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

## RFP-NIH-NIAID-DMID-07-16
## "Malaria Vaccine Production and Support Services"

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:** | 5. **Small Bus. Set-Aside:** [ ]Yes [X] No |
|---|---|---|
| **April 14, 2006** | **July 13, 2006** | **8(a) Set-Aside:** [ ]Yes [X] No |
| | **Time:** **4:00 P.M., Local Time** | **NAICS:** 541710 (See Part IV, Section L.) |

| 6. **Just In Time:** | 7. **Number of Awards:** | 8. **Technical Proposal Page Limits:** |
|---|---|---|
| [X] No<br>[ ] Yes (See Part IV, Section L.) | [X] Only 1 Award<br>[ ] Multiple Awards | [ ] No<br>[X] Yes (See Section J, Attachment 1, Packaging and Delivery of Proposal) |

| 9. **Issued By:** | 10. [X] **NIAID reserves the right to make awards without discussion.** | |
|---|---|---|
| Barbara A. Shadrick<br>Contracting Officer<br>Office of Acquisitions, DEA, NIH, NIAID<br>6700-B Rockledge Drive<br>Room 3214, MSC 7612<br>Bethesda, MD 20892-7612 | 11. **Options:**<br>**[X] No**<br>**[ ] Yes** (See Part IV, Section L.) | 12. **Period of Performance:**<br>May 16, 2007 through May 15, 2014 |

| 13. **Primary Point of Contact:** | 14. **Secondary Point of Contact:** | 15. **Protest Officer:** |
|---|---|---|
| **Name :** Amy Siller<br>**Phone:** 301- 496-6424<br>**Fax:** 301-402-0972<br>**E-Mail:** asiller@mail.nih.gov | **Name:** Barbara Shadrick<br>**Phone:** 301-496-7288<br>**Fax:** 301-402-0972<br>**E-Mail:** bs92y@nih.gov | Branch Chief, MIDRCB-B, OA<br>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** |
|---|---|
| Amy Siller<br>Contract Specialist<br>Office of Acquisitions, DEA, NIH, NIAID<br>6700-B Rockledge Drive, Room 3214<br>Bethesda, MD 20817 | Amy Siller<br>Contract Specialist<br>Office of Acquisitions, DEA, NIH, NIAID<br>6700-B Rockledge Drive, Room 3214, MSC 7612<br>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 FAR 15.208 entitled "Submission, Modification, Revision, and Withdrawal of Proposals." FACSIMILE AND E-MAIL 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 objective of this contract is to acquire the necessary research and development services to support process development and pilot lot production of promising candidate malaria vaccines into well-characterized malaria vaccine products suitable for evaluation in clinical studies.

### 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, equipment) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

## SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

### ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated April 14, 2006, attached hereto and made a part of this Solicitation (See Section J - List of Attachments).

### ARTICLE C.2. REPORTING REQUIREMENTS

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. **Please refer to Attachment 5, "Reporting Requirements and Deliverables" under this solicitation.**

## SECTION D - PACKAGING, MARKING AND SHIPPING

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

## SECTION E - INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this SECTION, _____ is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at 6610 Rockledge Drive, Bethesda, MD 20817.

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

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

FAR Clause 52.246–8, Inspection of Research and Development–Cost Reimbursement (May 2001)

## SECTION F - DELIVERIES OR PERFORMANCE

### ARTICLE F. 1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the items in SECTION C, ARTICLE C.2. in accordance with the stated delivery schedule.

The items described in SECTION C, ARTICLE C.2., will be required to be delivered F.O.B. Destination as set forth in FAR Clause 52.247-35, F.O.B. Destination, Within Consignees Premises (April 1984), and in accordance with and by the dates specified in SECTION C, ARTICLE C.2. and any specification stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of the contract.

### 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**

The personnel specified in this contract are considered to be essential to the work to be performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent of the Contracting Officer required by this article. The contract may be amended from time to time during the course of the contract to either add or delete personnel, as appropriate.

The following individuals 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. HHSN266200711000C.)

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-71234.)

(b) An original and two (2) copies to the following designated billing office:

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

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

b. The Contractor shall include the following certification on every invoice for reimbursable costs incurred with Fiscal Year funds subject to the salary rate limitation provisions as specified in SECTION H. of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with the applicable Public Law Number for the applicable Fiscal Year as stated in SECTION H. of the above referenced contract."

**ARTICLE G.4. 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.5. GOVERNMENT PROPERTY**

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the 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.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually 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 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

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

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

[Applicable information to be included at award]

### ARTICLE H.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. INTRODUCTION OF RODENTS AND RODENT PRODUCTS

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

## ARTICLE H.6. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan**

(1) The Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract.

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

b. **Subcontracting Reports**

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

(1) Individual Subcontract Reports (ISR)

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

April 30th
October 30th

(2) Summary Subcontract Report (SSR)

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

October 30th

For both the Individual and Summary Subcontract Reports, the Contract shall be included as a contact for notification purposes at the following e-mail address: asiller@niaid.nih.gov

**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 "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b.

| **Public Law No.** | **Fiscal Year** | **Dollar Amount of Salary Limitation*** |
|---|---|---|

[Applicable information to be included at award]

c. Payment of direct salaries is limited to the Executive Level I 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 I 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 "DHHS Information Security Program Policy" (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.) *******

**[ ] Administrative, Management and Support Information:**
**[ ] 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 | **[ ]** Moderate | **[ ]** High |
| Integrity | Level: | **[ ]** Low | **[ ]** Moderate | **[ ]** High |
| Availability | Level: | **[ ]** Low | **[ ]** Moderate | **[ ]** High |
| **Overall** | **Level:** | **[ ] Low** | **[ ] Moderate** | **[ ] High** |

c. Position Sensitivity Designations

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

******** ***(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).

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

(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, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at:
http://ais.nci.nih.gov/forms/Suitability-roster.xls

**(NOTE:** Be aware that website 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.)

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 "NCI Information Technology Security Policies, Background Investigation Process" website: http://ais.nci.nih.gov.

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 _____. 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 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 "Employee 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) NCI 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**

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 "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR Part 1194. The complete text of Section 508 Final Standards can be accessed at http://www.access-board.gov/.

**ARTICLE H.10. 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 & Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. _____.

**ARTICLE H.11. 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 non-governmental sources.

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

[Applicable information to be included at award]

**ARTICLE H.12. 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.13. 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.14. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

a. Sharing of Model Organisms for Biomedical Research

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

## ARTICLE H.15. SHARING RESEARCH DATA

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

The NIH endorses the sharing of final research data to 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.16. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

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

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

## ARTICLE H.17. 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:

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

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

### ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations. This is a Full and Open Competition solicitation. However, the clauses listed are for a commercial contractor. If the offeror is an educational institution or non-profit organization, the offeror should use the applicable clauses.

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.

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

FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefor. **[NOTE: When this contract is fully funded, FAR Clause 52.232-22, LIMITATION OF FUNDS will no longer apply and FAR Clause 52.232-20, LIMITATION OF COST will become applicable.]**

### ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

Additional clauses other than those listed below which are based on the type of contract/Contractor shall be determined during negotiations. This is a Full and Open Competition solicitation. However, the clauses listed are for a commercial contractor. If the offeror is an educational institution or non-profit organization, the offeror should use the applicable clauses. 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 **52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting** (October 1999).

(3) FAR Clause **52.223-12, Refrigeration Equipment and Air Conditioners** (May 1995).

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

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

Under FAR 52.227-14, Alternate V, the Government, its Contractors and representatives have the right to inspect data at Contractor's facility to evaluate work performance. Upon reasonable notice to Contractor, the Government, its Contractors, and representatives have the right to visit and inspect Contractor's facilities at anytime.

(6) FAR Clause **52.227-15, Representation of Limited Rights Data and Restricted Computer Software** (May 1999).

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

(8) FAR Clause **52.229-8, Taxes-Foreign Cost-Reimbursement Contracts** (March 1990).

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

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

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

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

(13) FAR Clause **52.242-4, Certification of Final Indirect Costs** (January 1997).

(14) FAR Clause **52.245-5, Government Property (Cost-Reimbursement, Time-and-Material, or Labor-Hour Contracts)** (May 2004).

(15) FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).

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

(1) HHSAR Clause **352.223-70, Safety and Health** (January 2001). [This clause is provided in full text in Section J - Attachments.]

(2) HHSAR Clause **352.224-70, Confidentiality of Information** (April 1984 - including revisions mandated by the 1/3/2005 Federal Register notice which was effective March 2005).

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

(4) 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. This is a Full and Open Competition solicitation. However, the clauses listed are for a commercial contractor. If the offeror is an educational institution or non-profit organization, the offeror should use the applicable clauses. 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 canceled, 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.

b. FAR Clause **52.223-11, Ozone-Depleting Substances** (May 2001)

(a) **Definition.** Ozone-depleting substance, as used in this clause, means any substance the Environmental Protection Agency designates in 40 CFR part 82 as--

(1) Class I, including, but not limited to, chlorofluorocarbons, halons, carbon tetrachloride, and methyl chloroform; or
(2) Class II, including, but not limited to, hydrochlorofluorocarbons.

(b) The Contractor shall label products which contain or are manufactured with ozone-depleting substances in the manner and to the extent required by 42 U.S.C. 7671j (b), (c), and (d) and 40 CRF Part 82, Subpart E as follows:

"WARNING: Contains (or manufactured with, if applicable) _____*, a substance(s) which harm(s) public health and environment by destroying ozone in the upper atmosphere."

*The Contractor shall insert the name of the substance(s).

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

## SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP and can be found in the Attachments at the end of this document:

**SOLICITATION ATTACHMENTS:**

| Attachment No. | Title | Location |
|---|---|---|
| Attachment 1 | Packaging and Delivery of Proposal | See Attachment Section at end of this RFP |
| Attachment 2 | Proposal Intent Response Sheet | See Attachment Section at end of this RFP |
| Attachment 3 | Background | See Attachment Section at end of this RFP |
| Attachment 4 | Statement of Work | See Attachment Section at end of this RFP |
| Attachment 5 | Reporting Requirements and Deliverables | See Attachment Section at end of this RFP |
| Attachment 6 | Appendix A - Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents | See Attachment Section at end of this RFP |
| Attachment 7 | Appendix B - Additional Business Proposal Instructions and Uniform Cost Assumptions | See Attachment Section at end of this RFP |
| Attachment 8 | Appendix C - Project Request Form - Performance of Non-Core Functions | See Attachment Section at end of this RFP |
| Attachment 9 | Appendix D - Safety Controls and Standards | See Attachment Section at end of this RFP |
| Attachment 10 | Government Furnished Property - Schedule II-A | See Attachment Section at end of this RFP |

**TECHNICAL PROPOSAL ATTACHMENTS:** (The following attachments must be completed, where applicable, and submitted with the Technical Proposal. They may be accessed at: http://www.niaid.nih.gov/contract/forms.htm.)

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

**BUSINESS PROPOSAL ATTACHMENTS:** (The following attachments must be completed, where applicable, and submitted with the Business Proposal. They may be accessed at: http://www.niaid.nih.gov/contract/forms.htm.)

| Title | Location |
|---|---|
| Proposal Summary and Data Record, NIH-2043 | http://www.niaid.nih.gov/contract/forms.htm |
| Small Business Subcontracting Plan | http://rcb.cancer.gov/rcb-internet/forms/sb-subplan-nci.pdf |
| Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet | http://www.niaid.nih.gov/contract/forms.htm<br>http://ocm.od.nih.gov/contracts/spsh/spshexcl.xls |
| Offeror's Points of Contact | http://www.niaid.nih.gov/contract/forms.htm |
| 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. They may be accessed at: http://www.niaid.nih.gov/contract/forms.htm.)

| Title | Location |
|---|---|
| Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4 | http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf |
| Safety and Health, HHSAR Clause 352.223-70 | http://www.niaid.nih.gov/contract/forms/form10.pdf |
| Procurement of Certain Equipment, NIH(RC)-7 | http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf |
| Disclosure of Lobbying Activities, OMB Form SF-LLL | http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf |
| Commitment To Protect Non-Public Information Contractor Agreement | http://irm.cit.nih.gov/security/Nondisclosure.pdf |
| Roster of Employees Requiring Suitability Investigations | http://ais.nci.nih.gov/forms/Suitability-roster.xls |
| 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:

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

(3) Offerors are cautioned that proposals submitted with restrictive 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)

b. **NAICS CODE AND SIZE STANDARD**

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

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.

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

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

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

It is anticipated that one (1) award will be made from this solicitation and that the award(s) will be made on/about May 16, 2007.

It is anticipated that the award from this solicitation will be a cost-reimbursement, completion type contract with a period of performance of seven (7) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

d. **ESTIMATE OF EFFORT**

It is expected that 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 13 Full-Time Equivalents (FTEs) per year for the entire seven (7) years. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

e. **COMMITMENT OF PUBLIC FUNDS**

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

f. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

g. **RELEASE OF INFORMATION**

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

h. **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.

i. **PREPARATION COSTS**

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

j. **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:

Branch Chief,
Microbiology and Infectious Diseases Research Contracts Branch-B
Office of Acquisitions, DEA
National Institute of Allergy & Infectious Diseases
6700B Rockledge Drive
Room 3214, MSC-7612
Bethesda, MD 20892-7612

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

(End of Provision)

k. **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.

(End of provision)

## 2. INSTRUCTIONS TO OFFERORS

### a. GENERAL INSTRUCTIONS

**INTRODUCTION**

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

(1) **Contract Type and General Clauses**

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

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

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addresses, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments. **(See Attachment 6, Appendix A - Additional Technical Proposal Instructions and Format for Technical Proposal Table of Contents.)**

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. **(See Attachment 7, Appendix B - Additional Business Proposal Instructions and Uniform Cost Assumptions.)**

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

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

(4) **Separation of Technical and Business Proposals**

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be

evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY). However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

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

(6) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in Part IV, Section M of this RFP.

(7) **Potential Award Without Discussions**

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

(8) **Use of the Metric System of Measurement**

It is the policy of the Department of Health and Human Services to support the Federal transition to the metric system and to use the metric system of measurement in all 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.

(9) **Specific Copyright Provisions Applicable to Software Development and/or Enhancement(s)**

Under the provisions of the Rights in Data General clause (52.227-14), contractors must seek permission to establish a copyright for software and associated data generated under a contract. As a general rule, permission is normally granted provided, a paid-up, world-wide, irrevocable, nonexclusive license to the government is provided. This is to advise offerors that for this project, the government intends to assert additional copyright permissions under this contract. The scope of the Government's interest in the copyright will be determined during negotiations.

(10) **Privacy Act - Treatment of Proposal Information**

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

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

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

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

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

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

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

- to the cognizant audit agency and the 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.

(11) **Selection of Offerors**

a. The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.

b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.

c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.

d. If the Government intends to conduct discussions prior to awarding a contract-

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

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

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

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

e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. 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.

(12) **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.

(12) **Past Performance Information**

a) Offerors shall submit the following information as part of their business proposal.

A list of the last five (5) contracts completed during the past three (3) years and the last contracts awarded 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. Standard Industrial 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 any subcontract over $550,000.

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) **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 .

(14) **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 "Government Notice for Handling Proposals." The NIH Form 1688-1 is to be completed as follows:

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

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

b) **Statement of Work**

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

c) **Personnel**

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

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

(1) 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 offeror's technical proposal:

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

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

-The Animal Welfare Assurance number.
-The date last certified by OLAW. (i.e. assurance letter from OLAW)
-Evidence of recent AAALAC Accreditation.

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

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

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

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

(a) **Sharing Research Data**

The NIH endorses the sharing of final research data to expedite the translation of research results into knowledge, products, and procedures to improve human health. This contract is expected to generate research data. Therefore, the offeror must submit a plan in its technical proposal for data sharing or state why data sharing is not possible. If data sharing is limited, the offeror should explain such limitations in its data sharing plan. NIH's data sharing policy may be found at the following Web site: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html

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

to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.

(b) **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 “reach-through” requirements (as discussed in the NIH Research Tools Policy) on materials transferred be discussed?

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

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

(7) **Information Technology Systems Security**

**IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled, “Information 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:**
**[ ] Mission Based Information:**

(b) Security Categories and Levels

| | | | | |
|---|---|---|---|---|
| Confidentiality | Level: | **[X]** Low | **[ ]** 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**

(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.

(f) 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

## c. BUSINESS PROPOSAL INSTRUCTIONS

### (1) Basic Cost/Price Information

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

### (2) Proposal Cover Sheet

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

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

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

### (3) Information Other than Cost or Pricing Data

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

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

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

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

#### 1. Direct Labor

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

2. **Materials**

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

3. **Subcontracted Items**

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $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.

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

(a) Exceptions from cost or pricing data.

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

(i) Identification of the law or regulation establishing the price offered. If the price is controlled under law by periodic rulings, reviews, or similar actions of a governmental body, attach a copy of the controlling document, unless it was previously submitted to the contracting office.

(ii) Commercial item exception. For a commercial item exception, the offeror shall submit, at a minimum, information on prices at which the same item or similar items have previously been sold in the commercial market that is adequate for evaluating the reasonableness of the price for this acquisition. Such information may include--

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), e.g., wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

(B) For market-priced items, the source and date or period of the market quotation or other basis for market price, the base amount, and applicable discounts. In addition, describe the nature of the market;

(C) For items included on an active Federal Supply Service Multiple Award Schedule contract, proof that an exception has been granted for the schedule item.

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

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

(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.

(2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

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.(4) Cost and Pricing Data, subparagraph 3. 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.

(5) **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.*

(6) **Small Business Subcontracting Plan**

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, Section J - List of Attachments, Business Proposal Attachments, 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
3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

(7) **HUBZone Small Business Concerns**

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

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

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS 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 “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) code, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). TheNAICS 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 “Contractor team arrangements” to include two or more companies forming a partnership or joint venture to act as a potential prime contractor, or a potential prime contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

(9) **Qualifications of the Offeror**

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

a) **General Experience**

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

b) **Organizational Experience Related to the RFP**

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

c) **Performance History**

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

d) **Pertinent Contracts**

*Pertinent contracts* is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

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

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

(10) **Other Administrative Data**

a) **Property**

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

(a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.

(b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.

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

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

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

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

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.
(3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.
(4) The name, address, and 9-digit Routing Transit Number of the offeror's financial agent.
(5) The offeror's account number and the type of account (checking, savings, or lockbox).
(6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.
(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9-digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on-line to the Fedwire and, therefore, not the receiver of the wire transfer payment.

c) **Financial Capacity**

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

d) **Incremental Funding**

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

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

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

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

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

(End of Provision)

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

**[ ]** 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.

(11) **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

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

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

(13) **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.

(14) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

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

b) **Travel Policy**

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

# SECTION M - EVALUATION FACTORS FOR AWARD

a. **GENERAL**

Selection of an offeror for contract award will be based on an evaluation of proposals against four (4) factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

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

b. **EVALUATION OF 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.

c. **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 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” by the Government after discussions, your proposal may not be considered further for award.

d. **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 of technical proposals.

**CRITERIA** **WEIGHT**

**A. CORE FUNCTIONS** **40 points**

1. Overall Project Management

   Adequacy, thoroughness and feasibility of the plans and procedures for providing, overseeing and managing vaccine development and support services, with respect to the following:

   a) Proposed overall project organization and staffing and plans and procedures for close monitoring, coordination and management of all contract activities.
   b) The proposed mix and balance of key personnel in relation to their specific responsibilities and time commitments.
   c) Communication with the Project Officer and Contracting Officer.
   d) The safeguarding of confidentiality and intellectual property.

2. Subcontract Acquisition and Management

   Adequacy, thoroughness and feasibility of the detailed technical approaches and plans for soliciting, evaluating, executing, and post-award administration of subcontracts for Non-Core Functions with respect to the following:

   a) Experience using contracting procedures and requirements in accordance with Federal regulations.
   b) Developing solicitations, performing qualified, non-conflicted reviews of proposals received, performing cost analyses, and negotiating and awarding subcontracts in an objective and efficient manner.
   c) Closely monitoring and assessing technical, administrative and operational performance of subcontractors and for taking remedial actions, including termination and replacement, as necessary to ensure successful completion of requirements.

3. Regulatory Support; Receipt, Storage, Shipping and Inventory; Technology Transfer; Data Management and System Security; and Ad Hoc Advisory Meeting Support

   Adequacy, thoroughness, soundness, and feasibility of the plans and approaches with respect to the following:

   a) Providing the NIAID with materials and documentation that support submission of an IND or Master File to the FDA by NIAID Offices of Regulatory Affairs.
   b) Receipt, storage, shipping, and inventory of specimens, reagents, and vaccines.
   c) Technology transfer for assays, processes, methods, SOPs, reagents, products, and other materials or data developed under the contract.
   d) Maintenance and implementation of a secure in-house data management system to support contract activities including the containment and protection of confidential information.
   e) Identifying qualifications of scientists to serve as advisors, and providing NIAID with ad hoc advisory support on strategic, scientific or technical issues relevant to malaria vaccine development.

**B. NON-CORE FUNCTIONS** **20 points**

**1. Case Studies - Process Development and Pilot Lot Production (10 points)**

Adequacy, thoroughness, soundness, and feasibility of the scientific and technical approach for preparing the proposed three (3) categories of experimental vaccines suitable for clinical studies, with respect to the following:

a) Understanding of the scientific basis for process development and pilot lot production.
b) Nonclinical development plan to address FDA required nonclinical laboratory IND-enabling studies for candidate malaria vaccines.
c) Sample Project Management Plans for process development and pilot lot production for three (3) categories of candidate malaria vaccines.

**2. Provision of Non-Core Functions (10 points)**

a) Suitability and feasibility of the methodology for identifying and obtaining the appropriate expertise necessary to fulfill the requirements under the Non-Core Functions.
b) Adequacy and thoroughness of the understanding of the knowledge, experience, and expertise required to carry out the Non-Core Functions.

**C. PERSONNEL QUALIFICATIONS** **30 points**

**1. Principal Investigator (10 points)**

Adequacy of the documented experience and qualifications of the Principal Investigator to lead and direct the activities under this contract and through any subcontracts. This includes appropriate knowledge and expertise to solicit for and evaluate the technical merit of subcontract proposals; and the capacity to monitor progress, access performance, identify performance problems and implement corrective actions.

**2. Key and Other Scientific and Technical Personnel (20 points)**

a) Adequacy, appropriateness and relevance of the documented training, expertise, experience, and availability of the key professional and technical staff to provide administrative support and to fulfill the "Core" management and oversight requirements. This includes: previous experience and proven track record in managing similar product development projects of biologicals; adequacy of the understanding of and experience with assuring conformity with FDA guidelines and providing regulatory support for submission of INDs and/or Master Files to the FDA.

b) Relevance and extent of documented experience of key personnel in coordinating and tracking complex sets of inter-related functions conducted within the Offeror's organization or in concert with subcontractors.

c) Appropriateness and relevance of the documented training, experience and availability of proposed other scientific and technical staff.

**D. FACILITIES AND RESOURCES** **10 points**

1. Availability of adequate facilities, equipment and resources necessary to accomplish the "Core Functions" as described in the Statement of Work.

2. Capacity for accomplishment of the stated task in a timely and efficient manner.

3. Soundness and feasibility of the approach to ensuring adequate facilities for candidate vaccine development, production, and preclinical testing including the provision of care and housing for laboratory animals.

**TOTAL POSSIBLE POINTS 100 points**

e. **PAST PERFORMANCE FACTOR**

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

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

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

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

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

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

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

f. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

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

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

(a) Extent to which SDB concerns are specifically identified;
(b) Extent of commitment to use SDB concerns; and
(c) Extent of participation of SDB concerns in terms of the value of the total acquisition.

g. **PRE-AWARD SITE VISIT (*For offerors who are determined to be in the competitive range*)**

Offerors determined to be in the competitive range shall undergo a pre-award site visit with an emphasis on assessing their GMP, GLP, GCP and QA/QC capabilities for the Contractor and subcontractors. The results of this pre-award site visit shall be a factor in final Source Selection for award of the contract. Offerors will be requested to make all records, including previous regulatory inspection reports, responses to FDA form 483 observations or comments from other regulatory bodies, and staff available in response to a pre-award site visit or audit by NIAID or its designee.

## 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 OR E-MAIL IS **NOT** ACCEPTABLE.

## A. EXTERNAL PACKAGE MARKING:

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

"**RFP NO. NIH-NIAID-DMID-07-16**
**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 |
|---|---|
| Amy Siller<br>Contract Specialist<br>Office of Acquisitions, DEA, NIAID, NIH<br>6700-B Rockledge Drive, Room 3214, MSC 7612<br>Bethesda, Maryland 20817 | Amy Siller<br>Contract Specialist<br>Office of Acquisitions, DEA, NIAID, NIH<br>6700-B Rockledge Drive, Room 3214, MSC 7612<br>Bethesda, Maryland 20892-7612 |

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

**NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with HHSAR 352.215-70, Late Proposals and Revisions (NOV 1986).**

## C. NUMBER OF COPIES:

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

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

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

- Type size must be 10 to 12 points.
- Type spacing should be no more than 15 characters per inch. Within a vertical inch, there must be no more than six lines of text.
- Print margins must be at least one inch on each edge of the paper.
- Print setup should be single-sided on standard letter size paper (8.5 x 11" in the U.S., A4 in Europe).

**CREATING AND NAMING ELECTRONIC FILES:**

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

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

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

*EXAMPLE: XYX Company/07-16/Technical/Approach/3-6-06*

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

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

*EXAMPLE: XYX Company/07-16/Business/Staffing/3-6-06*

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

**PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED. OFFERORS MUST CERTIFY THAT THE INFORMATION IN THE PAPER AND ELECTRONIC COPIES IS THE SAME.**

| Document | Number of Copies | Page Limits |
|---|---|---|
| **Technical Proposal and all Appendices** | **PAPER**<br>One (1) unbound SIGNED ORIGINAL.<br>Five (5) unbound COPIES<br><br>**ELECTRONIC FILES ON CD**<br>Twenty (20) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices) in a Portable Document Format (PDF) | **Not to Exceed 150 pages** |
| **Business Proposal** | **PAPER**<br>One (1) unbound SIGNED ORIGINAL.<br>Five (5) unbound COPIES<br><br>**ELECTRONIC FILES ON CD**<br>Four (4) Compact Disks containing an electronic copy of the Business Proposal in a Portable Document Form (PDF). | N/A |
| **Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook** | This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk.<br><br>**See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.** | N/A |

# PROPOSAL INTENT RESPONSE SHEET

**RFP No.:** NIH-NIAID-DMID-07-16
**RFP Title:** Malaria Vaccine Production and Support Services

Please review the attached Request for Proposal. Furnish the information requested below and return this page by no later than **June 13, 2006**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

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

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

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

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

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

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

Attn: Amy Siller
RFP-NIH-NIAID-DMID-07-16
FAX# (301) 402-0972
Email: asiller@mail.nih.gov

**Background**
**Malaria Vaccine Production and Support Services**
**RFP-NIH-NIAID-DMID-07-16**

The National Institute of Allergy and Infectious Diseases (NIAID, www.niaid.nih.gov) supports research to understand, and ultimately prevent and/or treat, infectious and immune-mediated diseases that continue to threaten millions of lives each year. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents. This includes basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics, which are funded through a variety of grants and contracts.

NIAID's Research Plan for Malaria Vaccine Development (http://www.niaid.nih.gov/dmid/malaria/malvacdv/toc.htm) outlines the Institute's commitment to accelerate research leading to the development of a vaccine to reduce the mortality and morbidity resulting from malaria, a disease caused by protozoan parasites of *Plasmodium* spp. (primarily *P. falciparum* and *P. vivax*). In response to this Plan, NIAID awarded a contract in FY00 for "Malaria Vaccine Production and Support Services" to Science Applications International Corporation (SAIC) (NIAID contract No. N01-AI-05421) to provide process development, pilot lot production, and FDA regulatory support services to produce clinical-grade malaria vaccine material.

Malaria claims an estimated two (2) to three (3) million lives annually and accounts for untold morbidity in the approximately 300 to 500 million people infected annually. Currently available drugs are losing their utility as a result of the spread of drug-resistant parasites. Research is needed to develop new tools to control this deadly disease. Since many of the poorest nations of the world are afflicted with malaria, any effective intervention must be inexpensive, cost-effective and relatively easy to administer and maintain. Historically, vaccines have been one of the most cost-effective and easily administered means of controlling infectious diseases, but as yet no licensed vaccines exist for malaria. Data accumulating from basic and clinical research suggest that effective vaccines for malaria can be developed and could significantly reduce morbidity and mortality, as well as potentially reduce the spread of infection. Human populations residing in malaria endemic areas naturally acquire protective immunity. Experimental vaccination with attenuated malaria parasites can result in effective immune protection against challenge with malaria parasites. Recently, encouraging results have been obtained with a subunit vaccine against *P. falciparum* pre-erythrocytic stages demonstrating protective efficacy in a series of clinical trials involving both experimental challenge of previously unexposed volunteers (reviewed in Heppner et al., *Vaccine*, 2005), and naturally occurring infections in malaria endemic regions (Alonso et al., *Lancet* 2004, 2005). An optimal vaccine will likely combine subunits from different parasite stages, thus having the ability to elicit protective immunity that not only blocks infection, but also prevents pathology and blocks transmission of parasites. This may require simultaneous stimulation of multiple components of the immune response, both humoral and cellular, that participate in resistance against the various life cycle stages of the parasite.

The NIAID Research Plan for Malaria Vaccine Development provides for:

1) improved access to well characterized research materials;
2) increased discovery and preclinical testing of new vaccine candidates;
3) enhanced capacity for production and evaluation of candidate malaria vaccines; and
4) establishment of clinical research and trial preparation sites in endemic areas.

NIAID has implemented this Plan systematically through solicitations and awards from DMID's Parasitology and International Programs Branch (PIPB), and through the establishment of a Malaria Vaccine Development Branch (MVDB) within NIAID's Division of Intramural Research (DIR). These activities have led to expanded extramural and intramural preclinical and clinical malaria vaccine research, and creation of a Malaria Research and Reference Reagent Resource Center (http://www.malaria.mr4.org/). The DMID currently supports a portfolio of extramural grants and contracts dealing with vaccine candidates from several parasite life-cycle stages and produced in various systems (e.g. recombinant proteins from mammalian expression systems, synthetic peptides, viral or bacterial-vectored vaccines, and DNA vaccines). The MVDB focuses its research efforts on vaccine discovery and process development for recombinant blood-stage and sexual stage antigens.

The purpose of this solicitation is to re-compete the Malaria Vaccine Production and Support Services contract, scheduled to expire on September 21, 2007. This Request for Proposals (RFP) addresses the Institute's continuing need for additional services and facilities for malaria vaccine development and testing. This includes: project management to provide oversight for the transition of lead candidates through development, characterization and production, to initial clinical trial material; process development to identify optimal production and purification strategies for clinical-grade immunogens; pilot production and formulation of clinical-grade material; and regulatory support for compiling documentation necessary for submission of an Investigational New Drug (IND) application and/or Master Files to the Food and Drug Administration (FDA). One (1) award for a term of seven (7) years is expected to be made in response to this solicitation.

The NIAID recognizes that no single organization or institution may have all the expertise and facilities required to perform all of the malaria vaccine production and support services set forth in the Statement of Work, and consequently, that the Contractor may need to utilize the expertise and resources of subcontractors. **Core Functions** are services that must be performed directly by the Contractor--the only allowable exception for subcontracting of Core Functions would be for performance of "Receipt, Storage, Shipping and Inventory." **Non-Core Functions** are projects in support of process development or pilot lot production that may be performed either directly by the Contractor or by designated subcontractors**.** The Contractor shall solicit for, and identify subcontractors based upon the candidate malaria vaccine selected and the product development service requested. The Contractor shall be responsible for ALL work performed under this contract including that performed by any subcontractor(s).

# Statement of Work
# Malaria Vaccine Production and Support Services
# RFP-NIH-NIAID-DMID-07-16

## OVERALL OBJECTIVE AND SCOPE:

The objective of this contract is to acquire the necessary research and development services to support process development and pilot lot production of promising candidate malaria vaccines into well-characterized malaria vaccine products suitable for evaluation in clinical studies. The scope of work to be performed includes:

1. Process development to identify optimal production and purification strategies for clinical-grade malaria immunogens;
2. Pilot lot production, formulation of clinical-grade material, and preclinical testing;
3. Regulatory support for compiling documentation necessary for submission of an Investigational New Drug (IND) application and/or Master File; and
4. Project management of the above-mentioned activities for candidate vaccine development.

For purposes of this contract, a *candidate vaccine* is defined to be material(s) that when administered appropriately to humans could reasonably be expected to provide immunologically-mediated protection against malaria. Such materials may comprise: 1) an immunogen, i.e., a material, typically based on a malaria antigen, that elicits an immune response specific for that antigen; 2) an immunologic enhancer, i.e., a material or means of administration that augments the desired specific immune response; and 3) a delivery system, e.g., DNA, recombinant vectors, viral-like particles, or direct administration. The Contractor shall optimize the immunogen(s), and the delivery system(s) selected by the Project Officer for vaccine development services. Optimization may include development and methods of immunogen expression, formulation, or adjuvanting/administration of candidate vaccines to enhance the breadth, intensity, immunologic memory, and/or persistence of appropriate specific immune responses.

NOTE: It is **not** the purpose of this contract to provide funds to support:

- Phase 1 clinical trials, or
- Monitoring of subsequent clinical investigations after a Malaria Vaccine Production Support Services (hereafter referred to as the "MVPSS")-supported IND has been filed.

The work under this contract has been divided into **Core Functions** and **Non-Core Functions** (see the introduction information to the Technical Requirements section, below). The Contractor shall provide services for preclinical development of candidate malaria vaccines identified through NIAID-funded grants and contracts, the NIAID intramural program, the private sector, or other sources selected by the Project Officer. The Contractor shall establish qualified teams of scientists either at its own institution or through subcontractors, to perform preclinical process development and pilot lot production services specific to the malaria vaccine candidate selected for product development. The Contractor shall provide overall project management and regulatory support services, and shall carry out activities only as requested by the Project Officer; and shall not conduct work on the contract without concurrence by the Project Officer. The Contractor shall be responsible for project planning, initiation, implementation, management and communication, including solicitations, evaluation, selection, and post-award administration of subcontractors, as well as for all deliverables specified in the contract. The Contractor/subcontractor(s) shall use state-of-the-art techniques and technologies in evaluating promising malaria vaccines and incorporate new and improved techniques and technologies into the contract activities.

## TECHNICAL REQUIREMENTS:

Independently, and not as an agent of the Government, the Contractor shall furnish all necessary services, qualified professional and technical personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed, to perform the work set forth below.

**Core Functions:** The Core Functions in SECTION 1, below, must be performed by the prime Contractor and cannot be performed by any subcontractors, with the exception of receipt, storage, shipping and inventory, which may be performed by a subcontractor. The Core Functions are critical for the effective oversight, management and operational integrity of the malaria vaccine development projects to be supported under this contract.

1. Initial Transition
2. Project Management
3. Regulatory Support
4. Receipt, Storage, Shipping and Inventory (may be performed by subcontractor)
5. Data Management and System Security
6. Technology Transfer
7. Ad hoc Advisory Group Meeting Support
8. Final Transition

**Non-Core Functions:** The Non-Core Functions in SECTION 2, below, are defined as those projects requiring highly specialized support to perform the preclinical malaria vaccine development activities. These Non-Core Functions may either be performed by the Contractor or by subcontractors.

1. Process Development
2. Pilot Lot Production

## SECTION 1 - CORE FUNCTIONS

### 1. Initial Transition

If applicable, the successor Contractor shall carry out the following tasks to provide for an orderly, safe and efficient initial transition:

a. Provide for the safe and efficient assumption of activities from the incumbent contractor to ensure a seamless transition without loss of time, loss of resources, and that would not pose obstacles to the conduct of on-going malaria vaccine research and development activities.

b. Within ten (10) business days of the effective date of the contract, meet with the Project Officer and incumbent contractor to coordinate and plan the initial transition including the tasks that are associated with the relocation effort from the incumbent contractor, and the type and manner of operations required by the Contractor during the transition period. This shall include safe and effective coordination with the incumbent contractor at the start of the new contract period for transfer of contract-related materials including: original data, reagents, stored specimens and any related documentation, Standard Operating Procedures (SOPs), and Government-owned equipment and property.

c. Complete the transition within the first ninety (90) calendar days following the effective date of the contract. The functions of the contract must be maintained during the transition period and ongoing activities of the MVPSS must not be interrupted at any time.

### 2. Project Management

Provide project management support for the development of specific malaria vaccine candidates designated by the Project Officer, to oversee their transition from early process development to late process development, through pilot lot production of clinical grade material, lot release, and pre-clinical testing, to support the use of the final product as clinical trial material. Project Management responsibilities shall include:

a. Overall Project Management

1) Provide a scientific, technical, and administrative infrastructure to ensure the efficient planning, initiation, implementation and management of all projects carried out under this contract and effective communications with the Project Officer and Contracting Officer. This infrastructure shall include a Principal Investigator with responsibility for:

   a) overall project management and communications;
   b) tracking, monitoring and reporting on project status and progress;
   c) recommending modifications to project requirements and timelines, including projects undertaken by subcontractors; and
   d) providing all deliverables according to the Reporting Requirements and Other Deliverables section of this contract.

   This infrastructure shall include Project Managers to coordinate activities for lead vaccine candidates as they transition from process development through pilot lot production, lot release, and pre-clinical studies; and administrative staff with responsibility for financial management and financial reporting on all activities conducted by the Contractor and subcontractors.

2) Develop and implement Project Management Plans for development of candidate malaria vaccines that include:

   a) specification of the resources and services to be provided;
   b) description of the key development objectives;
   c) delineation of project milestones and timelines for the accomplishment of milestones;
   d) Go/No Go decision points with quantitative and qualitative criteria for evaluating the scientific merit of progressing to the next stage of vaccine product development;
   e) description of the technical approach to carrying out the project and the physical facilities and other necessary resources to be made available;
   f) plan for the transfer of assays, technology, processes, methods, SOPs, reagents, products or other materials, data and documentation among parties involved in the project;
   g) description of the key scientific, technical and managerial risks posed by the project, and plans to mitigate such risks;
   h) description of all project reports and other deliverables, and timelines for their completion;
   i) list of proposed scientific and technical personnel and a description of their qualifications and relevant experience;
   j) plan for Quality Assurance and Quality Control (QA/QC) of the project; and
   k) proposed budget.

3) Based on the candidate malaria vaccine selected by the Project Officer, establish a qualified team of scientists to conduct process development, pilot lot production services, lot release, and/or preclinical testing. Work with such teams to obtain any additional reagents (e.g., malaria-specific reagents, adjuvants) that may be needed, and complete any documentation necessary (e.g., material transfer agreements) to accomplish this task.

4) Perform site visits and audits, as needed to meet Food and Drug Administration (FDA) required current Good Manufacturing Practice (cGMP) and Good Laboratory Practice (GLP) standards, and submit reports on all such audits to the Project Officer. NIAID reserves the right to conduct independent audits of the Contractor and its subcontractors as needed to evaluate compliance with FDA required cGMP and GLP standards and expects that all records and staff will be available in response to site visits or study-specific audits by NIAID or its designee.

5) Assure effective communications with the Project Officer and Contracting Officer. This shall involve meetings and conference calls with the Contractor's key personnel, including the Principal Investigator, Project Managers (as needed), Business Representative (as needed), and the Project Officer, at periodic intervals to be scheduled after contract award, to review the project status, progress and future plans. These meetings shall be arranged and coordinated by the Contractor.

6) At the request of the Project Officer, provide for the transfer of test articles, information, and advice to NIAID contractors and collaborators for purposes of advancing the NIAID malaria vaccine development effort.

b. Initiation and Acquisition of Non-Core Functions

During the performance of this contract, the Contractor may choose to execute Non-Core Functions specified in SECTION TWO of this Statement of Work within its own organization, or may choose to execute Non-Core Functions through a subcontract. For projects to be performed by subcontractors, the Contractor shall solicit, execute, and manage this subcontracting activity, as well as related tasks, and shall ensure that the award and management of subcontracts is in accordance with FAR Clause 52.244-2, entitled "Subcontracts".

1) Upon notification by the Project Officer of a requirement for support, determine whether the work can be performed in-house by the Contractor, or whether it should be out-sourced to a subcontractor. ***The Project Officer will submit the request to the Contractor utilizing the Attachment entitled "Project Request Form – Performance of Non-Core Functions."***

2) If the Contractor determines that they can perform the work in-house, they must respond to the request using the Project Request Form and provide the Project Officer with the information required in the Project Management Plan. The Project Management Plan shall be submitted for review to the Project Officer within thirty (30) calendar days of notification for services. Project initiation shall proceed only upon written approval of the Project Management Plan by both the Project Officer and Contracting Officer.

3) If the Contractor determines that the project must be out-sourced to a subcontractor, the Contractor shall develop a solicitation for the specified project within fourteen (14) calendar days of notification of project requirement. The solicitation package shall include the following and be provided to the Project Officer for review prior to issuance.

   a) Statement of Work,
   b) Milestones and Timeframes,
   c) Deliverables and Reporting Requirements,
   d) Evaluation Criteria, and
   e) Independent Cost Estimate.

4) Perform cost and technical analyses of proposals received from subcontractors. Provide all of the information to support your selection for award to the Contracting Officer and Project Officer within ten (10) business days of receipt of all proposals associated with a specific project, for review, acceptance and consent to award. Supporting documentation shall include a Project Management Plan (as outlined above) and a review of the strengths and weaknesses of the technical and cost proposals from potential subcontractors. Assure that all subcontracts include the appropriate flow-down clauses and provisions from the prime contract and that the subcontractor is in compliance with subcontracting, salary rate limitations, privacy and any other requirements mandated by current Public Laws.

5) Consent to subcontract will be provided by way of a bilateral modification to the contract or through the issuance of a Contracting Officer's Authorization (COA) letter that must be signed by the Contracting Officer or Contracting Officer's designated representative. The Project Officer cannot provide consent to subcontract.

6) Timeframes, including milestones and deliverables, for projects carried out by both the Contractor and by subcontractors will be commensurate with the complexity of the requirement and discussed and agreed upon by the Project Officer and Contracting Officer.

c. Subcontract Management and Reporting

1) Oversee the technical, administrative and operational activities of subcontractors on an on-going basis, including auditing subcontractor facilities, financial monitoring, and tracking deliverables and reporting requirements as well as subcontractor performance and achievement of milestones. The period of performance of each subcontract cannot exceed the period of performance of this contract.

2) Include in the Quarterly Technical Progress Reports, for each active, individual subcontract, an assessment of subcontractor performance, progress toward achievement of defined milestones, and status of funds.

3) Include in the monthly invoices, separate expenditure reporting for each project along with the cumulative expenditures for that month and all required documentation to support costs expended.

4) Identify and resolve problems with performance of active, individual subcontractors including both technical and financial aspects.

5) Ensure that subcontractor personnel, equipment and facilities are compliant with regulatory requirements in effect throughout the contract period.

6) Ensure the complete and effective transfer of technology by the subcontractors to the Contractor, the Government, or a third party as designated by the Project Officer.

7) Perform all necessary transition and closeout functions on each subcontract.

d. Intellectual Property and Disposition of Contract-Developed Materials

The Contractor shall consult with the Project Officer prior to the acquisition of any new third-party technology necessary for the performance of this contract. It is the responsibility of the Contractor to ensure that any license agreements between the Contractor and a third party, to acquire such technology, are consistent with the goals of this contract and in compliance with Federal laws and the terms of this contract.

3. **Regulatory Support**

Prepare, assemble, review and deliver materials and documents supportive of submission, by NIAID Offices of Regulatory Affairs, of INDs (as described in 21 CFR 312.23), and/or Master Files (as described in 21 CFR 314.420) to the Center for Biologics Evaluation and Research (CBER), FDA.

a. Obtain and review for presentation to the Project Officer, preclinical and clinical information needed for the IND and/or Master File submission through contacting appropriate individuals, other contractors, literature research, and accessing of appropriate databases.

b. Prepare or update the Investigator's Brochure (e.g., vaccine description and formulation, summary of preclinical and clinical safety, immunogenicity, activity data, and side effects).

c. Distribute the Investigator's Brochure to appropriate third parties (e.g., clinical investigators) as requested by the Project Officer.

d. Collect and submit the required documentation for the original IND submission and/or Master File (e.g., chemistry, manufacturing, control, in-process/release testing data, pharmacology, toxicology, and previous human experience) to the Project Officer and NIAID Offices of Regulatory Affairs.

e. Obtain authorization for cross-filing of information when appropriate. Obtain lot release protocols and Investigator Brochures prepared by the manufacturer.

f. Prepare a categorical exclusion request (21 CFR 25.30) or an environmental assessment, as described in 21 CFR 25.31, if required.

g. Provide additional information and data to support filing of submissions and amendments as necessary by NIAID Offices of Regulatory Affairs or its designee(s).

h. Participate in discussions with the FDA during pre-IND and IND meetings.

4. **Receipt, Storage, Shipping, and Inventory**

***Note: This Core Function may be performed by the prime Contractor or by a designated subcontractor.***

a. Develop and maintain efficient and effective procedures sufficient to support contract activities for receiving, storing, shipping and inventory of specimens, reagents, and candidates/vaccines.

b. Obtain the appropriate licenses and permits required by international, Federal, state, and local authorities for the safe transport, storage, and distribution of specimens, reagents, and candidates/vaccines.

c. Provide for safe packing, labeling, and shipping of specimens, reagents, and candidates/vaccines to sites designated by the Project Officer so that shipments are coordinated for timely receipt.

d. Provide shipping containers that comply with domestic and international postal regulations; pertinent International Air Transport Association (www.iata.org); and the International Civil Aviation Organization (www.icao.int) regulations. The shipping containers shall provide a sufficient margin of safety for maintaining appropriate environmental safeguards and desired refrigeration levels for specific products in transit, depending on the mode of transportation employed.

e. Provide secure, safe and stable storage of specimens, reagents, and candidates/vaccines under the required conditions (e.g., Biosafety Level, cGMP, aseptic).

f. Establish and maintain an electronic inventory of all specimens, reagents, and candidates/vaccines received, produced, stored, and shipped, such as in an Excel spreadsheet or database, compatible with Microsoft Office XP or software currently used and approved by NIAID, that includes searchable information, such as compound identifiers, amounts available, storage locations, shipping data and other biological and chemical characteristics of the compound.

5. **Technology Transfer**

The Contractor shall transfer assays, processes, methods, SOPs, reagents, products or other materials, data and documentation developed under the contract from one subcontractor to other subcontractors, to a third party designated by the Project Officer, or directly to the Project Officer.

6. **Data Management and System Security**

a. Maintain secure in-house data management capabilities and equipment to support all contract activities described in the Statement of Work. This database will contain confidential proprietary information that cannot be used for data-mining purposes by the Contractor or subcontractors.

b. Ensure secure electronic communications, including e-mail, word processing and transmission of data files, among the Contractor, NIAID staff, subcontractors and consultants. Organize, maintain, and transfer information on protocols and test results and provide electronic copies of all reports to the Project Officer.

c. Provide equipment and operational systems to maintain the confidentiality of data received from the NIAID or third parties, and data generated under this contract.

d. The Government reserves the right to have complete access to the databases, provide access to third parties, and to transfer all rights and custody to a successor contractor.

7. **Ad hoc Advisory Group Meeting Support**

a. Identify scientists working in industry or academia who possess expertise relevant to projects of the NIAID malaria vaccine development program to serve as ad hoc advisors.

b. Organize and coordinate meetings of ad hoc advisory groups for the purpose of providing strategic, scientific or technical advice to the NIAID in all aspects of malaria vaccine development (e.g., NIAID Malaria Vaccine Consultants Group and other technical advisory groups). The meetings shall be held in the Bethesda, Maryland area and should be attended by the Principal Investigator, relevant contract and subcontractor staff, the Project Officer and relevant NIAID staff identified by the Project Officer. The Contractor shall develop the agenda and submit to the Project Officer two (2) weeks prior to each ad hoc advisory group meeting.

1) Arrange for meeting and hotel space; coordinate audiovisual and other equipment; prepare, assemble, and distribute materials prior to the meetings.

2) Requests to use contract funds to provide light refreshments to either Federal or non-Federal employees must be submitted to the Project Officer, with a copy to the Contracting Officer, at least six (6) weeks in advance of the event. The request shall contain the following information:

(a) the name, date, and location of the event at which the light refreshments and/or meals will be provided;
(b) a brief description of the purpose of the event;
(c) a cost breakdown of the estimated light refreshment (meals will be unallowable);
(d) the number of non-Federal and Federal attendees partaking of the light refreshments; and
(e) if the event will be held somewhere other than a Government facility, provide an explanation of why the event is not being held at a Government facility.

3) Travel costs, per diem, and honorarium for invited non-Federal attendees shall be the responsibility of the Contractor.

c. Following each ad hoc advisory group meeting, prepare a report detailing the content and substance of the meeting as well as any relevant discussion that may have occurred. An Executive Summary and a list of key recommendations shall be included in the report. Reports shall be submitted to the Project Officer.

8. **Final Transition**

Six (6) months prior to the completion date of the contract, prepare and submit, for review and approval by the Contracting Officer and the Project Officer, a Final Transition Plan detailing how the resources generated under this contract shall be transferred in an orderly manner to a subsequent contractor or the Government.

a. Include a comprehensive list of original data, intermediate and final products data, databases, technologies, all stored reagents, stored specimens and any related information, SOPs, unused supplies, and any other resources generated under this contract.

b. Include a plan to ensure transfer of these resources and all deliverables listed under paragraph 10. of ARTICLE C.2., Reporting Requirements and Other Deliverables, to a successor contractor or the Government.

c. Coordinate and implement the NIAID-approved Final Transition Plan for the orderly and safe transition to a successor contractor or the Government of all original data, reagents, stored specimens and any information related thereto, SOPs, unused supplies, and any other resources generated under this contract.

## SECTION 2 – NON-CORE FUNCTIONS

1. **Process Development Services**

a. Construct, develop, optimize, purify, and evaluate specific vaccine candidates. The number and types of products to be developed will be identified by the Project Officer and may involve the following categories:

1) recombinant proteins expressed in prokaryotic systems [e.g. *E. coli*],
2) recombinant proteins expressed in eukaryotic systems [e.g. baculovirus, *Pichia*, *Saccharomyces,* mammalian cells],
3) synthetic peptides,
4) vector-based vaccines in bacterial [e.g. BCG, *Salmonella*] systems,
5) vector-based vaccines in viral [e.g. adenovirus, vaccinia] systems, and
6) DNA vaccines.

b. Optimize immunogen production in systems suitable for further vaccine development. Provide expert capabilities in:

1) gene or peptide synthesis,
2) vector construction,
3) prokaryotic and eukaryotic expression systems (including transformation/transfection and gene expression optimization),
4) cell cloning, and
5) relevant related technologies.

c. Develop and provide assays for in-process Quality Assurance/Quality Control (QA/QC), including:

1) methods for monitoring the antigenicity of candidate vaccine constructs and identification of contaminants; and
2) production, acquisition, or improvement of specific reagents necessary for such characterization and evaluation.

d. Develop and optimize methods for product recovery, characterization and purification, including:

1) initial screening for production;
2) initial growth studies;
3) initial recovery studies, and
4) assessment of the scalability of methods for product recovery, characterization, and purification at a level suitable for production of clinical-grade material.

e. Provide research-grade as well as GLP-grade routine or generic analytics, including:

1) physical appearance,
2) osmolality,
3) conductivity,
4) optical density,
5) SDS-PAGE (reduced and non-reduced),
6) Coomassie-stained and silver-stained),
7) 2-dimensional gel electropheresis,
8) Edman degradation,
9) amino acid analysis,
10) mass spectroscopy,
11) HPLC analysis,
12) capillary electropheresis,
13) circular dichroism,
14) limulus amebocyte lysis assay,
15) DNA content,
16) carbohydrate content,
17) lipid content,
18) heavy metal content,
19) host contamination, and
20) sterility.

f. Provide QA/QC support (off site) for the process development activities of the Malaria Vaccine Development Branch (MVDB) facility, within NIAID's Division of Intramural Research.

g. Provide assessment of final product for predesignated characteristics, such as yield, conformation, antigenicity, and biologic function.

h. Acquire and evaluate any adjuvants, immunostimulatory cytokines or genes, or other products that may be necessary to enhance the immunogenicity of the candidate vaccine antigen.

i. Formulate, vial, label, test, store and ship candidate products to sites designated by the Project Officer, utilizing procedures and materials that maximize product stability and meet Federal guidelines.

j. Characterize candidate vaccines for identity and stability using routine GLP-grade analytics.

k. Test vaccine immunogenicity (both cellular and humoral) in small animals (e.g., rodents, rabbits).

l. As requested by the Project Officer, provide written SOPs for all steps in the production and purification process that can be utilized in pilot lot production.

m. Provide and appropriately store characterized research-grade reagent stocks (e.g. cell banks, bacterial or viral clones).

2. **Pilot Lot Production Services**

Produce, formulate, characterize, package, store, and evaluate, vaccine products suitable for testing in clinical studies.

a. Produce pilot lots of promising vaccine candidates appropriate for human clinical trials. This may involve production and purification of bulk immunogen by a variety of means, including:

1) microbial fermentation,
2) bioreactor or hollow fiber,
3) peptide synthesis, or
4) production of live vector systems [prokaryotes, such as mycobacteria or salmonella; or viruses, such as vaccinia or adenovirus].

b. Prepare and characterize, where applicable, cGMP-grade Master stocks, cell banks, bacterial or viral seed banks, etc. Services to be provided include:

1) expansion of cell banks, characterization of Master stocks, drug substance and product characterization to meet lot release specifications, including:

a) DNA sequencing,
b) restriction analysis,
c) assays to support plasmid stability,
d) host stability,
e) host identity,
f) auxotrophy/prototrophy, purity (non-host contamination),
g) sterility, and
h) potency (cfu or pfu).

2) safety assessment studies for cell lines derived from mammalian and other higher eukaryote sources, including:

a) in vivo and in vitro viral and non-viral adventitious agent detection,
b) tumorigenicity, and
c) karyotyping.

c. Provide products and materials suitable for production of clinical-grade vaccine, including adjuvants, along with appropriate documentation of such products and materials as needed to meet regulatory requirements for submission of an IND and/or Master File, New Drug Application (NDA) or Biologic License Application (BLA) to the FDA.

d. Produce candidate vaccines in a form suitable for use in human clinical trials. These products shall meet FDA standards as described in the CFR, Title 21, Parts 58, 210 & 211, 600-640 and 800-868 and the Guidelines on Sterile Drug Products Produced by Aseptic Processing, September 2004.(http://www.fda.gov/cder/guidance/5882fnl.htm)

e. Formulate, vial, label, package, inventory, store and ship vaccine candidate products to sites specified by the Project Officer, utilizing procedures and materials according to GMP that maximize product stability and meet Federal guidelines.

f. Perform vaccine lot characterization tests for release specification, including potency, general safety, sterility, purity, pyrogenicity, and identity (as described in the regulations for General Biological Product Standards 21 CFR 610.10-14) or any additional testing required by FDA.

g. Perform stability testing in accordance with a plan for ongoing testing that shall satisfy FDA regulations. At a minimum, this testing shall be performed every month for the first three (3) months following production and then every three (3) months for the first year. Testing thereafter, and until the end of the contract, shall comply with FDA guidance and shall include, at a minimum, assay protocols and tests for identity, sterility, potency, and pH.

h. Provide preclinical safety evaluations and other safety tests that may be required for a particular vaccine type, such as:

   1) systemic toxicity,
   2) local reactogenicity,
   3) genetic toxicity,
   4) reproductive toxicity, and
   5) developmental toxicity.

i. Perform immunogenicity testing in appropriate animal models (e.g., rodents, rabbits).

j. Provide all data, information and records required for the writing and submission of the Master File, Investigator's Brochure and all other documents related to IND submission to the Project Officer or to a designated third party.

k. Provide information pertaining to the chemistry, manufacture and quality control of the vaccine product as appropriate for particular investigations to be covered by an IND to the Project Officer or to a designated third party.

l. Perform appropriate study to support the packaging and procedure used for shipping or transfer of the drug substance and/or product.

**[END OF STATEMENT OF WORK]**

**Reporting Requirements and Other Deliverables**
**Malaria Vaccine Production & Support Services**
**RFP-NIH-NIAID-DMID-07-16**

The Contractor shall prepare and submit to both the Contracting Officer and the Project Officer the following plans and reports. The plans and reports are subject to the technical inspection and requests for clarification by the Contracting Officer and Project Officer. The plans and reports shall be concise, factual and prepared in accordance with the following format:

**Format of Cover Page**: Each of the below Reports shall consist of a cover page containing:

- Report title;
- Contract number and project title;
- Period of performance being reported;
- Contractor's name and address, telephone, fax and e-mail;
- Author(s) and/or Principal Investigator's name; and
- Date of submission.

**1. Project Management Plans for Development of Candidate Malaria Vaccines**

The Contractor shall provide Project Management Plans for the development of candidate malaria vaccine(s). Project Management Plans shall include:

a. specification of the resources and services to be provided;
b. description of the key development objectives;
c. delineation of project milestones and timelines for the accomplishment of milestones;
d. Go/No Go decision points with quantitative and qualitative criteria for evaluating the scientific and technical merit of progressing to the next stage of vaccine product development;
e. description of the technical approach to carrying out the project, and the physical facilities and other necessary resources to be made available;
f. plan for the transfer of assays, technology, processes, methods, SOPs, reagents, products or other materials, data and documentation among parties involved in the project;
g. description of the key scientific, technical and managerial risks posed by the project, and plans to mitigate such risks;
h. description of all project reports and other deliverables, and timelines for their completion;
i. list of proposed scientific and technical personnel and a description of their qualifications and relevant experience;
j. plan for QA/QC of the project; and
k. proposed budget.

**2. Interim Status Report for Particular Malaria Vaccine Projects**

The Contractor shall provide Interim Status Reports, in electronic format, for a particular malaria vaccine project, including:

a. current project status;
b. progress to date;
c. "burn rates" (i.e., rates of expenditure of project funds) based on prior activities;
d. future "burn rates" based on anticipated activities;
e. any encountered problem and its resolution, or any anticipated problem and a plan for problem resolution;

f. estimated time to project completion; and
g estimated cost(s) to project completion.

**3. Summary Project Report for the Completion of Each Malaria Vaccine Project**

The Contractor shall provide a Summary Project Report including:

a. the original objectives of the project;
b. final status of the project;
c. a listing of milestones achieved;
d. deliverables from the project; and
e. an analysis of any deviations from the timeline and/or anticipated budget.

**4. Monthly Status Reports**

The Contractor shall provide a Monthly Status Report of work performed during the reporting period.

**5. Quarterly Technical Progress Reports**

The Quarterly Technical Progress Report shall include a brief summary of the work performed during the reporting period as follows:

a. A report on the status of each vaccine candidate being developed under the contract as of the last day of each quarter to include: progress since the previous report; outcomes achieved; problems encountered; and, proposed solutions to these problems.
b. A list of any other work undertaken during the quarter (e.g. meetings organized or attended);
c. Copies of any abstracts, manuscripts, and publications generated as a result of contract work;
d. A report on all active, individual subcontractor performance including problems identified and resolutions to these problems; and
e. A report on the status of funds for the contract and for all active subcontractors.

**6. Final Transition Plan**

The Final Transition Plan shall include all of the information required in Section 1, paragraph 8., of the Statement of Work.

**7. Ad hoc Advisory Group Meeting Agendas and Reports**

The Contractor shall develop the meeting agenda and submit it to the Project Officer for review and approval. The Contractor shall provide reports following each Ad hoc Advisory Group Meeting detailing the content and substance of the meeting as well as any relevant discussion that may have occurred. An Executive Summary and a list of key recommendations shall be included in the Ad hoc Advisory Group Meeting Report.

8. **Ad hoc Reports**

The Contractor shall provide Ad hoc Reports of any scientific discussions, or other documents pertaining to malaria vaccine development projects prepared at the request of the Project Officer. The information contained within the Ad hoc Reports may be provided to various branches of the Government and/or public health related agencies and NIAID collaborators and other groups upon their request and with the approval of the Project Officer. The Project Officer will specify the Ad hoc Report format at the time of the request.

9. **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 Office of 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 on the completion date of the contract to the Contracting Officer.

The annual utilization report shall be submitted in accordance with ARTICLE F.1. DELIVERIES, of this contract. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the completion date of the contract to the following address:

Contracting Officer
NIAID, NIH, DHHS
DEA, Office of Acquisitions
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892-7612

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

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

10. **Final Report and Summary of Salient Results**

The Final Report shall provide a summary of the results of the entire contract work for the complete performance period. The Final Report shall be in sufficient detail to explain comprehensively the results achieved and shall be submitted on or before the completion date of the contract. The Final Report shall contain:

a. an introduction covering the purpose and scope of the contract effort;
b. a description of the overall progress, plus a separate description of the final status of each vaccine candidate addressed under this contract and all subcontracts. Descriptions will include detailed information on significant results achieved, as well as any technology developed or improved, together with pertinent data;
c. copies of any abstracts, manuscripts, publications; and
d. copies of any patents filed or granted to the Contractor for work performed during the period of performance of this contract;

The Contractor shall submit, with the Final Report, a Summary of Salient Results, achieved during the performance of the contract, not to exceed 250 words.

11. **Technical reports shall be submitted as follows:**

| Item | Deliverable | Number of Copies | Delivery Schedule |
|---|---|---|---|
| 1. | Project Management Plans for Development of Candidate Malaria Vaccines | **Project Officer**<br>1 paper copy<br>1 electronic copy (by CD)<br><br>**Contracting Officer**<br>1 paper Original<br>1 electronic copy (by CD) | Within thirty (30) calendar days of notification of services by the Project Officer. |
| 2. | Interim Status Reports for a Particular Malaria Vaccine Project | **Project Officer**<br>1 paper copy<br>1 electronic copy (by CD)<br><br>**Contracting Officer**<br>1 paper Original<br>1 electronic copy (by CD) | To be identified in Project Management Plans for particular Malaria Vaccine Projects. |
| 3. | Summary Project Reports | **Project Officer**<br>1 paper copy<br>1 electronic copy (by CD)<br><br>**Contracting Officer**<br>1 paper Original<br>1 electronic copy (by CD) | Within sixty (60) calendar days following the completion of each Malaria Vaccine Project. |
| 4. | Monthly Status Reports | **Project Officer**<br>1 electronic copy (by e-mail)<br><br>**Contracting Officer**<br>1 paper Original<br>1 electronic copy (by CD) | 1st Report due on/before _____. Thereafter, each report shall be due on/before the 15th of the following month. |
| 5. | Quarterly Technical Progress Report | **Project Officer**<br>1 paper copy<br>1 electronic copy (by CD)<br><br>**Contracting Officer**<br>1 paper Original<br>1 electronic copy (by CD) | The first reporting period consists of the first full three (3) months of performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three (3) full calendar months. First report is due on/before _____. Thereafter, each report shall be due on/before the 30th of the following month. Not due when the final report is due. |
| 6. | Annual Utilization Report | **Contracting Officer**<br>1 paper Original<br>1 electronic copy (by CD) | Due on/before the 30th of the month following each anniversary date of the contract. |
| 7. | Final Invention Statement | **Contracting Officer**<br>1 paper Original<br>1 electronic copy (by CD) | Due on/before completion date of the contract. |

| | | | |
|---|---|---|---|
| 8. | All reports and documentation including the invention disclosure report, the confirmatory license, and the government support certification | **OPERA**<br>1 paper copy | As required by FAR Clause 52.227-11. |
| 9. | Final Transition Plan | **Project Officer**<br>1 paper copy<br>1 electronic copy (by CD)<br><br>**Contracting Officer**<br>1 paper Original<br>1 electronic copy (by CD) | Six (6) months prior to the completion date of the contract. |
| 10. | Ad hoc Advisory Group Meeting Agendas and Reports | **Project Officer**<br>1 paper copy<br>1 electronic copy (by CD)<br><br>**Contracting Officer**<br>1 paper Original<br>1 electronic copy (by CD) | Agenda: Due fourteen (14) calendar days prior to the Ad hoc Advisory Group Meeting.<br><br>Reports: Due thirty (30) calendar days after the completion of each Ad hoc Advisory Group Meeting. |
| 11. | Ad Hoc Reports | **Project Officer**<br>1 paper copy<br>1 electronic copy (by CD)<br><br>**Contracting Officer**<br>1 paper Original<br>1 electronic copy (by CD) | As needed. |
| 12. | Final Report and Summary of Salient Results | **Project Officer**<br>1 paper copy<br>1 electronic copy (by CD)<br><br>**Contracting Officer**<br>1 paper Original<br>1 electronic copy (by CD) | On or before the completion date of the contract. |

12. **Other Deliverables**

The Contractor, subject to Project Officer approval, shall deliver to the Government or its designee on/before the completion date of the Contract, the following items:

a. All Master seeds and banks, as well as vaccine candidates in various stages of production at completion of the contract, appropriately preserved, inventoried and identified.
b. Completed Batch Production Records for all candidates produced for clinical use.
c. A complete listing of accurate and updated information on design, development, production, and regulatory support activities of the Contractor and subcontractors, including computerized data files, original data, SOPs, and any information related thereto.

d. Process development reports, assay development reports, validation protocols, validation reports, technology transfer reports, GLP audit reports, and GMP audit reports, as requested by the Project Officer.
e. Reagents, stored specimens and any information related thereto, unused supplies, and any other resources generated under this contract.

**13. <u>Addressees</u>:**

**Project Officer**
Parasitology and International Programs Branch (PIPB)
Division of Microbiology and Infectious Diseases (DMID)
National Institute of Allergy and Infectious Diseases (NIAID), NIH, DHHS
6610 Rockledge Drive, Room 5103, MSC 6603
Bethesda, MD 20892-6603
For overnight delivery, use Zip Code 20817

**Contracting Officer**
Office of Acquisitions (OA), Division of Extramural Activities (DEA)
National Institute of Allergy and Infectious Diseases (NIAID), NIH, DHHS
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612
For overnight delivery, use Zip Code 20817

**OPERA**
Office of Extramural Inventions and Technology Resources Branch
OPERA, NIH
6705 Rockledge Drive, Room 1040 A, MSC 7980
Bethesda, Maryland 20892-7980

**Malaria Vaccine Production & Support Services**
**RFP NIH-NIAID-DMID-07-16**

**APPENDIX A – ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS**
**FORMAT FOR TECHNICAL PROPOSAL – TABLE OF CONTENTS**

**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 Technical Proposal. Offerors should follow the instructions in Section L of the solicitation and include the information requested in this appendix.

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

**Offerors are reminded that the total page limitation for the entire Technical Proposal package is 150 pages including all Appendices and Attachments.**

**Pages submitted in excess of the total page limit will be removed from the proposal and will not be considered further for award.**

**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)

**GENERAL NOTES**

1. The NIAID recognizes that the regulatory pathway for the development of a malaria vaccine may not be fully defined and that iterative modifications to the development process may be required as specific FDA guidance becomes available following pre-IND meetings. Proposals shall however, address the preclinical development, production, testing and characterization of candidate malaria vaccines in compliance with FDA requirements.

2. It is anticipated that the Contractor shall not hold the IND or Master File for any subsequent human trials to be conducted on the candidate malaria vaccines developed under this contract. The IND or Master File will be held by either NIAID or the organization that holds proprietary rights to the product. The

Contractor, however, may be requested to work directly with NIAID Offices of Regulatory Affairs to prepare for Master File and IND submission to the FDA.

## SECTION 2: CORE FUNCTIONS

### A. Project Management

#### 1. Overall Project Management

a) Describe how the project will be staffed, organized and managed. Describe in detail the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, and an administrative framework indicating clear lines of authority and responsibility for the personnel. Include a diagram of the proposed organizational/management structure for the project.

b) Describe project management systems that will be used to track activities and to keep multiple activities on time and within budget. The plan must include a description of quality control methods that will be used to ensure the effective initiation, implementation, management and oversight of contract requirements.

c) Outline how the Principal Investigator will communicate and interact with the Contracting Officer and Project Officer, and how the Principal Investigator will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).

d) Provide a plan for how the Contractor will safeguard confidentiality and intellectual property of data and materials provided to them by third parties of the U.S. Government, as well as data generated during the contract.

#### 2. Subcontract Acquisition and Management

a) Describe experience with different types of contracts (cost, fixed price, etc.), and provide a plan for soliciting, evaluating, negotiating, awarding and managing subcontracts in accordance with the requirements established by Federal contracting regulations and utilizing the process identified in the Statement of Work.

b) Describe experience and education of contract management staff in the acquisition and management of subcontracts under a Federal contract.

c) Describe experience with, and provide a plan for identification and remediation of subcontractor performance or noncompliance with subcontract terms and conditions.

### B. Regulatory Support

1. Describe the proposed approach to providing the NIAID with all relevant information and/or the ability to cross-reference an IND that will support NIAID filing a U.S. Government held IND. Include a detailed list of required documents and a plan for the production of the Investigator's Brochure, Master File, IND and all other documents required by the FDA for a new vaccine. The NIAID and/or the Contractor may use data developed during performance of this contract for consultations with the FDA in planning subsequent product development and/or clinical trials.

C. **Receipt, Storage, Shipping, and Inventory**

***NOTE: This is the only Core Function that may be subcontracted. If the offeror proposes a subcontractor to support this Core Function, technical information about the subcontractor must be included in the Technical Proposal. Related cost information should be included separately in the Business Proposal.***

1. Provide a plan for receiving, storing, and shipping specimens, reagents and vaccines.

2. Describe the electronic inventory system for the management of associated records and documents.

D. **Technology Transfer**

1. Provide a plan to transfer assays, processes, methods, SOPs, reagents, products or other materials and data developed under this contract from one subcontractor to other subcontractors; to a third party designated by the Project Officer; or directly to the NIAID. The plan must ensure that assays, processes, products or other materials and data developed by subcontractors shall be transferred to other parties when requested by the Project Officer.

E. **Data Management and System Security**

1. Describe the secure in-house data management system that will be used to support all contract activities described in the Statement of Work.

2. Describe experience and capacity to obtain, store, collate and arrange data and information and to keep all information secure.

F. **Ad hoc Advisory Meeting Support**

1. Describe the qualifications of scientists working in industry or academia who possess expertise to serve as advisors. Do NOT include the names of proposed advisors in the Technical Proposal.

2. Describe your approach(es) for providing ad hoc advisory meeting support to NIAID on strategic, scientific or technical issues relevant to malaria vaccine development.

## SECTION 3: NON-CORE FUNCTIONS

**A. Case Studies**

1. Prepare a detailed operating plan with a full technical approach utilizing the Project Management Plan described in the Statement of Work [Section I, paragraph 2.a.2)] for process development and pilot lot production for the three (3) categories of vaccine candidates listed below. ***Each Project Management Plan should not exceed 20 pages.*** Copies of SOPs do not need to be submitted; a list of applicable SOPs may be submitted. Copies of SOPs may be requested from offerors with proposals determined to be in the competitive range.

   a) A candidate vaccine based on a recombinant protein expressed in mammalian cells;
   b) A candidate vaccine based on a recombinant protein expressed in eukaryotic expression systems, excluding *Saccharomyces*; and
   c) A vector-based candidate vaccine.

2. Do not list the proposed scientific and technical personnel for Non-Core Functions; rather include a description of the necessary qualifications and relevant experience.

3. For each malaria vaccine candidate, include a description of the scientific basis for process development, scale up, production, analytical and lot release assays, formulation strategy and adjuvants, if appropriate.

4. For each malaria vaccine candidate, include a nonclinical development plan to evaluate preclinical safety that includes the conduct of all FDA-required IND enabling studies.

**B. Provision of Non-Core Functions**

1. Discuss your methodology for identifying and obtaining the appropriate expertise necessary to fulfill the requirements under the Non-Core Functions. This should include a discussion which demonstrates your understanding of the knowledge, experience and expertise required to carry out the Non-Core Functions, and your approach to establishing productive, qualified teams of scientists.

   **OFFERORS ARE ADVISED THAT THIS EXERCISE IS *NOT* FOR THE PURPOSE OF PROPOSING SPECIFIC ORGANIZATIONS WITH WHICH THEY PLAN TO SUBCONTRACT FOR PERFORMANCE OF NON-CORE FUNCTIONS. THEREFORE, OFFERORS ARE *NOT* TO IDENTIFY ANY ACTUAL SUBCONTRATORS IN THIS EXERCISE. REVIEWERS WILL ONLY BE EVALUATING YOUR METHODOLOGY AND EXPERTISE AS STATED IN PARAGRAPH 1., ABOVE.**

2. Describe any previous problem(s) experienced with subcontract relationships and their resolution.

3. Provide plans for identifying and mitigating conflicts of interest.

## SECTION 4: PERSONNEL QUALIFICATIONS

1. Principal Investigator: Describe the experience, training, expertise, and qualifications, as well as percentage of effort to be devoted to this contract, in planning, initiation, implementation, management and coordination of projects of similar size and complexity. Include experience with leading and directing project activities either directly or indirectly through subcontracts. Identify and discuss problems encountered in meeting milestones and discuss how those issues were resolved. Describe experience with meeting similar preclinical product development milestones in a timely manner. Limit the CV to 2-3 pages and provide selected references for publications relevant to the scope of requirements for the contract.

2. Key Scientific and Technical Personnel: Describe the training, qualifications, knowledge, experience, education and competence (as they relate to the Statement of Work), as well as the percentage of the total time each will be committed to the project. Provide documentation to describe:

   a) Key Scientific and Technical Personnel (limit CVs to 2-3 pages);
   b) Qualifications and relevant training;
   c) Knowledge and experience in regulatory activities for the submission of INDs and/or Master Files to the Center for Biologics Evaluation Research (CBER), FDA;
   d) References to all relevant publications;
   e) Availability of all staff for the proposed project; and
   f) Summary of ongoing and completed activities directly related to the requirements of the Statement of Work

3. Other Personnel: Describe responsibilities and document the relevant experience, training and expertise of other personnel as needed to address the requirements of the Statement of Work.

## SECTION 5: FACILITIES AND RESOURCES (Core Functions)

1. Document availability and adequacy of facilities, equipment, space and other resources necessary to carry out the Statement of Work including:

   a) a description of the organization of the facility including floor diagrams (lease or ownership information should be provided); and
   b) identification and description of ALL support resources (including IT systems) which will be required to effectively complete the SOW.

2. Discuss your approach to ensuring the adequacy of facilities for the scale-up, manufacture and preclinical testing of vaccine candidates with particular attention to meeting GLP and GMP requirements.

3. Discuss your approach to ensuring adequate care and housing of laboratory animals, including: a description of the requirements for appropriate veterinary coverage; the physical plant housing all animals and laboratories; the safety procedures; and the expertise and training of the technical staff to be employed.

4. Include a letter with the Technical Proposal, signed by the appropriate administrative authority, allowing for ***pre-award site visits*** to the offeror's facilities. Site visits may include cGMP and GLP audits performed by professional auditors contracted by NIAID.

## SECTION 6 - DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

1. **Biohazard Safety**

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

2. **IT Systems Security**

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

3. **Animal Welfare**

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

**Malaria Vaccine Production and Support Services**
**RFP-NIH-NIAID-DMID-07-16**

# 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; the technical evaluation criteria; and the RFP as a whole, in the development of their Business Proposals. The information requested in these instructions should be used as a guide for the development and formatting of your Business Proposal. Offerors should consider and include the information requested in this Appendix, as well as **any other** information which will benefit the proposal.

## BUSINESS PROPOSAL

### BUSINESS PROPOSAL – TABLE OF CONTENTS

**SECTION 1 – PROPOSAL COVERSHEET** (use form NIH 2043 identified in Section J)

**SECTION 2 – COST OR PRICE SUPPORT**

Section L of the RFP specifies the minimum documentation requirements for cost data and all cost related support. All related documentation should be included in the proposal in a clearly marked section.

**SECTION 3 – UNIFORM BUDGET ASSUMPTIONS**

For purposes of the budget preparation, the offeror shall assume the following activities will occur each year, unless otherwise stated.

**Annual Capacity**

Although the number of vaccine doses required for any given product cannot currently be specified, for purposes of responding to this RFP, the offeror shall submit budgets for each of the six categories of vaccine candidate described in the Statement of Work, Section 2, Non-Core Functions, paragraph 1.a), assuming single dose vialing of the highest anticipated dose for initial clinical evaluation in humans, and using the following estimated total amounts:

- 1 gm of protein or peptide;
- 2000 doses of vectored vaccine; and
- 2000 doses of DNA vaccine.

Assume one candidate/year will be designated for process development from each of the six categories.

Assume that one candidate will be taken into pilot production in the first, third and fifth years of the contract, for a total of three candidates. Furthermore, assume that the first candidate will be based on a recombinant protein expressed in a eukaryotic system, the second candidate vaccine will be a viral-vectored candidate vaccine, and the third candidate will be based on a recombinant protein expressed in a eukaryotic system.

Assume that an IND for one vaccine product per year shall be submitted to the FDA.

Assume that two additional GLP toxicology studies shall be performed each year for vaccines or immunogens produced by other groups including the MVDB under separate arrangement with the NIAID, or for novel formulations of vaccines produced under this contract.

**Scientific and Technical Meetings, and Ad hoc Reports**

Assume that the NIAID Malaria Vaccine Consultants Group consists of five individuals traveling from the eastern U.S., and meeting for one and one-half days, three times a year in the Bethesda, MD, area. In addition, there may be up to six, one-day meetings of ad hoc technical advisory groups per year, each consisting of five members anticipated to be traveling from within the continental U.S. The Contractor is responsible for all costs incurred for conducting the logistical tasks associated with the meeting including: travel and per diem expenses for invited participants; honorarium (assume each honorarium equals $200/day) for non-Government ad hoc advisory members; preparing meeting agendas; collecting, organizing, and disseminating meeting materials; preparing and disseminating the summary of the meeting to participants; securing conference rooms; and the coordination of audiovisual and other relevant equipment. All cost estimates for these meetings should be based on Government per diem rates.

Assume one pre-IND and one IND meeting for each IND that shall be submitted to the FDA.

Assume the preparation of 10 ad hoc reports per year as requested by the Project Officer. Estimate 12 pages of written text for each ad hoc report, not including supporting documentation such as Power Point slides.

**PROJECT REQUEST FORM - PERFORMANCE OF NON-CORE FUNCTION**

Project No:_____ Modification No.: _____
Project Initiator: _____

Non-Core Function: [See Box checked below] Date Prepared: _____

☐ Process Development
☐ Pilot Lot Production

==========

**Part I. INITIATOR'S REQUEST**

A. Period of Performance: From: _____ To: _____

B. Description of Non-Core Function:

C. Project Leader: _____

D. Deliverables:

E. Response Due Date: _____

**PROJECT REQUEST FORM - PERFORMANCE OF NON-CORE FUNCTION**

Project No:_____ Modification No.: _____
Project Initiator: _____

Non-Core Function: [See Box checked on page 1 of Form] Date Prepared: _____

==========

**PART II CONTRACTOR'S PROPOSAL FOR PROJECT**

(The Contractor may attach additional sheets to this form to present requested data.)

A. Estimated Cost and Effort

1. Labor hours - list Project leader, specific individuals to be assigned, labor category, and estimated hours for each.
2. Labor costs - list by labor category and total.
3. Employee fringe benefits.
4. Direct materials (provide breakdown)
5. Travel (provide breakdown)
6. Subcontracts (provide breakdown)
7. Other direct costs (provide breakdown)
8. Indirect costs
9. Total estimated costs for this Project

B. Detailed description of the approach to be used and of the deliverable(s). (Be specific.)

APPROVAL TO PROCEED: The Contractor shall not exceed the estimated labor hours, estimated cost of project, or change the Project Leader without the prior written approval of the Project Officer and the Contracting Officer.

l. For the Contractor:_____ Date: _____
(Signature)

Typed name: _____

2. For the Government: _____ Date: _____
(Project Officer)

_____ Date: _____
(Contracting Officer)

**PROJECT REQUEST FORM - PERFORMANCE OF NON-CORE FUNCTION**

Project No:_____ Modification No.: _____
Project Initiator: _____

Non-Core Function: [See Box checked on page 1 of Form] Date Prepared: _____

==========

**PART III. CONTRACTOR'S REPORT OF PROJECT PERFORMANCE**

(The Contractor may attach additional sheets to this form to present the requested data.)

A. Actual Cost and Effort

1. Labor hours - list specific assigned individuals, labor category, and actual hours worked.
2. Labor costs - list labor category, individual, and total amount.
3. Employee fringe benefits
4. Direct materials (provide breakdown)
5. Travel (provide breakdown)
6. Subcontracts (provide breakdown)
7. Other direct costs (provide breakdown)
8. Indirect costs
9. Total costs for this Project.

B. Report of Deliverables

REVIEW AND APPROVAL OF SATISFACTORY PERFORMANCE

The signatures below indicate that the services/products required under Project No. _____ has been delivered, received and satisfactorily meet the requirements of this Project.

l. For the Contractor:_____ Date: _____
(Signature)

Typed name: _____

2. For the Government: _____ Date: _____
(Project Officer)

_____ Date: _____
(Contracting Officer)

**Malaria Vaccine Production & Support Services**
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**SAFETY CONTROLS AND STANDARDS**
**APPENDIX D**

a. In order to provide safety controls for protection to the life and health of employees and other persons; to prevent damage to all property; and to avoid work interruptions in performance of the contract, the Contractor and any subcontractors shall comply with the following standards, subsequent issues and any supplements. In addition, the Contractor shall comply with all applicable Federal, state and local laws, codes, ordinances and regulations, including obtaining of all required licenses and permits in connection with biological and hazardous materials.

(1) "Biosafety in Microbiological and Biomedical Laboratories," U.S. Department of Health and Human Services, Centers for Disease Control (CDC) and the NIH, Fourth Edition (and updates) http://www.cdc.gov/od/ohs/biosfty/biosfty.htm; http://www.cdc.gov/od/ohs/pdffiles/4th%20BMBL.pdf
(2) If animals or animal products will be used: http://www.aphis.usda.gov/programs/ag_selectagent/index.html
(3) "Recommendations for the Safe Handling of Cytotoxic Drugs," NIH Publication No. 92-2621: http://www.nih.gov/od/ors/ds/pubs/cyto/index.htm
(4) NIH Chemical Hygiene Plan: http://www.nih.gov/od/ors/ds/pubs/chp/chemhygplan03.pdf
(5) Occupational Safety and Health Administration (OSHA) Publications:

a) 29 CFR Part 1910.1030, Occupational Exposure to Blood Borne Pathogens, Final Rule, http://iforms.osha-slc.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051
b) 29 CFR Part 1910.1540, Occupational Exposure to hazardous chemicals in Laboratories, Final Rule. http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10106

(6) NIH Guidelines for Research Involving Recombinant DNA Molecules (49 FR 46266 or latest revision) and Administrative Practices Supplement (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html)

Additionally the Contractor must comply with the current regulations governing handling, transportation and import/export of etiologic agents in accordance with the Select Agent Program (http://www.cdc.gov/od/sap/index.htm).

Further, the Contractor shall take, or cause to be taken, such additional safety measures as reasonably necessary; provided, that if compliance with such additional safety measures results in a material increase in the cost or performance effort of the contract, an equitable adjustment will be negotiated with the Contracting Officer in accordance with the clause in this contract entitled "Changes."

b. Prior to commencement of work, the Contractor shall submit a written plan for complying with the safety and health requirements of this contract; and meet with the Contracting Officer, or his/her designated representative, to discuss and develop a mutual understanding relative to administration of the overall security and safety program.

c. During the performance of work under this contract, the Contractor shall comply with all regulated standards and procedures for the control and safety of persons visiting the job site, and comply with such requirements to prevent accidents.

d. The Contractor shall maintain an accurate record and report to the Contracting Officer all accidents and incidents resulting in death, traumatic injury, occupational disease, and/or damage to property that occur during the performance of the contract.

e. The Contracting Officer shall notify the Contractor in writing of any noncompliance with the provisions of this Appendix and corrective action to be taken. After receipt of such notice, the Contractor shall immediately take such corrective action. Such notice, when delivered in writing to the Contractor or its representative at the site of the work, shall be deemed sufficient for the purpose. If the Contractor fails to comply promptly, the Contracting Officer may issue a stop-work order to halt part of, or all work until satisfactory corrective action has been taken. No time lost due to such a stop order shall be the subject of claim for time extension, costs, or damages made by the Contractor.

f. The Contractor shall insert the substance of this Appendix in each subcontract involving the use of hazardous materials or operations. Compliance with the provisions of this Appendix by subcontractors shall be the responsibility of the Contractor.

## GOVERNMENT FURNISHED PROPERTY

Pursuant to the clause, GOVERNMENT PROPERTY, incorporated in this contract, the Contractor is hereby authorized to retain custody of the property listed in the below Schedule II-A for use in direct performance of this contract. Accountability for the items listed in Schedule II-A is hereby transferred to this contract from predecessor Contract No. _____, under which these items were provided by the Government. Title to this property shall remain in the Government.

### SCHEDULE II-A

The government property to be provided includes:

1) 24.4 Cubic Foot Upright Freezer;
2) Applikon Bio Controller ADI 1010;
3) Applikon Stirrer Controller P1000;
4) Applikon Bio Console ADI 1025;
5) Applikon Bioreactor Motor; and
6) Applikon 15-Liter Bioreactor Vessel.