience and the role of other personnel as needed to address the requirements of the Statement of Work.

SECTION 4 – PROJECT MANAGEMENT

1. Provide a plan for project organization, staffing, and management in relation to the design, implementation, conduct, monitoring and completion of the 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.

2. Outline how the PI will communicate with the NIAID Contracting Officer and the NIAID Project Officer and how the PI will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities). The cost estimate associated with meetings with the NIAID Project Officer shall be included in the Business Proposal.

3. Provide a plan for maintaining confidentiality of data collected during the execution of the responsibilities of this contract.

SECTION 5 – FACILITIES, RESOURCES, SAFETY and TRAINING

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

a. Location and features of facilities (lease or ownership information should be provided which demonstrates the availability of the facility for the period of performance of the contract);

b. Identification and description of ALL support resources (including IT systems) which will be required to effectively perform the Statement of Work.

2. Provide a summary of the experience and expertise of the Offeror and proposed subcontractors for working with potentially hazardous pathogens, specimens, and nonhuman primates.

3. Describe the level of training required for proposed staff working with pathogens, specimens, and infected nonhuman pathogens.

4. Provide a thorough summary of safe practices and facilities that will be available to assure a safe working environment for all personnel handling or in contact with pathogens, specimens, and infected nonhuman primates.

5. Provide a description of, and relevant documentation for, your facility biocontainment procedures for the housing and care of nonhuman primates especially infected nonhuman primates. Provide documentation describing your training programs for animal care personnel.

6. If an approximate number of six (6) microbicides may be tested per year, it is estimated 72 animals would have to be acquired and housed, both in laboratory and colony, per year. Document your ability to house a total of approximately 72 macaques or other nonhuman primate species per year (Laboratory and Colony).

7. Describe the security system that will be used to ensure facilities are under 24 hour per day, seven days a week security.

8. Provide documentation to demonstrate compliance with the Office of Laboratory Animal Welfare (OLAW) "The PHS Policy on Humane Care and Use of Laboratory Animals," and documentation of Association for the Assessment and Accreditation of Laboratory Animal Care (AAALAC) accreditation.

SECTION 6 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

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

2. **Data Sharing Plan**
   Section L of the RFP specifies the minimum documentation requirements for Data Sharing. All related documentation shall be included in the proposal in a clearly marked section. The Technical Proposal shall include a plan for Data Sharing as required by the RFP.

3. **Biohazard Safety**
   The Technical Proposal shall include a plan for biohazard security requirements.

4. **IT Systems Security**
   The Technical Proposal shall include a plan for IT Systems security and shall comply with Section 508 (see www.section508.govwww.section508.gov) and comply with technical security, information security, personnel security, web applications issues, reporting, etc. as prescribed by the "Secure One HHS".

5. **Project Objectives NIH 1688-1**
   The Technical Proposal shall include a completed NIH Form 1688-1.

APPENDIX B - ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

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, and the technical evaluation criteria, and, the RFP as a whole, in the development of their proposals. The information requested in these instructions should be used as a guide for the development and formatting of the 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

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. Cost and Pricing support should be provided for all proposed subcontractors.

SECTION 3 – UNIFORM COST ASSUMPTIONS

1) Travel

A. Assume there will be two (2) trips per year @ two (2) days each to Washington, D.C. for the Principal Investigator (PI) and key personnel.

B. Assume there will be one (1) scientific meeting per year, for three (3) days, for two (2) persons, for example, the PI and an individual from the PI's laboratory. This trip will be domestic.

2) Special Shipping and Packaging

Assume 15 domestic shipments per year, containing frozen animal specimens, to include microbiological specimens and serum.

3) Storage

Assume 100 new specimens to be stored each year and the storage of Chlamydia trachomatis challenge stocks from the previous contract (10 vials).

4) Equipment - N/A

5) Other

A. Microbicide Testing Cost: If approximately six (6) microbicides may be tested per year, it is estimated 72 animals would have to be acquired and housed, both in laboratory and colony, per

year. Offerors shall provide cost estimates for conducting the three safety and three efficacy evaluations per year from the examples they provide for Appendix A. These costs should be based on the two sample microbicide evaluation protocols requested in the Technical Proposal. The cost proposal shall include, at minimum, documentation to support all personnel costs, animal purchase expenses, animal per diem charges, required laboratory test expenses, and reporting requirements.

B. Communication and Document Transfer: Provide a cost estimate to establish the reporting system to provide the data from the safety and efficacy testing of candidate microbicides to the NIAID Project Officer and to the product supplier, where appropriate.

C. Microbicide Supply: All candidate topical microbicide products will be provided by or through the NIAID Project Officer at no cost to the Contractor.

SECTION 4 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

1. Small Business Subcontracting Plan
Section L of the RFP specifies the minimum documentation requirements for completing a subcontracting plan. This plan should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

2. Extent of Small Disadvantaged Business Participation
Section L of the RFP specifies the minimum documentation requirements for small disadvantaged business utilization. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.

3. Past Performance Data, including references
Section L of the RFP specifies the minimum documentation requirements for providing past performance information. This information should be turned in with the original proposal. All related documentation should be included in the proposal in a clearly marked section.