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

RFP-NIH-NIAID-DMID-07-06
"DEVELOPMENT OF ANIMAL MODELS AND ASSAYS FOR PLAGUE VACCINES"

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:**
September 12, 2006	November 16, 2006 **Time:** 4:00 PM, Local Time	[ ]Yes [x] No **8(a) Set-Aside:** [ ]Yes [x] No **NAICS: 541710** (See Part IV, Section L.)

6. **Just In Time:**	7. **Number of Awards:**	8. **Technical Proposal Page Limits:**
[x] No [ ] Yes (See Part IV, Section L.)	[ ] Only 1 Award [X] Multiple Awards	[ ] No [x] Yes **200 Pages** **See Attachment 1, Packaging and Delivery of Proposal**

9. **Issued By:**	10. [x] **NIAID reserves the right to make awards without discussion.**	
David T. Lisle Contracting Officer Office of Acquisitions, DEA, NIH, NIAID 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	11. **Options:** **[ ] No** **[X] Yes** (See Part IV, Section L.)	12. **Period of Performance:** **Base:** **September 10, 2007 through September 9, 2010** **Option:** **September 10, 2010 through September 9, 2011**

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : David T. Lisle **Phone:** 301- 451-2617 **Fax:** 301-402-0972 **E-Mail:** DLisle@niaid.nih.gov	**Name:** Ross Kelley **Phone:** 301-402-2234 **Fax:** 301-480-4675 **E-Mail:** RKelley@nih.gov	Director, OA Address (see Block 9.)

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

17. Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See Part III, SECTION J – Attachments)

18. **DELIVERY ADDRESS INFORMATION**

19. **Hand Delivery or Overnight Service:**	20. **U.S. Postal Service or an Express Delivery Service**
David T. Lisle Contracting Officer Office of Acquisitions DEA, NIH, NIAID, DHHS 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	David T. Lisle Contracting Officer Office of Acquisitions DEA, NIH, NIAID, DHHS 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with FAR 15.208 entitled " Submission, Modification, Revision, and Withdrawal of Proposals." FACSIMILE OR 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 CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR *(i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval)* WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This contract will develop, optimize, qualify and validate product-neutral immunological assays, potency assays and animal efficacy models for the evaluation and assessment of plague vaccine candidates based on F1 and V antigens.

ARTICLE B.2. ESTIMATED COST AND FIXED FEE

a. The estimated cost of the Base Period of this contract is $_____.

b. The fixed fee for the Base Period of this contract is $_____. [The fixed fee shall be paid in installments based on the percentage of completion of work, as determined by the Contracting Officer./The fixed fee shall be paid in direct ratio to the level of effort expended; that is, the percent of fee paid shall be equal to the percent of total effort expended.] Payment shall be subject to the withholding provisions of the clauses ALLOWABLE COST AND PAYMENT and FIXED FEE referenced in the General Clause Listing in Part II, ARTICLE I.1. of this contract. Payment of fixed fee shall not be made in less than monthly increments.

c. The Government's obligation, represented by the sum of the estimated cost plus the fixed fee for the Base Period of this contract is $_____.

d. If the Government exercises its option pursuant to the OPTION PROVISION Article in SECTION H of this contract, the Government's total obligation represented by the sum of the estimated cost plus the fixed fee will be increased as follows:

	Estimated Cost ($)	**Fixed Fee ($)**	**Estimated Cost Plus Fixed Fee ($)**
Base Period Option Period(s): Total [Base Period and Option(s)]			

e. Total funds currently available for payment and allotted to this contract are $_____ of which $_____ represents the estimated costs, and of which $_____ represents the fixed fee. For further provisions on funding, see the LIMITATION OF FUNDS clause referenced in Part II, ARTICLE I.2. Authorized Substitutions of Clauses.

f. It is estimated that the amount currently allotted will cover performance of the contract through_____.

g. The Contracting Officer may allot additional funds to the contract without the concurrence of the Contractor.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

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 09/12/2006, 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 the 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 the “Reporting Requirements and Deliverables” in SECTION J - List of Attachments.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by [FAR Clause 52.227-11/FAR Clause 52.227-11 (Deviation)] including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

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

Contracting Officer
OA, DEA, NIAID, NIH, DHHS
6700-B Rockledge Drive, Room 3214, MSC 7612
Bethesda, Maryland 20892 - 7912

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

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

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

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

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

c. Inspection and acceptance will be performed at the address listed for the Project Officer in Section G, ARTICLE G.1. 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. PERIOD OF PERFORMANCE

a. The period of performance of this contract shall be from _____ through _____.

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

Option	Option Period

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the STATEMENT OF WORK in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the items specified in the delivery schedule described in SECTION C of this contract.

The items described in SECTION C, ARTICLE C.2. will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the dates specified in SECTION C, ARTICLE C.2. and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of this contract.

ARTICLE F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

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

[To be specified prior to award]

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

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

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

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

NAME TITLE
[To be specified prior to award]

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

a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The instructions and the following directions for the submission of invoices/financing request must be followed to meet the requirements of a "proper" payment request pursuant to FAR 32.9.

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

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

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

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN266200700006C.)

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-70006.)

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

Contracting Officer
National Institutes of Health, NIAID
DEA, Office of Acquisitions
6700-B Rockledge Drive, Room 3214, MSC 7612
BETHESDA MD 20892-7612

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

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 LEGISLATION PROVISIONS Article in SECTION H of this contract. For billing purposes, certified invoices are required for the billing period during which the applicable Fiscal Year funds were initially charged through the final billing period utilizing the applicable Fiscal Year funds:

"I hereby certify that the salaries charged in this invoice are in compliance with the applicable Public Law Number for the applicable Fiscal Year and the SALARY RATE LIMITATION LEGISLATION PROVISIONS 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 Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 EXECUTIVE BLVD MSC 7540
BETHESDA MD 20892-7540

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

ARTICLE G.5. GOVERNMENT PROPERTY

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

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

ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared following Year 1 and every other year thereafter (or more frequently as determined by the Contracting Officer) 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. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained

constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

ARTICLE H.3. RESEARCH INVOLVING RECOMBINANT DNA MOLECULES (Including Human Gene Transfer Research)

All research involving Recombinant DNA Molecules shall be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html) and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules (http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html) (and any subsequent revisions to the Guide Notice) which stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the Guidelines). These guidelines apply to both basic and clinical research studies.

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

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

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

ARTICLE H.4. 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.5. 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.6. 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.7. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL:
http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/

ARTICLE H.8. OPTION PROVISION

Unless the Government exercises its option pursuant to the Option Clause set forth in ARTICLE I.3., the contract will consist only of the Base Period of the Statement of Work as defined in Sections C and F of the contract. Pursuant to clause 52.217-7 set forth in ARTICLE I.3. of this contract, the Government may, by unilateral contract modification, require the Contractor to perform additional options set forth in the Statement of Work and also defined in Sections C and F of the contract. If the Government exercises this option, notice must be given at least 60 days prior to the expiration date of this contract, and the estimated cost [plus fixed fee] of the contract will be increased as set forth in SECTION B of this contract.

ARTICLE H.9. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

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

b. Subcontracting Reports

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

(1) Individual Subcontract Reports (ISR)

Regardless of the effective date of this contract, the Report shall be 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 [Contracting Officer/Contract Specialist/or title of alternate designee] shall be included as a contact for notification purposes at the following e-mail address:

[Contracting Officer/Contract Specialist e-mail to be included at award]

ARTICLE H.10. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Pursuant to the P.L.(s) cited in paragraph b., below, no NIH Fiscal Year funds may be used to pay the direct salary of an individual through this contract at a rate in excess of the applicable amount shown or the applicable Executive Level for the fiscal year covered. Direct salary is exclusive of fringe benefits, overhead and general and administrative expenses (also referred to as "indirect costs" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor. The per year salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b.

Public Law and Section No.*	**Fiscal Year***	**Dollar Amount of Salary Limitation***

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

[*Applicable information to be included at award]

ARTICLE H.11. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN2662007XXXXC.

ARTICLE H.12. 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.13. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

ARTICLE H.14. 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.15. 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.16. SHARING RESEARCH DATA

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

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

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

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

ARTICLE H.17. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

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

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

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

Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http://www.cdc.gov/od/sap/ and http://www.cdc.gov/od/sap/docs/salist.pdf. Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at: http://www.aphis.usda.gov/programs/ag_selectagent/index.html and:
http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html.

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

ARTICLE H.18. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

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

ARTICLE H.19. 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.

It is expected that the following clause(s) will be made part of the resultant contract:

FAR Clause **52.204-7, Central Contractor Registration** (July 2006) is deleted in its entirety. **(FOREIGN CONTRACTORS ONLY)**

FAR Clauses **52.215-15, Pension Adjustments And Asset Reversions** (October 2004); **52.215-18, Reversion Or Adjustment Of Plans For Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, **52.215-19, Notification Of Ownership Changes** (October 1997), are deleted in their entirety.

Alternate IV (October 1997) of FAR Clause **52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data--Modifications** (October 1997) is added.

Alternate II (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (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.]***

Alternate I (February 2002), of FAR Clause **52.232-25, Prompt Payment** (February 2002) is deleted.

FAR Clause **52.232-33, Payment By Electronic Funds Transfer--Central Contractor Registration** (October 2003) is deleted in its entirety and FAR Clause **52.232-34, Payment by Electronic Funds Transfer--Other Than Central Contractor Registration** (May 1999) is substituted therefor. **(FOREIGN CONTRACTORS ONLY)**

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

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

(2) 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."

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

(4) FAR Clause **52.222-29, Notification of Visa Denial** (June 2003). **(FOREIGN CONTRACTOR ONLY)**

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

(6) FAR Clause **52.227-1, Authorization and Consent** (July 1995).

(7) FAR Clause **52.227-2, Notice and Assistance Regarding Patent and Copyright Infringement** (August 1996).

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

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

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

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

(12) FAR Clause **52.227-15, Representation of Limited Rights Data and Restricted Computer Software** (June 1987).

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

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

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

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

(17) FAR Clause **52.230-4, Consistency in Cost Accounting Practices** (August 1992). **(UNITED KINGDOM CONTRACTORS ONLY)**

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

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

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

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

(22) FAR Clause **52.247-68, Report of Shipment (REPSHIP)** (February 2006).

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).

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

(4) HHSAR Clause **352.333-7001, Choice of Law (Overseas)** (March 2005).

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

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

(1) **NIH (RC)-7, Procurement of Certain Equipment** (April 1984) (OMB Bulletin 81-16).

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

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

This contract incorporates the following clauses in full text.

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

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

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

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

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

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

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

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at end of RFP
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at end of RFP
Attachment 3:	Statement of Work	See Attachment Section at end of RFP
Attachment 4:	Reporting Requirements and Deliverables	See Attachment Section at end of RFP
Attachment 5:	Additional Technical Proposal Instructions	See Attachment Section at end of RFP
Attachment 6:	Additional Business Proposal Instructions	See Attachment Section at end of RFP

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

Attachment No.	Title	Location
Attachment 7:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 8:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 9:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 10:	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.)

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

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

Attachment No.	Title	Location
Attachment 16:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Attachment 17:	Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Attachment 18:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.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).

NOTE : In accordance with HHSAR 352.215-1, the following paragraph (e) is substituted for the subparagraph (e) of the provision at FAR 52.215-1.

(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 AWARDS**

It is anticipated that Multiple Awards will be made from this solicitation and that the awards will be made on/about September 10, 2007.

It is anticipated that the awards from this solicitation will be multiple-year, cost reimbursement, completion type contracts with a 3 year base period of performance and options which could extend the period of performance for 1 additional year. 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 25.8 FTE for each year of the base period and 5 FTE for the performance of each option (a total of 15 FTE for all options). 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:

Contracting Officer
Office of Acquisitions, DEA
NIAID, NIH, DHHS
6700-B Rockledge Drive, Rm. 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 multiple cost-reimbursement, completion type contracts will be awarded. (See General Information) Any resultant contracts 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 contracts.

(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 also, Additional Technical Proposal Instructions, Attachment 5).

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 also, Additional Business Proposal Instructions, Attachment 6).

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

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

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

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

amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

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

(6) **Evaluation of Proposals**

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

(7) **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) **Standards for Privacy of Individually Identifiable Health Information**

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

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

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

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

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

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

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

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

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

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

- to the cognizant audit agency and the 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.

(13) **Past Performance Information**

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

A list of the last 5 contracts completed during the past three years and the last 3 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 $500,000. .

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

b) Each offeror will be evaluated on its performance under existing and prior contracts for similar products or services. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

(14) **Prohibition on Contractor Involvement with Terrorist Activities**

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

(15) **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).

e) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).

f) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).

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 found in Section M.

(3) **Additional Technical Proposal Information**

a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

(4) **Other Considerations**

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

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

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

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

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

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

(5) **Care of Live Vertebrate Animals**

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

Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (Revised 1986, Reprinted 2000)

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

OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

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

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

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

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

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

Notice to Offerors of Requirements of: 42 CFR Part 73, Possession , Use, and Transfer of Select Agents and Toxins (relating to public health and safety):
(http://www.cdc.gov/od/sap/42_cfr_73_final_rule.pdf);
7 CFR Part 331, Possession, Use, and Transfer of Select Agents and Toxins (relating to plant health or plant products):
(http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf); and,
9 CFR Part 121, Possession, Use, and Transfer of Select Agents and Toxins (relating to human and animal health, animal health or animal products):
(http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) - March 18, 2005.

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

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

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

Domestic Institutions

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

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

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

Foreign Institutions

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

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

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

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

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

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

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

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

Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

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

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

(a) **Sharing Research Data**

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

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

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

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

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

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

The NIH Guidelines for Research Involving Recombinant DNA Molecules at:
(http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules at:
(http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html)
and any subsequent revisions to the Guide Notice) stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the NIH Guidelines). These guidelines apply to both basic and clinical research studies.

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

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

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

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)

(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, Attachment to this RFP is an example of such a plan.

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

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

c) The offeror understands that:

(1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.

(3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a

subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.

(4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.

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

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and/or Service Disabled Veteran-Owned Small Business Concerns.

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

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

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

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

(8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $500,000 adopt a plan similar to the plan agreed upon by the offeror.

(10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

For additional information about each of the above elements required to be contained the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

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

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

(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 - SECTION K**

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

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

a) **Travel Costs - Commercial**

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

b) **Travel Policy**

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

(15) **Certification of Visas for Non-U.S. Citizens**

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

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost 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.

2. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s). In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

3. EVALUATION OF DATA SHARING PLAN

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

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

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

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

5. TECHNICAL EVALUATION CRITERIA:

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

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

CRITERIA **WEIGHT**

CRITERION 1: Technical Approach **30**

A. Adequacy and feasibility of the documentation and preliminary data that describes the offeror's current plague animal model(s) and the proposed approaches and rationale for developing small animal and NHP efficacy models for pneumonic and bubonic plague that meet the requirements of the FDA "Animal Rule."
B. Adequacy and feasibility of the scientific rationale for identifying and selecting correlates of protection for *Y. pestis*.
C. Adequacy and feasibility of the preliminary data and proposed approaches for developing immunological assays enabling the analyses of correlates of protection for *Y. pestis*.
D. Adequacy and feasibility of preliminary data and proposed approaches for developing potency assays for assessing the effectiveness of vaccine candidates.
E. Adequacy and feasibility of the proposed validation study plans for the proposed immunoassays, potency assay(s), and procedures that ensure the reproducibility of the small animal and NHP models.
F. Adequacy and feasibility of the scientific rationale and proposed approaches for identifying and manufacturing critical assay components, developing specifications for Certificates of Analysis, and determining shelf life and stability.

CRITERION 2: Quality System **30**

A. Adequacy, and thoroughness of the documentation (Quality System Plan and SOPs) supporting an implemented, comprehensive, GLP, GMP, and GCP compliant Quality System.
B. Evidence (QA organizational chart) of a QA Unit independent of the Principal Investigator.
C. Evidence of a comprehensive QA Unit as demonstrated by complementary areas of expertise within the QA Unit.
D. Evidence (internal and external audit reports and responses to observations) demonstrating a current and compliant GLP, GMP and GCP Quality System.
E. Demonstrated experience (technical SOP of a validated procedure) performing validation studies.
F. Evidence of ability to commit and maintain quality standards with NIAID as shown through a Quality Agreement.
G. Evidence of ability to commit and maintain quality standards with subcontractors as shown through Quality Agreements.
H. Feasibility of the plan to manage and successfully implement an effective Technology Transfer Plan including timelines and sample tracking.

CRITERION 3: Personnel **15**

Adequacy, appropriateness, and relevance of the documented training, expertise, experience and availability of proposed scientific, technical and Quality Assurance personnel of the offeror and any proposed subcontractors in relation to their specific duties and responsibilities as follows:

A. Qualifications and expertise of the Principal Investigator (PI) and senior scientific staff for performing animal efficacy studies, immunoassays, and potency assays as described in the Statement of Work.
B. Qualifications and expertise of the offeror's Quality Assurance personnel to ensure conformity to GLP, GMP, and GCP compliant quality.
C. Qualifications and ability of the PI and Project Manager (PM) to ensure adherence to the GLP, GMP, and GCP compliant Quality System.
D. Evidence (training records) of the technical staff with the expertise and training to perform studies under GLP, GMP, and GCP.
E. Qualifications and expertise of the technical personnel for performing animal efficacy studies, immunoassays, and potency assays as described in the Statement of Work.
F. Evidence (training records) of the technical staff with the expertise and training to perform animal studies and work with pathogenic organisms.

G. Qualifications and ability of the PI and Project Manager (PM) to lead, direct, coordinate, and monitor all contract activities, including activities carried out by subcontractors.
H. Appropriateness of the qualifications, experience, and expertise of proposed contract management staff with respect to the financial management and reporting, and the execution, management, and reporting of subcontracts.

CRITERION 4: Project Management **15**

A. Adequacy and feasibility of the proposed Strategic Work Plan to ensure the effective initiation, implementation, quality assurance, and conduct of all the Tasks described in the Statement of Work.
B. Adequacy and feasibility of the plan for overall project organization, staffing, and management, including the management of any subcontractors and consultants; appropriateness of the proposed mix and balance of personnel in relation to the Tasks described in the Statement of Work; and adequacy and completeness of the plan for PI communication and interaction with the Project Officer and the Contracting Officer.
C. Feasibility of the plan to safeguard confidentiality of intellectual property, data and material provided by third parties or the United States Government.

CRITERION 5: Facilities and Other Resources **10**

Adequacy, suitability, and availability of safe facilities for the development of animal models and assays for plague vaccines as specified in the Statement of Work including:

A. Adequate biocontainment facilities, safety procedures, and training requirements to operate the facilities and conduct studies in accordance with the Biosafety Level (BSL) 2 and 3 guidelines (BMBL or non-US equivalent), and in accordance with DHHS regulations regarding the Possession, Use and Transfer of Select Agents and Toxins (42 CFR Parts 72 and 73).
B. Adequate facilities for the housing and care of laboratory animals including veterinary coverage, the physical plant housing animals and laboratories, safety precautions, and training requirements.
C. GLP, GMP, and GCP compliant facilities.
D. Adequate facilities and procedures for receipt, shipment, cold chain management, tracking, storing, and archiving of non-clinical and clinical samples, critical reagents, and samples for stability testing.
E. Adequate support resources (i.e. Information Technology) to complete the SOW.

TOTAL WEIGHT (BASE PERIOD) **100**

CRITERION 6: Options **20**

A. **Option 1**
Soundness and feasibility of technical proposal to plan, implement, and execute animal efficacy studies using the validated procedures and SOPs to be developed in Tasks 1 and 2, and to analyze the associated samples following the procedures and SOPs developed in Task 5.

B. **Option 2**
Soundness and feasibility of technical proposal to plan, implement, and execute validated immunoassay studies of clinical trial samples using the validated procedures and SOPs to be developed in Task 5.

C. **Option 3**
Soundness and feasibility of technical proposal to plan, implement, and execute validated potency assays for lots of vaccine candidates using the validated procedures and SOPs to be developed in Task 6.

D. **For All Options: Quality, Facilities, and Resources**

1. Evidence of adequate facilities for animal housing and care, biocontainment, and GLP/GMP/GCP compliance as appropriate. Evidence of implemented procedures for training and monitoring procedures associated with safety, biohazards, handling animals, and a GLP, GMP, and GCP compliant Quality System.

2. Documented expertise of PI, QA personnel, and technical personnel to perform the Task. Demonstration of an efficient project management plan to successfully manage the Task.

TOTAL MAXIMUM POINTS (BASE + OPTIONS) **120**

6. PAST PERFORMANCE FACTOR

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

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

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

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

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

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

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

7. 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) Complexity and variety of the work SDB concerns are to perform
(c) Extent of participation of SDB concerns in terms of the value of the total acquisition.

8. SITE VISIT OR SITE AUDIT

Offerors determined to be in the competitive range may undergo a pre-award site visit. The Government retains the right to perform a pre-award site visit with an emphasis on assessing GLP, GMP, GCP, and Quality Assurance capabilities of the offeror and proposed 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 or comments from any regulatory bodies, and staff available in response to a pre-award site visit by NIAID or its designee. ***Due to timeline requirements, pre-award site visits may be made with short notice. Offerors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.***

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-07-06**
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
David T. Lisle Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	David T. Lisle Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

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

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

C. NUMBER OF COPIES:

TOTAL PAGE COUNT DOES NOT INCLUDE: Title and Back Page; NIH-2043; Table of Contents; Section Dividers that do not contain information other than title of Section; Requested SOPs; Audit and assessment reports and responses to those reports.

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

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

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

CREATING AND NAMING ELECTRONIC FILES:

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

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

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

EXAMPLE: XYX Company/07-06/Technical/Approach/9-18-06

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/07-06/Business/Staffing/9-18-06

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 EXCESS PAGES WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

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

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Twenty (20) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)	**Not to Exceed 200 pages**
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Five (5) Compact Disks containing an electronic copy of the Business Proposal	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk. **See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.**	N/A

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-07-06
RFP Title: "DEVELOPMENT OF ANIMAL MODELS AND ASSAYS FOR PLAGUE VACCINES"

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **October 26, 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, DHHS
Room 3214
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: David T. Lisle
RFP-NIH-NIAID- DMID-07-06
FAX# (301) 402-0972
Email : DLisle@niaid.nih.gov

ATTACHMENT 2

STATEMENT OF WORK
DEVELOPMENT of ANIMAL MODELS and ASSAYS for PLAGUE VACCINES
RFP NIH-NIAID-DMID-07-06

BACKGROUND and INTRODUCTION

The National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), supports research related to the basic understanding of microbiology and immunology leading to the development of vaccines, therapeutics, and medical diagnostics for the prevention, treatment, and diagnosis of infectious diseases. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports a comprehensive extramural research program focused on the prevention and control of diseases caused by virtually all infectious agents with the exception of the human immunodeficiency virus. This includes basic research, such as studies of microbial biology and physiology; applied research, including the development of vaccines, therapeutics and medical diagnostics; and clinical studies to evaluate experimental drugs and vaccines.

Plague is an infectious disease caused by *Yersinia pestis*, a gram-negative bacterium of the *Enterobacteriaceae* family. Its potential for use as a biological weapon is based on methods that were developed to produce and aerosolize large amounts of bacteria and on its transmissibility from person to person in certain forms. An additional factor is the wide distribution of samples of the *Y. pestis* bacilli to research laboratories throughout the world. Infection by inhalation of even small numbers of virulent aerosolized *Y. pestis* bacilli can lead to pneumonic plague, a highly lethal form of plague that can be spread from person to person. The disease progression of pneumonic plague is rapid and mortality is near 100% unless aggressive antibiotic therapy is initiated within the first 24 hours after the onset of symptoms. Natural epidemics of plague have been primarily bubonic plague, which is transmitted by fleas from infected rodents. A deliberate release of *Y. pestis* into the environment could result in an infection of local wildlife, and the bubonic form of the disease could spread to man. This endemic form of plague has a longer course of presentation and is more effectively treated with antibiotics, but is nonetheless about 50% fatal without aggressive therapy.

A whole cell killed vaccine, which is no longer available, was used in the United States until 1999 for immunization of individuals considered to be at high risk for developing bubonic plague, including laboratory workers and military personnel in areas where plague is endemic. This vaccine did not prevent or reduce the disease from pneumonic plague, the primary form anticipated as a bioterrorism agent.

New vaccine candidates are currently being evaluated for their ability to protect against both the bubonic and pneumonic forms of plague. These vaccine candidates are based on two *Y. pestis* proteins, F1 and V. F1 is a proteinaceous capsule found in most virulent strains of plague, and was a major component of the whole cell killed vaccine. F1 immunogenic properties are generally thought to be an important component in these new vaccine candidates. A second antigen that also produces a strong antibody response and is also considered an important component in these new vaccines is the V (virulence) antigen. This is a multifunctional protein with regulatory roles in both the bacterial cell and in the host cell where it is secreted.

In 1991, U.S. Department of Defense (DoD) investigators began developing a new plague vaccine based on a recombinant F1-V fusion protein. In the same timeframe, scientists in the United Kingdom Ministry of Defense (MoD) started working on a new vaccine candidate based on the recombinant F1+V combined subunits. Preclinical safety and efficacy studies as well as clinical safety trials have been conducted on both vaccines. In 2004, NIAID awarded a three year contract to Avecia Biotechnologies Ltd. for initial product development of the MoD designed rF1+rV vaccine candidate which included Good Manufacturing Practice (GMP) pilot lot manufacture of the vaccine and a subsequent Phase I trial, to demonstrate feasibility of an intermediate scale production, and

to conduct a Phase II trial using GMP manufactured material. In April 2005, the U.S. DoD entered into an international Project Arrangement (PA) with their counterparts in the United Kingdom and Canada to advance the development of Avecia's plague vaccine, while continuing in parallel to develop the U.S. DoD fusion vaccine through a contract with DynPort Vaccine Company. Data is being collected from both vaccine candidates for the eventual selection of a single vaccine candidate that will be funded through licensure. The current PA efforts being put forth on these candidates focus primarily on manufacturing activities such as the validation of drug substance and drug product and full scale fill/finish; whereas animal model and assay development activities are limited.

In order to prevent duplication of the U.S. Government effort and to structure the most comprehensive plague vaccine program, NIAID is awarding this contract to complement the PA scope. Development of these plague vaccine candidates will require: evaluation of candidate vaccine immunogenicity in various small animal and nonhuman primate (NHP) models, as well as in human clinical trials; development and evaluation of correlates of protection generated after immunization; and validation of assays used for the assessment of protective immunity. This contract provides for the development, optimization, qualification, and validation via Good Laboratory Practices (GLP) (21 CFR Part 58) and Good Manufacturing Practices (GMP) (21 CFR Part 211) of product-neutral immunological assays, potency assays, and animal efficacy models for the evaluation and assessment of plague vaccine candidates based on F1 and V antigens. These immunoassays and animal models will be developed under GLP and GMP and in a manner that will support licensure of a plague vaccine under the FDA "Animal Rule," (21 CFR Part 601.90-95) (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=601.91&SearchTerm=601%2E90). The development and subsequent validation of immunoassays includes the identification and provision for adequate amounts of standardized reagents for subsequent studies. Animal models will be developed and characterized for both the pneumonic and bubonic forms of plague. Each indication will be studied in a small animal model and a NHP model. Once validated, these immunoassays, potency assays, and animal models will provide important tools for researchers and manufacturers and, therefore, reagents, methods and procedures must be transferable. This effort will become a crucial part of a joint effort with the U.S. DoD to cooperatively develop and license a plague vaccine for both military and civilian needs.

NOTE:

To meet the urgent timeline requirements of this contract, funds will be provided to support the development of well-characterized animal models and immunoassays that are well understood, are routinely used in the field of immunology, and can be adapted to plague immunology; however, this contract will NOT provide funds for researching novel, untested or hypothetical approaches.

Additionally, Contractors are expected to have a pre-existing, comprehensive, and well developed Quality System able to meet GLP, GMP, and Good Clinical Practice (GCP) standards.

SCOPE

This contract will consist of a base period of three (3) years that provides for the development, optimization, qualification and validation of animal efficacy models, immunological assays and potency assays for the evaluation and assessment of plague vaccine candidates based on F1 and V antigens. Options for the establishment of Central Reference Laboratories to assess and evaluate newly developed F1 and V antigen-based plague vaccines and samples generated from non-clinical studies and human clinical trials supporting the eventual licensure of a vaccine candidate may be exercised at the discretion of the Government and will extend the period of performance by up to one (1) year.

The scope of work to be performed shall include:

1. Develop, optimize, and characterize a minimum of two species of animal efficacy models for both the pneumonic and bubonic forms of plague that meet the requirements of the FDA "Animal Rule" (21 CFR Part 601.90-95) using both respiratory and parenteral challenge routes. These animal models will be adequate and well controlled. Animal models themselves cannot be validated; however, they must be reproducible and transferable, and the procedures that contribute to the establishment of the models and can be controlled (are amenable to validation) will be validated using GLP. Each indication will be studied in a small animal model and a NHP model.

2. Identify and characterize innate and adaptive immune responses that occur after exposure to *Y. pestis* in animal models and after vaccination with F1 and V antigen-based vaccines in both animal models and humans, and use these to identify correlates of protection for *Y. pestis*.

3. Develop, optimize, qualify, and validate immunoassays based on identified correlates of protection for both F1 and V antigens that can be used to evaluate and assess new plague vaccine candidates in both non-clinical and clinical studies.

4. Develop, optimize, qualify, and validate at least one potency assay that can be performed under GMP.

5. Identify, characterize, produce, and make provisions for adequate amounts of standardized reagents with defined specifications to conduct future immunoassays and potency assays.

6. Using GLP, GMP, and GCP standards, prepare Standard Operating Procedures (SOPs) and develop a Technology Transfer Plan for the transfer of all methodologies.

7. Provide documentation in a format suitable for FDA submission and compliant with GLP or GMP for NIAID to submit to the FDA as a Master File that will be held by NIAID.

8. Options for establishing Central Reference Laboratories to assess and evaluate newly developed F1 and V antigen-based plague vaccines and samples generated from non-clinical and human clinical trials supporting the eventual licensure of a vaccine candidate using the animal efficacy models and validated assays developed during the base contract period. Performance of these Options will require compliance with Good Clinical Practices (GCP) and GMP.

TECHNICAL REQUIREMENTS (BASE PERIOD)

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

I. ANIMAL MODEL/ASSAY DEVELOPMENT TASKS

The Project Officer will review and approve in writing, all protocols and plans prior to initiation by the Contractor. Unless otherwise agreed upon by the Project Officer and the Principal Investigator, studies shall be performed using GLP.

A. **Animal Models**

Develop, optimize, and characterize small animal and NHP models to meet the FDA Animal Rule (21 CFR Part 601.90). Validate the procedures that contribute to the establishment of the models and that can be controlled to ensure the models are reproducible and transferable. Animal models shall assess the full range of vaccine development parameters, including the history of natural infection, innate and adaptive immune responses, efficacy using respiratory and parenteral challenge routes, markers of protective immunity, and product potency. Animal models should mimic the human form of the disease to the extent possible by presenting similar clinical symptoms, pathophysiology, and immune responses. During contract performance, the Contractor shall continually assess how amenable these animal models are to supporting a licensure strategy dependent on the Animal Rule.

Task 1: Small Animal Efficacy Models

1.1 **Small Animal Model Development**: Develop two or more well-characterized small animal models each for pneumonic plague and bubonic plague, using respiratory and parenteral infection routes, and compare the models to the disease processes in humans. Preparation and administration of *Y. pestis* challenge materials shall be consistent throughout the execution of the studies.

1.1.1 **Draft and Final Protocols**: Develop and submit, for Project Officer review, **draft** small animal model protocols and provide the rationale for the proposed study designs and animal species selected. Within 7 calendar days after receiving the Project Officer review, revise the draft protocols as necessary, and submit the **final** protocols for Project Officer approval. Written approval by the Project Officer of the final protocols shall be required prior to study initiation.

1.1.2 **Develop and evaluate the small animal models in accordance with the approved protocols**:

1.1.2.1 Evaluate the models using quantitative assessments, including the following: LD_{50}, clinical indicators of infection, markers of disease progression, and indicators of morbidity.

1.1.2.2 Evaluate the models via microbiological and histological analysis, including special stains, cultures, necropsy, and pathophysiological data.

1.1.2.3 Evaluate the models using measures of general toxicity and telemetry, including body weight, blood chemistries, hematological measures, body temperature, defined clinical parameters, and behavior.

1.1.2.4 Evaluate the models for innate and adaptive immune responses that could potentially correlate with protective immunity.

1.2 **Model Selection**: Use the data collected in 1.1.2 to bridge animal data to human data. Maintain ongoing discussions with the Project Officer and the FDA regarding the Animal Rule (21 CFR Part 601.90). In consultation with the Project Officer and with the approval of the Project Officer, select the models that best resemble the human disease processes and are reproducible and predictive.

1.3 **Efficacy Testing**

1.3.1 **Draft and Final Protocols**: Develop and submit, for Project Officer review, **draft** efficacy and passive transfer protocols and provide the rationale for the proposed study designs. Within 7 calendar days after receiving the Project Officer review, revise the draft protocols as necessary, and submit the **final** protocols for Project Officer approval. Project Officer written approval of the final protocols shall be required prior to study initiation.

1.3.2 In accordance with approved protocols, vaccinate the animals with vaccine candidates provided by the Project Officer and subsequently challenge the models using respiratory and parenteral infection routes. Evaluate the models using the criteria established in Task 1.1.2.

1.3.3 In accordance with approved protocols, perform passive transfer experiments challenging the models via respiratory and parenteral infection routes. Evaluate the models using the criteria established in Task 1.1.2.

1.4 **Draft and Final Study Reports**: Prepare and submit **draft** Study Reports within 30 calendar days after completing each study conducted in Tasks 1.1, 1.2, and 1.3. The Study Report format shall be suitable for FDA submission and compliant with GLP (21 CFR Part 58) and each Study Report shall include a statistical analysis of the data using software that is fully validated and acceptable to the FDA. Submit **draft** Study Reports to the Project Officer for review and approval. Within 7 calendar days after receiving the Project Officer review, revise the draft Study Reports as necessary, and submit the signed, **final** Study Reports and CDs containing the original study data.

1.5 **Working SOPs**: Using GLP standards, develop working SOPs for all processes and procedures associated with the models. Fifteen (15) calendar days prior to initiating Task 1.6 submit the SOPs to the Project Officer for review and approval.

1.6 **Validation Studies**: Validate the procedures that contribute to the establishment of the models and that can be controlled to ensure the models are reproducible and transferable.

1.6.1 **Draft and Final Validation Protocols**: Within 15 calendar days after delivering the final Study Reports per Task 1.4, and using GLP standards, prepare Validation Protocols that include a Statistical Analysis Plan (SAP) for the processes and procedures that contribute to the models and can be controlled. Submit the Validation Protocols to the Project Officer for review and approval. The Project Officer will submit the Validation Protocols to the FDA for review. Within 7 calendar days after receiving the Project Officer review, revise the **draft** validation protocols as necessary, and submit the **final** validation protocols for Project Officer approval. Written Project Officer approval of the final protocols shall be required prior to study initiation.

1.6.2 **Validation**: Using the approved Validation Protocols and GLP standards, validate the processes and procedures that contribute to the models and can be controlled. Analyze the data using statistical methods and software that is fully validated and acceptable to the FDA.

1.7 **Validation Study Reports**: Within 30 calendar days after completion of validation, and in a format suitable for FDA submission and compliant with GLP, prepare and submit a **draft** Validation Study Report for each of the validated processes and

procedures for Project Officer review and approval. The Validation Study Reports shall include a statistical analysis of the data collected during each Validation Study. Within 7 calendar days after receiving the Project Officer review, revise the draft Validation Study Reports as necessary, and submit the signed, **final** Validation Study Reports and CDs containing the original study data to the Project Officer.

1.8 **Final SOPs**: Using GLP standards, develop final SOPs incorporating the validation data for all processes and procedures associated with the models. Within 30 calendar days after completion of the Validation Studies, submit the SOPs to the Project Officer for review and approval.

Task 2: Nonhuman Primate (NHP) Efficacy Models

2.1 **NHP Model Development**: Develop two or more well-characterized NHP animal models each for pneumonic plague and bubonic plague, using respiratory and parenteral infection routes, and compare the models to the disease processes in humans. Preparation and administration of *Y. pestis* challenge materials shall be consistent throughout the execution of the studies.

2.1.1 **Draft and Final Protocols**: Develop and submit, for Project Officer review, **draft** NHP model protocols and provide the rationale for the proposed study designs and animal species selected. Within 7 calendar days after receiving the Project Officer review, revise the draft protocols as necessary, and submit the **final** protocols for Project Officer approval. Written approval by the Project Officer of the final protocols shall be required prior to study initiation.

2.1.2 **Develop and evaluate the NHP models in accordance with the approved protocols**

2.1.2.1 Evaluate the models using quantitative assessments, including the following: LD_{50}, clinical indicators of infection, markers of disease progression, and indicators of morbidity.

2.1.2.2 Evaluate the models via microbiological and histological analysis, including special stains, cultures, necropsy, and pathophysiological data.

2.1.2.3 Evaluate the models using measures of general toxicity and telemetry, including body weight, blood chemistries, hematological measures, body temperature, defined clinical parameters, and behavior.

2.1.2.4 Evaluate the models for innate and adaptive immune responses that could potentially correlate with protective immunity.

2.2 **Model Selection**: Use the data collected in 2.1.2 to bridge animal data to human data. Maintain ongoing discussions with the Project Officer and the FDA regarding the Animal Rule (21 CFR Part 601.90). In consultation with the Project Officer and with the Project Officer's approval, select the models that best resemble the human disease processes and are reproducible and predictive.

2.3 **Efficacy Testing**

2.3.1 **Draft and Final Protocols**: Develop and submit, for Project Officer review, **draft** efficacy and passive transfer protocols and provide the rationale for the

proposed study designs. Within 7 calendar days after receiving the Project Officer review, revise the draft protocols as necessary, and submit the **final** protocols for Project Officer approval. Written Project Officer approval of the final protocols shall be required prior to study initiation.

2.3.2 In accordance with approved protocols, vaccinate the animals with vaccine candidates provided by the Project Officer and subsequently challenge the models using respiratory and parenteral infection routes. Evaluate the models using the criteria established in Task 2.1.2.

2.3.3 In accordance with approved protocols, perform passive transfer experiments challenging the models via respiratory and parenteral infection routes. Evaluate the models using the criteria established in Task 2.1.2.

2.4 **Draft and Final Study Reports**: Prepare and submit **draft** Study Reports within 30 calendar days after completing each study conducted in Tasks 2.1, 2.2, and 2.3. The Study Report format shall be suitable for FDA submission and compliant with GLP (21 CFR Part 58) and each Study Report shall include a statistical analysis of the data using software that is fully validated and acceptable to the FDA. Submit draft Study Reports to the Project Officer for review and approval. Within 7 calendar days after receiving the Project Officer review, revise the draft Study Reports as necessary, and submit the signed, **final** Study Reports and CDs containing the original study data.

2.5 **Working SOPs**: Using GLP standards, develop working SOPs for all processes and procedures associated with the models. Fifteen (15) calendar days prior to initiating Task 2.6, submit the SOPs to the Project Officer for review and approval.

2.6 **Validation Studies**: Validate the procedures that contribute to the establishment of the models and that can be controlled to ensure the models are reproducible and transferable.

2.6.1 **Draft and Final Validation Protocols**: Within 15 calendar days after delivering the final Study report per Task 2.4 and using GLP standards, prepare Validation Protocols that include a Statistical Analysis Plan (SAP) for the processes and procedures that contribute to the models and can be controlled. Submit the Validation Protocols to the Project Officer for review and approval. The Project Officer will submit the Validation Protocols to the FDA. Within 7 calendar days after receiving the Project Officer review, revise the **draft** Validation Protocols as necessary, and submit the **final** validation protocols for Project Officer approval. Written approval by the Project Officer of the final protocols shall be required prior to study initiation.

2.6.2 **Validation**: Using the approved Validation Protocols and GLP standards, validate the processes and procedures that contribute to the models and can be controlled. Analyze the data using statistical methods and software that is fully validated and acceptable to the FDA.

2.7 **Validation Study Reports**: Within 30 calendar days after completion of validation, and in a format suitable for FDA submission and compliant with GLP, prepare and submit a **draft** Validation Study Report for each of the validated processes and procedures for Project Officer review and approval. The Validation Study Reports shall include a statistical analysis of the data collected during each Validation Study. Within 7 calendar days after receiving the Project Officer review, revise the draft Validation

Study Reports as necessary and submit the signed, **final** Validation Study Report and CDs containing the original study data.

2.8 **Final SOPs**: Using GLP standards, develop final SOPs incorporating the validation data for all processes and procedures associated with the models. Within 30 calendar days after completion of the Validation Studies, submit the SOPs to the Project Officer for review and approval.

B. **Correlates of Protection**

Using the animal models developed in Tasks 1 and 2, above, and employing research based immune assays, conduct a coordinated, multidisciplinary investigation that correlates protection in animal models with human immunological responses to *Y. pestis* infection or vaccination. The assays that demonstrate these correlates shall be further refined to evaluate vaccine candidates based on F1 and V plague antigens and to demonstrate efficacy in accordance with the FDA Animal Rule (21 CFR Part 601.90).

Task 3: Immunological Responses to Vaccination

3.1 **Draft and Final Protocols**: Develop and submit, for Project Officer Review, **draft** study protocols that include SOPs and SAPs to analyze immunological responses to vaccination with F1 and V antigens in the small animal and NHP efficacy models. Provide the rationale for the proposed study designs. Within 7 calendar days after receiving the Project Officer review, revise the draft protocols as necessary, and submit the final protocols for Project Officer approval. Written approval by the Project Officer of the final protocols shall be required prior to study initiation.

3.1.1 **Immune response to vaccination in animal models**: Using the evaluation criteria developed in Tasks 1.1 and 2.1, identify and characterize the immune responses, including onset and duration, to vaccination with F1 and V antigen based vaccine candidates in the animal efficacy models.

3.1.2 **Immune response to vaccination in humans**: Using the applicable quantitative evaluation criteria developed in Tasks 1.1 and 2.1, identify and characterize the immune responses, including onset and duration, to vaccination with F1 and V antigen-based vaccine candidates in human clinical samples provided by the Project Officer.

3.2 **Draft and Final Study Reports**: Prepare and submit draft Study Reports within 30 calendar days after completing each study conducted in Task 3.1. The Study Report format shall be suitable for FDA submission and compliant with GLP (21 CFR Part 58) and each Study Report shall include a statistical analysis of the data using software that is fully validated and acceptable to the FDA. Submit **draft** Study Reports to the Project Officer for review and approval. Within 7 calendar days after receiving the Project Officer review, revise the draft Study Reports as necessary, and submit the signed, **final** Study Reports and CDs of the original study data.

Task 4: Correlates of Protection

4.1 **Bridging Studies**: Analyze and compare the immunological data collected in Tasks 1 and 2 to the data collected in Task 3 and identify correlates of protection. Analyze the data using statistical methods and software that is fully validated and acceptable to the FDA. Use the data collected to bridge animal data to human data.

4.2 **Identification of Correlates of Protection**: Maintain ongoing discussions with the Project Officer and the FDA regarding the Animal Rule (21 CFR Part 601.90). In consultation with, and as approved by the Project Officer, select relevant correlates of protection for assay development. Use this knowledge to develop the immunoassays in Task 5.

4.3 **Draft and Final Study Reports**: Prepare and submit **draft** Study Reports within 30 calendar days after completing each study conducted in Tasks 4.1 and 4.2. The Study Report format shall be suitable for FDA submission and compliant with GLP (21 CFR Part 58) and each Study Report shall include a statistical analysis of the data using software that is fully validated and acceptable to the FDA. Submit draft Study Reports to the Project Officer for review and approval. Within 7 calendar days after receiving the Project Officer review, revise the draft Study Reports as necessary and submit the signed, **final** Study Reports and CDs containing the original study data.

C. **Assays**

Develop, optimize, characterize, qualify, and validate existing *in vitro* tests and assays or adapt tests and assays based on established technology to assess the relevant humoral and cellular immune responses of the host when exposed to either natural infection or vaccination that are correlates of protection. Assess the contribution of both adaptive and innate immune responses that achieve protective immunity.

Task 5: Immunoassays

5.1 **Immunoassay Development**: Using the immunological data generated in Tasks 1, 2, 3, and 4, develop, optimize, and characterize immunoassays for the evaluation of the correlates of protection. Techniques and methods should be sensitive enough to make useful comparisons between species.

5.1.1 **Draft and Final Protocols**: Develop and submit, for Project Officer review, **draft** immunoassay protocols and provide the rationale for the proposed study designs and immunological assays selected. Within 7 calendar days after receiving Project Officer Review, revise the draft protocols as necessary, and submit the **final** protocols for Project Officer approval. Written approval by the Project Officer shall be required prior to study initiation.

5.1.2 Characterize assay components including reagents, standards, and control articles. See related Task 7.

5.2 **Draft and Final Study Reports**: Prepare and submit **draft** Study Reports within 30 calendar days after completing each study conducted in Task 5.1. The Study Report format shall be suitable for FDA submission and compliant with GLP (21 CFR Part 58) and each Study Report shall include a statistical analysis of the data using software that is fully validated and acceptable to the FDA. Submit draft Study Reports to the Project Officer for review and approval. Within 7 calendar days after receiving the Project Officer review, revise the draft Study Reports as necessary, and submit the signed, **final** Study Reports and CDs containing the original study data.

5.3 **Working SOPs**: Using GLP standards, develop working SOPs for all processes and procedures associated with all immunoassays. Fifteen (15) calendar days prior to the initiation of Task 5.4 submit the SOPs to the Project Officer for review and approval.

5.4 **Validation Studies**

5.4.1 **Draft and Final Validation Protocols**: Using GLP standards, prepare Validation Protocols that include SAPs for each immunoassay developed in Task 5.1. Submit the **draft** Validation Protocols to the Project Officer for review and approval. Subsequently, the Project Officer will submit the Validation Protocols to the FDA for review. Within 7 calendar days after receiving the Project Officer review, revise the draft Validation Protocols as necessary and submit the **final** Validation Protocols for Project Officer approval. Written Project Officer approval shall be required prior to study initiation.

5.4.2 **Validation**: Using the approved Validation Protocols and GLP standards, validate the immunoassays developed in Task 5.1. Analyze the data using statistical methods and software that is fully validated and acceptable to the FDA.

5.5 **Validation Study Reports**: Within 30 calendar days after completion of validation, and in a format suitable for FDA submission and compliant with GLP, prepare and submit a **draft** Validation Study Report for each of the validated processes and procedures to the Project Officer for review and approval. The Validation Study Reports shall include a statistical analysis of the data collected during each Validation Study. Within 7 calendar days after receiving the Project Officer review, revise the draft Validation Study Reports as necessary, and submit to the Project Officer for approval. Upon approval, provide the Project Officer with the signed, **final** Validation Study Reports and CDs containing the original study data.

5.6 **Final SOPs**: Using GLP standards, develop final SOPs incorporating the validation data for all processes and procedures associated with all immunoassays. Within 30 calendar days after completion of the Validation Studies, submit the SOPs to the Project Officer for review and approval.

Task 6: Potency Assay

6.1 **Potency Assay Development**: Using the data generated in Tasks 1, 2, 3, and 4, develop, optimize, and characterize at least one potency assay that is stability indicating.

6.1.1 **Draft and Final Protocols**: Develop and submit, for Project Officer review, **draft** potency assay protocols and provide the rationale for the proposed study designs and assay methodology selected. Within 7 calendar days after receiving the Project Officer Review, revise the draft protocols as necessary, and submit the **final** protocols for Project Officer approval. Written approval by the Project Officer shall be required prior to study initiation.

6.1.2 Characterize assay components including reagents, standards, and control articles. See related Task 7.

6.2 **Draft and Final Study Reports**: Prepare and submit **draft** Study Reports within 30 calendar days after completing each study conducted in Task 6.1. The Study Report format shall be suitable for FDA submission and compliant with GMP (21 CFR Part 211) and each Study Report shall include a statistical analysis of the data using software that is fully validated and acceptable to the FDA. Submit draft Study Reports to the Project Officer for review and approval. Within 7 calendar days after receiving the

Project Officer review, revise the draft Study Reports as necessary and submit the signed, **final** Study Reports and CDs containing the original study data.

6.3 **Working SOPs**: Using GMP standards, develop working SOPs for all processes and procedures associated with the potency assay. Fifteen (15) calendar days prior to initiating Task 6.4 submit the SOPs to the Project Officer for review and approval.

6.4 **Validation Studies**

6.4.1 **Draft and Final Validation Protocols**: Using GMP standards, prepare Validation Protocols that include SAPs for the potency assay. Submit the Validation Protocols to the Project Officer for review and approval. Subsequently, the Project Officer will submit the Validation Protocols to the FDA for review. Within 7 calendar days after receiving Project Officer review, revise the **draft** Validation Protocols as necessary and submit the **final** Validation Protocols for Project Officer approval. Written Project Officer approval of the final Validation Protocols shall be required prior to study initiation.

6.4.2 **Validation**: Using the approved Validation Protocols and GMP standards, validate the potency assays developed in Task 6.1. Analyze the data using statistical methods and software that is fully validated and acceptable to the FDA.

6.5 **Validation Study Reports**: Within 30 calendar days after completion of validation, and in a format suitable for FDA submission and compliant with GMP, prepare and submit a **draft** Validation Study Report for each of the validated processes and procedures to the Project Officer for review and approval. The Validation Study Reports shall include a statistical analysis of the data collected during each Validation Study. Within 7 calendar days after receiving Project Officer review, revise the draft Validation Study Reports as necessary, and submit the signed, **final** Validation Study Report and CDs containing the original study data to the Project Officer.

6.6 **Final SOPs**: Using GMP standards, develop final SOPs incorporating the Validation Study data for all processes and procedures associated with the potency assay. Within 30 calendar days of completion of the Validation Studies, submit the SOPs to the Project Officer for review and approval.

Task 7: Critical Assay Components

7.1 **Identify Critical Assay Components**: Within 15 calendar days after completing Tasks 5.1.2 and 6.1.2, provide the Project Officer with a list of critical assay components including reagents, standards, and control articles that were identified for the immunoassays and potency assay(s) developed in Tasks 5 and 6.

7.2 **Source Identification**: Identify sources and obtain or produce reagents that meet the specification criteria in Tasks 7.3 and 7.4. Provide a list of qualified suppliers to the Project Officer. The list shall include the name and contact information of the supplier, the name of the critical component, catalog number, and any other identifying information needed to purchase assay components. Ensure adequate amounts of these reagents are needed to analyze at least 3,000 subjects in clinical trials and samples from an estimated 40 small animal studies and 20 NHP studies, to serve as gold standard reagents to support technology transfer, and for stability testing and retention samples.

7.3 **Manufacture of Critical Assay Components not Available Commercially**: For those critical assay components that are not commercially available, develop manufacturing methods.

7.3.1 Develop and submit, for Project Officer review, **draft** manufacturing protocols and provide the rationale for the proposed manufacturing designs. Within 7 calendar days after receiving the Project Officer review, revise the draft protocols as necessary, and submit the **final** protocols for Project Officer approval. Written approval by the Project Officer shall be required prior to manufacture.

7.3.2 Develop **draft** specifications and Certificate of Analysis (CoA) test method SOPs for all manufactured critical components based on the characterizations in Tasks 5.1.2 and 6.1.2 and submit to the Project Officer for review. Within 7 calendar days after receiving the Project Officer review, revise the draft specifications and CoA test method SOPs as necessary, and submit the **final** specifications and CoA test method SOPs for Project Officer approval. Written approval by the Project Officer shall be required prior to initiating CoA testing.

7.3.3 Using the approved protocols, manufacture the critical assay components.

7.3.4 Using the approved protocols, perform CoA testing on all manufactured critical assay components.

7.3.5 Submit Batch Manufacturing Records and the CoA testing data (such as Western blots and absorbance readings) and results for each manufactured critical assay component to the Project Officer for review and approval within 30 calendar days after completing each manufacture. The Batch Records shall include information on the sources and specifications for all raw materials used in the manufacture.

7.3.6 **Certificate of Analysis:** A CoA shall be provided to the Project Officer for each critical assay component lot produced listing the test method, specification, result and date of test.

7.3.7 Maintain all original manufacturing records, specifications, and CoA testing data for all lots of critical reagents produced for the duration of the contract. This documentation shall be transferred to the Project Officer at the end of the contract period. This documentation shall not be destroyed without receiving permission from the Project Officer.

7.4 **Commercially Available Critical Assay Components**

7.4.1 **Specifications for Critical Assay Components**: For commercially available critical assay components without a CoA, develop specifications and CoA test method SOPs based on the characterizations in Tasks 5.1.2 and 6.1.2 and submit to the Project Officer for review. Within 7 calendar days after receiving Project Officer review, revise the **draft** specification and CoA test method SOPs as necessary, and submit the **final** specifications and CoA test method SOPs for Project Officer approval. Written approval by the Project Officer shall be required prior to initiating testing.

7.4.2 Using the approved protocols, perform testing on the commercially available critical assay components without CoA.

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7.4.3 Submit the data (such as Western blots and absorbance readings) and results from the testing for each commercially available critical assay component without a CoA to the Project Officer for review and approval within 15 calendar days after testing.

7.4.4 **Certificate of Analysis**: A CoA shall be provided for each commercially available critical assay component lot listing the test method, result and date of test.

7.4.5 Maintain all original specifications and CoA testing data for all lots of commercially available critical reagents for the duration of the contract. This documentation shall be transferred to the Project Officer at the end of the contract period. This documentation shall not be destroyed without receiving permission from the Project Officer.

7.5 **Shelf Life and Stability Testing**

7.5.1 **Draft and Final Stability Testing Study Protocols**: Within 15 calendar days after completing Tasks 7.3 and 7.4 develop and submit, for Project Officer Review, **draft** Stability Testing Study Protocols to determine shelf life and expiration dates of all critical assay components. Within 7 calendar days after the Project Officer review, revise the draft protocols as necessary, and submit the **final** protocols for Project Officer approval. Written approval by the Project Officer shall be required prior to study initiation.

7.5.2 Using the approved Stability Testing Study Protocols, perform stability testing. Submit a CoA for each stability time point listing the test method, specification, result, and date of test.

7.6 **Draft and Final Stability Reports**: Prepare and submit **draft** Stability Reports for each critical assay component within 30 calendar days after completing each stability study conducted in Task 7.5. The Stability Report format shall be suitable for FDA submission and compliant with GLP (21 CFR Part 58) and each Stability Report shall include a statistical analysis of the data using software that is fully validated and acceptable to the FDA. Submit draft Stability Reports to the Project Officer for review and approval. Within 7 calendar days after receiving the Project Officer review, revise the draft Stability Reports as necessary and submit the signed, **final** Stability Reports and CDs containing the original study data.

II. Quality System / Good Laboratory Practice / Good Manufacturing Practice / Good Clinical Practice Tasks

A. Apply a Quality System that meets GLP standards to the animal model development, optimization, characterization, qualification, and validation activities in this contract thereby ensuring that the models and assays can support the licensure of a F1 and V antigen plague vaccine candidate.

B. Conduct all studies associated with the development, optimization, characterization, qualification, and validation of immunoassays and the regulated procedures that contribute to the establishment of the animal models in accordance with the Quality System and GLP.

C. Conduct all studies associated with the development, optimization, characterization, qualification, and validation of potency assays in accordance with the Quality System and GMP.

D. Conduct all studies associated with the analyses of clinical samples in accordance with the Quality System and GCP.

Task 8: GLP, GMP, and GCP Compliant Quality System Plan

8.1 Within 15 calendar days after contract award, submit to the Project Officer a **draft** Quality System Plan that meets GLP standards (21 CFR Part 58), GMP standards (21 CFR Part 211), and GCP standards (21 CFR Part 312) and allows for continuous improvement. The Project Officer will provide comments to the Contractor within 15 calendar days after receipt of the plan. Within 15 calendar days after receipt of the Project Officer comments, submit a **final** Quality System Plan, subject to approval by the Project Officer, which incorporates the Project Officer's comments. In consultation with and approval by the Project Officer, provide monthly updates to the Quality System Plan during the entire contract period of performance. The Quality System Plan shall include the following:

8.1.1 **Description and Organization of the Quality Assurance (QA) Unit**

8.1.1.1 Organizational chart showing: 1) the reporting structure within the QA Unit, and 2) the relationship between the QA Unit and management. QA personnel shall be independent of the Principal Investigator and the Project Manager to ensure compliance and affect company policy and project decision making.

8.1.1.2 Titles of QA personnel and descriptions of their roles and responsibilities.

8.1.2 **List of Quality SOPs addressing**

8.1.2.1 Management and Control of Quality Documentation
8.1.2.2 Personnel Qualification and Training
8.1.2.3 Facilities Suitability, Control, and Maintenance
8.1.2.4 Calibration and Maintenance of Equipment
8.1.2.5 Validation Status of Facilities and Equipment
8.1.2.6 Reagent and Solution Labeling and Storage
8.1.2.7 Management and Control of Computerized Systems
8.1.2.8 Management and Control of Data and Experimental Records
8.1.2.9 Records and Reports
8.1.2.10 Record Retention and Storage
8.1.2.11 Sample Tracking
8.1.2.12 Quality Assessments

8.2 **Quality System Implementation**: The QA Unit shall be responsible for implementing and maintaining all quality processes and procedures, and shall:

8.2.1 Maintain version control of all SOPs (both QA and technical) ensuring that the current version of SOPs are utilized and superseded versions are removed from circulation;

8.2.2 Review and approve all SOPs prior to distribution and use;

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8.2.3 Ensure that annual trainings are conducted for laboratory personnel that include biosafety procedures, animal care and handling, and QA procedures;

8.2.4 Maintain a list of facility accreditations and a record of facility maintenance;

8.2.5 Maintain a list of the validation status of facilities, equipment, and computer software;

8.2.6 Ensure that laboratory equipment is suitably calibrated and maintained;

8.2.7 Ensure that GLP, GMP, and GCP are followed;

8.2.8 Ensure that access to computerized systems is secure and that backups occur on a daily basis;

8.2.9 Ensure that scientific data is recorded in a timely way (daily), all original (unaltered) records are retained and signed and dated by the laboratory personnel directly conducting the study, and all laboratory records meet good record keeping standards;

8.2.10 Review all Study and Validation Study Reports and ensure that the summary data presented in these reports is traceable to the original, unaltered data;

8.2.11 Develop and implement a record retention and storage plan; and

8.2.12 Ensure the accuracy of sample tracking.

8.3 **Quality System Assessments and Audits:** The QA Unit shall:

8.3.1 Conduct assessments and audits of all laboratory areas and Quality System components following predetermined and prescribed methods that include defined procedures and periodicity. Draft audit and assessment schedules shall be updated monthly and submitted to the Project Officer as part of the Monthly Progress Report during the contract's period of performance.

8.3.2 Host external audit and assessment teams including regulatory agencies and representatives of the Project Officer. The Contractor shall inform the Project Officer of scheduled external audits within 2 business days of the Contractor's notification.

8.3.3 Provide all internal and external audit and quality assessment reports associated with animal model, immunoassay, potency assay, and critical assay component development to the Project Officer within 30 calendar days of the completion of an audit or assessment.

8.3.4 Within 15 calendar days of the receipt of audit and assessment reports associated with animal model, immunoassay, potency assay and critical component development, provide the Project Officer with all responses to observations made in the reports.

8.3.5 Conduct Failure Investigations:

8.3.5.1 In cooperation with the technical team, the QA Unit shall be responsible for Failure Investigations.

8.3.5.2 The Project Officer shall be informed within 2 business days of failures directly related to the contract.

8.3.5.3 Provide the Project Officer with Failure Investigation Reports within 15 calendar days of completing the Failure Investigation.

8.4 **Quality System Report**: The QA Unit shall provide the Project Officer with an annual Quality System Report. This report shall summarize the current status of Quality System including the Quality System components outlined in Task 8.2 and the assessments, audits and responses outlined in Task 8.3.

Task 9: Draft and Final Quality Agreements

9.1 Within 30 calendar days after contract award, submit to the Project Officer and the Contracting Officer a **draft** Quality Agreement that clearly defines the scope and delineates the roles and responsibilities of NIAID and the Contractor with respect to: materials and analytical activities, stability programs, sample storage, archiving, documentation and records, change management, deviation management, investigations, validation, technology and process transfers, and right to audit. The Project Officer and the Contracting Officer will provide comments to the Contractor within 15 calendar days after the receipt of the draft Quality Agreement. The Contractor shall incorporate the comments within 15 calendar days after receipt and shall submit the **final** Quality Agreement. The final Quality Agreement will be signed by the Contractor and the Contracting Officer. The Quality Agreement shall be modified and updated as necessary by the Contractor and with approval from the Project Officer and Contracting Officer.

9.2 Within 45 calendar days after contract award prepare a written Quality Agreement in accordance with the process described in 9.1 above, with each subcontractor. The Quality Agreement(s) shall be signed by the Contractor and each subcontractor. The Quality Agreement(s) shall be modified and updated as necessary by the Contractor. The Contractor will ensure that the terms of the Quality Agreements with all subcontractors are met throughout the course of the contract.

Task 10: Technology Transfers

10.1 Prepare Technology Transfer Plans for the receipt and delivery of animal efficacy models, immunoassays, and potency assays. The plan will include a summary, critical implementation requirements, circumstances that will lead to successful implementation, and the efforts that will be put forth by the Contractor to support implementation. It will also identify the knowledge, methodology, processes and procedures, and critical assay components that will be transferred and provide a schedule for transfer. The Project Officer will review and approve all Technology Transfer Plans.

10.2 Prepare Technology Transfer Plans for the transfer of qualified reagents, standards, and control articles to the Project Officer or to a third party designated by the Project Officer. Develop procedure and data transfer plans that include the Specifications for Critical Assay Components and their CoAs. Submit the plans and packages for review and approval by the Project Officer.

10.3 Upon request of the Project Officer, implement the Technology Transfer Plans, transferring models, reagents, assays, SOPs, processes, products or other materials,

software, data and documentation developed under the contract to the Project Officer or to a third party designated by the Project Officer.

III. Administration and Project Management

Task 11: Project Management

11.1 Organize, coordinate, and manage the activities of the contract and coordinate all contract and subcontract sites. When multiple investigators are involved, the roles and responsibilities of the participating organizations and individuals shall be carefully coordinated and clearly defined.

11.2 Provide for the management and coordination of all activities carried out under subcontracts.

11.3 **Draft and Final Strategic Work Plan**

Within 30 calendar days after contract award, submit to the Project Officer a **draft** Strategic Work Plan encompassing all contract activities. The Contractor's Strategic Work Plan shall link budget and effort, spread by month and task to include a breakdown by labor, materials, and subcontracts, to all activities contained in the work plan timeline. The Project Officer will provide comments to the Contractor within 15 calendar days after receipt of the plan. The Contractor shall incorporate the comments within 15 calendar days after the Project Officer's comments are received and submit the **final** Strategic Work Plan to the Project Officer for approval. Upon written approval by the Project Officer, the Contractor shall implement the final Strategic Work Plan. In consultation with the Project Officer, the Contractor shall provide monthly updates to the Strategic Work Plan as part of the Monthly Progress Report during the contract's period of performance. The Strategic Work Plan shall include the following:

11.3.1 Key objectives.

11.3.2 A detailed description of each step in the process including timelines for achieving objectives, preferably using Microsoft Project, and the total costs associated with completing each task. Both general project management (Tasks 11, 12, and 13) and Quality Assurance (Tasks 8, 9, and 10) will be described and tracked as tasks. These tasks shall run the duration of the contract and shall have budgets and dedicated personnel associated with them.

11.3.3 Gantt charts for each task.

11.3.4 Plans for ensuring Quality Assurance over the implementation and operation of the contract.

11.3.5 Description of the qualitative and quantitative criteria and the decision-making process that shall be used in relation to advancing through each stage of the tasks.

11.3.6 A plan describing the procedures and processes for allocating and utilizing resources in an efficient manner and for redirecting the focus, including the reallocation of resources such as personnel, facilities, and funds, to capitalize on new knowledge, changing needs and emerging scientific opportunities.

11.3.7 Procedures for obtaining patent coverage and for the resolution of potential legal issues that may arise. The Contractor shall provide intellectual property agreements signed by all parties involved, outlining procedures to be used for obtaining patent coverage and licensing wherever applicable (e.g. methods, models, processes), and resolving potential legal issues that may arise, such as intellectual property.

11.3.8 A risk management plan that identifies and quantifies the risks that may be encountered in the project, their relative likelihood and impact, and possible ways to avoid, mitigate, correct and prevent them.

11.4 **Meetings and Teleconferences**

Provide support for the following meeting types:

11.4.1 **Contract Initiation Meeting**: Within 30 days after award, the Contractor shall participate in a two-day contract initiation meeting with the Project Officer, the Contracting Officer, and other Project Officer-designated NIAID team members. Representatives from the Contractor and subcontractors shall include key scientific, technical, QA, and administrative personnel. The purpose of this initiation meeting is to orient the Contractor and subcontractors to NIAID contract procedures and to review the scientific and QA approaches to be employed during the contract period.

11.4.2 **Progress Review Meetings and Teleconferences**

11.4.2.1 Participate in weekly meetings and teleconferences with the Project Officer and other Project Officer-designated NIAID team members to review progress and discuss problems and approaches to resolve the problems.

11.4.2.2 Conduct monthly meetings with subcontractors, the Project Officer, and other Project Officer-designated NIAID team members to discuss study designs, progress, problems and obstacles, and approaches to resolve them.

11.4.2.3 Participate in one meeting annually in Bethesda, Maryland, for the purposes of future planning, study development and evaluation, and data discussion between investigators and other essential personnel. These meetings shall be convened at the request of the Project Officer and shall include NIAID scientific advisors as deemed necessary by the Project Officer.

11.4.2.4 Participate in other meetings (such as government led animal model and assay study groups) as requested by the Project Officer, to discuss proposed modifications to study designs or timelines, technology, regulatory and ethical aspects of the program.

11.4.2.5 Provide data, reports, and presentations to groups of outside experts and Government personnel, as requested by the Project Officer, in order to facilitate review of contract activities.

11.4.2.6 Achieve effective balance of expertise (in Project Management, QA, and scientific/technical areas) in attendance at such meetings

11.4.2.7 Prepare and submit materials (read-aheads, agendas, and minutes) for all progress review meetings and teleconferences to the Project Officer for review and approval. Read-aheads and agendas shall be provided to the Project Officer no less than 2 business days in advance, and minutes shall be provided to the Project Officer within 3 calendar days after each meeting or teleconference.

11.4.3 **Site Visits and Audits and Assessments**: The Government reserves the right to perform on-site visits and audits at all Contractor and subcontractor sites were work is performed to meet the objectives of this contract. The Project Officer and other Project Officer-designated individuals will attend these meetings.

11.4.3.1 Organize and participate in at least one annual site visit at the Contractor's facility. Read-ahead documents for site visits and audits and assessments shall be provided at least 2 weeks prior to the event, and summary reports on the results of the visit shall be delivered to the Project Officer in the next Monthly Progress Report.

11.4.3.2 Organize and participate in at least one annual site visit with each subcontractor. Read-ahead documents for audits and assessments shall be provided at least 2 weeks prior to the event, and summary reports on the results of the visit shall be delivered to the Project Officer within 14 calendar days of completion of the site visit.

11.4.4 **FDA Meetings**: The Contractor shall participate, along with the Project Officer and the Project Officer's designees, in all FDA meetings and teleconferences related to any activities being performed as part of this contract including work performed by subcontractors and collaborators. The Contractor shall provide information to NIAID for submission to an FDA Master File and shall participate in FDA communications and responses as required by the Project Officer.

11.5 **Laboratory Requirements**

11.5.1 **Biocontainment Facilities/Safety and Training/Select Agent Approval**

11.5.1.1 Provide facilities for the development, optimization, qualification, and validation of animal models, immunoassays, and potency assays that are compliant with GLP, GMP and GCP and the capacity to perform the required tasks.

11.5.1.2 Provide safe biocontainment facilities and resources to conduct the work in accordance with the Biosafety in Microbiology and Biomedical Laboratories (BMBL) Guidelines, Centers for Disease Control and Prevention and the National Institutes of Health, fourth edition, HHS Publication No. (CDC) 93-8395 published by the US Government Printing Office, May 1999, Stock Number 017-040-0547-4 or the current version as this document is updated

11.5.1.3 Where appropriate, provide staff with the required level of training, expertise and experience to operate the facilities and conduct the studies in accordance with the Biosafety Level (BSL) 2 and 3 guidelines that can be accessed at http://bmbl.od.nih.gov/ .

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11.5.1.4 Where applicable, conduct work in accordance with current US Government regulations including Possession, Use and Transfer of Select Agents and Toxins (42 CFR Parts 72 and 73).

11.5.2 **Animal Care and Use**

11.5.2.1 Acquisition and Selection of Laboratory Animals: the decision of which animal species is to be used and any requirements for specific – pathogen free (SPF) animals shall be made jointly by the Project Officer and the Contractor, with the Project Officer having final approval authority.

11.5.2.2 Housing and Care of Laboratory Animals and Maintenance of Animal Records

11.5.2.2.1 Provide well-equipped and maintained facilities with necessary biohazard containment capabilities, using appropriate biosafety procedures to care for and handle animals receiving respiratory and parenteral challenge with *Y. pestis*. Exposure of animals to *Y. pestis* and the housing of animals thereafter shall follow biocontainment practices for laboratory animals as described in the Biosafey in Microbiology and Biomedical Laboratories (BMBL) guidelines (http://bmbl.od.nih.gov).

11.5.2.2.2 All animal studies must be conducted in accordance with the requirements set forth in the Animal Welfare Act (7 U.S.C. 2131), the Guide for the Care and Use of Laboratory Animals and comply with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy can be accessed at http://grants1.nih.gov/grants/olaw/references/phspol.htm

11.5.2.2.3 Provide care and routine health surveillance for laboratory animals. The Contractor's veterinary and animal care staff shall perform and record observations, including each animal's health status and any treatments received, and euthanize animals according to humane procedures approved by the Contractor's Institutional Animal Care and Use Committee (IACUC) as well as the most current version (2000 or later) of the American Veterinary Medical Association (AVMA) Report of the Panel on Euthanasia.

11.5.2.2.4 Provide for on-call veterinary coverage of the animal facility 24 hours a day, seven days a week, and provide at least daily observations of the health status of each animal, including weekends and holidays.

11.5.2.2.5 Provide standard technical and veterinary assistance, as needed for the performance of routine procedures, such as inoculation, bleeding, and clinical surveillance of the selected laboratory animals. Provide veterinary capability

for the performance of post-mortem examinations and collection of tissue samples for histopathology.

11.5.2.2.6 Provide and manage a security system to prevent unauthorized entry into the animal care facility.

11.5.2.2.7 Ensure oversight and monitoring of animal care facilities including a sentinel program, as well as equipment, services and procedures, carried out under the contract.

11.5.3 **Receipt, Storage, Shipping, and Tracking of Non-clinical and Clinical Samples and Critical Assay Components**

11.5.3.1 Develop, implement and maintain robust procedures for materials handling. Materials may be generated in the execution of this contract, provided by NIAID, or commercially obtained. In all cases, proper storage and handling shall be tailored to the specific materials. Plan for a wide range of materials, including:

11.5.3.1.1 Human specimens, provided by NIAID, from clinical trials conducted outside this contract

11.5.3.1.2 Animal specimens, whether provided by NIAID or generated during the execution of this contract

11.5.3.1.3 Vaccines, reference standards, and other in vitro reagents, whether developed under this contract or supplied by NIAID.

11.5.3.2 Distribute materials referenced in 11.5.3.1 above as needed for the execution of this contract and maintain accurate and current records of specimen and reagent inventories; track assays performed on contract specimens; track reagent consumption, and advise the PO of replenishment needs.

11.5.3.3 Upon the PO's request, make available to the DMID Repository, or other Project Officer-designated third parties, those reagents that have been produced in excess or can be replenished and are of general usefulness to the research community.

11.6 **Publications**

Any press release, manuscript, scientific meeting abstract, or oral presentation containing data generated under the contract shall be submitted to the Project Officer for review before submission for publication or public presentation. Manuscripts shall be submitted no less than 30 calendar days in advance, and abstracts and oral presentations no less than 15 calendar days in advance of submission. Additionally, preprints and reprints of papers, abstracts, and slides used in oral presentations shall be submitted with the Monthly Progress Report. NIAID contract support and number shall be acknowledged in all such publications. The Government, through the Project Officer, shall have access to all data generated from the efforts funded under this contract.

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11.7 **Final Deliverables/Transition Plan**

11.7.2 **Final Deliverables**

Deliver to the Government upon request of the Project Officer or upon the completion date of the contract, all tangible materials including specimens generated during model development, reagents developed for assay performance, data, batch manufacturing records, CoAs, SOPs, and software.

11.7.3 **Draft and Final Transition Plans**

Submit a **draft** Transition Plan to the Project Officer and Contracting Officer 12 months prior to the completion date of the contract. The Plan shall describe how the Contractor will ensure the orderly transition of the SOPs, reagents, contract data, equipment, animals, and other materials to Government designated locations and contractors. The Project Officer and Contracting Officer shall recommend revisions that will be incorporated into the **final** Transition Plan by the Contractor, at which time the Plan shall be implemented and completed by the completion date of the contract.

[END OF BASE PERIOD – STATEMENT OF WORK]

IV. OPTIONS [TASKS 12, 13 & 14]

These Options are for the purpose of establishing Central Reference Laboratories to assess and evaluate newly developed F1 and V antigen-based plague vaccines and samples generated from non-clinical studies and human clinical trials supporting the eventual licensure of a vaccine candidate. These reference laboratories shall use the adequate and well-controlled small animal and nonhuman primate efficacy models and the validated potency assays developed in this contract to evaluate vaccine candidates provided through NIAID. The reference laboratories shall also use the validated immunological assays developed in this contract to analyze samples provided through NIAID from non-clinical and clinical trials.

Options may be exercised at the discretion of the Government. Exercising these Options may result in extending the period of performance by up to one year.

Unless the Government exercises these Option(s), this contract will only consist of Sections I. through III. (Tasks 1 through 11) of the Statement of Work – Base Period.

OPTION 1: CENTRAL REFERENCE LABORATORY FOR ANIMAL EFFICACY MODELS
The Contractor shall use GLP, described in the Base Period, above, to perform animal efficacy studies.

Task 12: Animal Efficacy Models

12.1 **Draft and Final Study Protocol**: Within 15 calendar days after receipt of samples from the Project Officer and prior to initiating a study, develop and submit for Project Officer review, a **draft** Study Protocol that includes SOPs, a statistical analysis plan, and a rationale for the proposed study design. Within 7 calendar days after receiving the Project Officer review, revise the draft Study Protocol as necessary, and submit the **final** Study Protocol to the Project Officer for approval. Project Officer written approval of the **final** Study Protocol shall be required prior to study initiation.

12.2 Following the approved Study Protocol, perform adequate and well-controlled animal efficacy studies using the Final SOPs developed in Tasks 1 and 2.

12.3 Collect and analyze the data generated from the studies using the Final SOPs developed in Tasks 1, 2, and 5. Provide statistical analysis of the data using software that is fully validated and acceptable to the FDA.

12.4 **Draft and Final Study Reports**: Within 30 calendar days after completing each study, prepare and submit to the Project Officer **draft** Study Reports. The Study Report format shall be compliant with GLP (21 CFR Part 58). Within 7 calendar days after receiving the Project Officer review, revise the draft Study Report as necessary, and submit the **final** Study Report to the Project Officer. Upon approval, provide the Project Officer with a signed, final version of the Study Report and CDs containing the original study data.

OPTION 2: CENTRAL REFERENCE LABORATORY FOR IMMUNOASSAY STUDIES

The Contractor shall use GLP and GCP described in the Base Period, above, to perform Immunoassay studies.

Task 13: Immunoassays

13.1 **Draft and Final Study Protocol**: Within15 calendar days after receipt of samples from the Project Officer and prior to initiating a study, develop and submit for Project Officer review, a **draft** Study Protocol that includes SOPs, a statistical analysis plan, and a rationale for the proposed study design. Within 7 calendar days of receiving the Project Officer review, revise the draft Study Protocol as necessary, and submit the **final** Study Protocol to the Project Officer for approval. Project Officer written approval of the final Study Protocol shall be required prior to study initiation.

13.2 Following the approved Study Protocol, perform validated immunoassay studies using the Final SOPs developed in Task 5.

13.3 Collect and analyze the data generated from the studies using the Final SOPs developed in Task 5. Provide statistical analysis of the data using software that is fully validated and acceptable to the FDA.

13.4 **Draft and Final Study Reports**: Within 30 calendar days after completing each study, prepare and submit **draft** Study Reports to the Project Officer. The Study Report format shall be compliant with GLP (21 CFR Part 58). Within 7 calendar days of receiving the Project Officer review, revise the draft Study Report as necessary, and submit the **final** Study Report to the Project Officer. Upon approval, provide the Project Officer with a signed, final version of the Study Report and CDs containing the original study data.

OPTION 3: CENTRAL REFERENCE LABORATORY FOR POTENCY ASSAYS

The Contractor shall use GMP described in the Base Period, above, to perform Potency Assay studies.

Task 14: Potency Assays

14.1 **Draft and Final Study Protocol**: Within 15 calendar days after receipt of samples from the Project Officer and prior to initiating a study, develop and submit for Project Officer review, a **draft** Study Protocol that includes SOPs, a statistical analysis plan, and a rationale for the proposed study design. Within 7 calendar days of receiving

the Project Officer review, revise the draft Study Protocol as necessary, and submit the **final** Study Protocol to the Project Officer for approval. Project Officer written approval of the final Study Protocol shall be required prior to study initiation.

14.2 Following the approved Study Protocol, perform validated potency assay studies using the Final SOPs developed in Task 6.

14.3 Collect and analyze the data generated from the studies using the Final SOPs developed in Task 6. Provide statistical analysis of the data using software that is fully validated and acceptable to the FDA.

14.4 **Draft and Final Study Reports**: Within 30 calendar days after completing each study, prepare and submit **draft** Study Reports to the Project Officer. The Study Report format shall be compliant with GMP (21 CFR Part 211). Within 7 calendar days of receiving the Project Officer review, revise the draft Study Report as necessary, and submit the **final** Study Report to the Project Officer. Upon approval, provide the Project Officer with a signed, final version of the Study Report and CDs containing the original study data.

[END OF OPTIONS]
[END OF STATEMENT OF WORK]

REPORTING REQUIREMENTS AND DELIVERABLES

RFP NIH-NIAID-DMID-07-06
Development of Animal Models and Assays for Plague Vaccines

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format to the Contracting Officer and the Project Officer. In addition, original reports shall be submitted to the Contracting Officer and one (1) hardcopy of each report shall be submitted to the Project Officer, unless otherwise specified.

A. Technical Progress Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with ARTICLE F.1. DELIVERIES of this contract:

The Contractor shall submit to the Contracting Officer and the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to the technical inspection and requests for clarification by the Project Officer. These reports shall be brief and factual and prepared in accordance with the format described below. The established due dates for delivery and submission of these reports and deliverables may only be changed through a formal Modification to the contract by the Contracting Officer. Temporary extensions to due dates may be authorized in writing or verbally by the Contracting Officer.

Format of Cover Page for each Report

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

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

1. Monthly Progress Report

Monthly Progress Reports shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. Monthly Progress Reports need not be submitted when the Semi-Annual, Annual and Final Reports are due. Each Report shall include the following specific information:

SECTION I

An introduction covering the purpose and scope of the contract effort.

SECTION II

For each Task, include a summary paragraph of accomplishments and issues for the time period covered in the report, including the work performed by subcontractors. Provide sufficient detail to explain comprehensively the results achieved and issues associated with the Task. For each Task document the following:

a. Any significant results achieved and preliminary interpretations resulting from analyses and scientific evaluation of data accumulated to date. Include pertinent data and/or graphs.
b. Progress associated with the Quality System in relationship to the performance of the tasks under GLP, GMP, or GCP.
c. Any problems encountered during the period, the effect of the problem on the project timeline and budget, proposed solution or action to resolve the problem, and a summary of the action taken to alleviate the reoccurrence of the problem.
d. A summary of the work proposed for the next reporting period.

SECTION III

a. An updated Strategic Work Plan including the Gantt chart with the current status and projected timelines for each task.
b. An updated Quality System Plan.
c. An updated assessment and audit schedule for the next reporting period.

SECTION IV

a. Submit upcoming travel requests requiring NIAID approval that are anticipated for the next reporting period.
b. Provide summaries and justifications for upcoming Contracting Officer Authorizations (COAs) that are anticipated for the next reporting period.
c. Submit preprints and reprints of papers and abstracts resulting from work performed on this contract during the reporting period.

2. Task Completion Reports (Tasks 1 – 7, Base Period and Tasks 12-14, Option Period)

Task Completion Reports, including Study Reports, shall be submitted following completion of Tasks 1 through 7 in the Base Period and Tasks 12-14 in the Option Period unless otherwise authorized in writing or through a modification to the contract by the Contracting Officer. The Task Completion Report shall detail, document, and summarize the results of the work done for the completed Task, as well as issues and solutions that occurred during the performance of the Task. The report will address both technical and quality details. Summary data and interpretations shall be included as well as cross-references to original data.

3. Semi-Annual Progress Report

Semi-Annual Progress Reports include a summation of previously submitted Monthly Progress Reports. A Semi-Annual Progress Report will not be required for the period when an Annual Progress Report or Final Report is due.

4. Annual Progress Report (Draft and Final)

The Contractor shall provide a **draft** Annual Progress Report that shall include a summation of the results of the entire contract work for the period covered. The Project Officer will review the draft Annual Progress Report and provide the Contractor with comments within 7 calendar days after receipt. The draft Annual Progress Report shall be corrected by the Contractor and the **signed, final version** submitted to the Project Officer. An Annual Progress Report will not be required for the period when the Final Report is due.

5. Final Contract Report (Draft and Final)

The Contractor shall provide a **draft** Final Contract Report that shall consist of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the study approach, methods used, results, and an interpretation of the data. Specifically, the report shall summarize each Task effort and discuss each corresponding deliverable. The Final Contract Report shall also contain an executive summary for activities performed under the contract. The Project Officer will review the draft Final Contract Report and provide the Contractor with comments. The report shall be corrected by the Contractor and the **signed, final version** will be submitted to the Project Officer.

6. Summary of Salient Results

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

B. Other Reports and Deliverables

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

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

Project Officer
Office of Biodefense Research Affairs (OBRA)
Division of Microbiology and Infectious Diseases (DMID)
National Institute of Allergy and Infectious Diseases (NIAID)
National Institutes of Health (NIH)
6610 Rockledge Drive, Room 5006, MSC 6604
Bethesda, MD 20892-6604

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

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

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ARTICLE F.2. 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 following items in accordance with the stated delivery schedule.

The items specified below as described in SECTION C, will be required to be delivered F.O.B. Destination as set forth in FAR 52.247-35, F.O.B. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below and any specifications stated in SECTION D, PACKAGING, MARKING AND SHIPPING, of the contract:

a. Technical Progress Reports Delivery Schedule

Satisfactory performance of the contract is deemed to occur upon satisfactorily performing the Statement of Work and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule.

Technical Progress Reports

Item	Type of Report	Recipients	Delivery Schedule
1.	Monthly Progress Report	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Due on/before the 15th of each month. Not due when Semi-Annual, Annual or Final Reports are due.
2.	Task Completion Report (Tasks 1 through 7, Base Period and tasks 12 through 14, Option Period)	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	Due within 30 calendar days following the completion of each task.
3.	Semi-Annual Progress Report	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	Due on/before the 30th of the month following each 6-month period Not due when an Annual or Final Report is due.
4.	Annual Progress Report	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	Due on/before the 30th of the month following each anniversary date of the contract. Not due when the Final Report is due.
5.	Annual Utilization Report	1 copy to CO	Due on/before the 30th of the month following each anniversary date of the contract.
6.	Final Invention Statement	1 copy to CO	Due on/before completion date of the contract.

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Item	Type of Report	Recipients	Delivery Schedule
7.	All reports and documentation including the invention disclosure report, the confirmatory license, and the government support certification	1 copy to OPERA	As required by FAR Clause 52.227-11.
8.	Draft Final and Final Report and Summary of Salient Results	1 hard copy to PO 1 original to CO 1 elec. copy to PO and CO	Draft Final Report is due 45 calendar days prior to the completion date of contract. Final Report is due on/before the completion date of the contract.

Other Reports and Deliverables (Delivery Schedule)

Item	Type of Deliverable	SOW Reference	Recipient	Delivery Schedule
1.	Draft and Final Study and Validation Protocols with SAP	Base Tasks: 1, 2, 3, 4, 5, 6 Option Tasks: 12, 13, 14	1 hard copy to PO 1 elec. Copy to PO	15 calendar days prior to initiating each study.
2.	Working Technical Standard Operating Procedures (SOPs)	Base Tasks: 1, 2, 5, 6	1 hard copy to PO 1 elec. Copy to PO	15 calendar days prior to initiating each study.
3.	Draft Study and Validation Study Reports with Statistical Analyses (SA)	Base Tasks: 1, 2, 3, 4, 5, 6 Option Tasks: 12, 13, 14	1 hard copy to PO 1 elec. Copy to PO	Within 30 calendar days after completion of each study.
4.	Signed, Final Study and Validation Study Reports with SA	Base Tasks: 1, 2, 3, 4, 5, 6 Option Tasks: 12, 13,14	1 hard copy to PO 1 elec. Copy to PO	Within 7 calendar days after approval of the draft report by the PO.
5.	CDs containing original (unaltered) study data sets	Base Tasks: 1, 2, 3, 4, 5, 6, 7, 10 Option Tasks: 12, 13, 14	1 hard copy to PO 1 elec. Copy to PO	Submit with signed, final Study Reports.
6.	Final SOPs	Base Tasks: 1, 2, 5, 6, 10	1 hard copy to PO 1 elec. Copy to PO	Submit with signed, final Study Reports.
7.	List of Critical Assay Components	Task 7	1hard copy to PO 1 elec. Copy to PO	15 calendar days after the completion of Tasks 5.1.2 and 6.1.2.
8.	List of Qualified Suppliers	Task 7	1 hard copy to PO 1 elec. Copy to PO	Within 30 calendar days after completing Task 7.

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Item	Type of Deliverable	SOW Reference	Recipient	Delivery Schedule
9.	Draft and Final Manufacturing Protocols and SOPs	Task 7	1 hard copy to PO 1 elec. Copy to PO	15 calendar days prior to initiating manufacture.
10.	Draft and Final Specifications and SOPs for Test Methods for Critical Assay Components	Task 7	1 hard copy to PO 1 elec. Copy to PO	15 calendar days prior to initiating manufacture.
11.	Batch Manufacturing Records	Task 7	1 hard copy to PO 1 elec. copy to PO original	15 calendar days after completing manufacture. Original due on or before completion date of contract.
12.	CoAs inclusive of data and results	Task 7	1 hard copy to PO 1 elec. Copy to PO original	Within 30 calendar days after completing Task. Original due on or before completion date of contract.
13.	Draft and Final Stability Study Protocols	Task 7	1 hard copy to PO 1 elec. Copy to PO	15 calendar days prior to initiating each study
14.	Draft Stability Study Report	Task 7	1 hard copy to PO 1 elec. Copy to PO	Within 30 calendar days after completion of each study.
15.	Final, Signed Stability Report	Task 7	1 hard copy to PO 1 elec. Copy to PO	Within 7 calendar days after approval of the draft report by the PO.
16.	Draft and Final Quality System Plan	Task 8	1 hard copy to PO 1 elec. Copy to PO	Draft due within 15 calendar days after the effective date of the contract. Final due 15 calendar days after receipt of PO comments on draft. Update monthly.
17.	Quality Audit and Assessment Reports	Task 8	1 hard copy to PO 1 elec. Copy to PO	Within 30 calendar days after completing each audit or assessment.
18.	Responses to Quality Audit and Assessment Reports	Task 8	1 hard copy to PO 1 elec. Copy to PO	Within 15 calendar days after receipt of each Quality Audit or Assessment Report.
19.	Failure Investigation Reports	Task 8	1 hard copy to PO 1 elec. Copy to PO	Within 15 calendar days after completing the Failure Investigation
20.	Annual Quality System Report	Task 8	1 hard copy to PO 1 elec. Copy to PO	Due 15 calendar days after each anniversary date of the contract
21.	Quality Agreement with NIAID	Task 9	1 hard copy each to PO and CO 1 elec. Copy each to PO and CO	Due within 30 calendar days after the effective date of the contract. Update as necessary.

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Item	Type of Deliverable	SOW Reference	Recipient	Delivery Schedule
22.	Quality Agreement with Subcontractors	Task 9	1 hard copy each to PO and CO 1 elec. Copy each to PO and CO	Due within 45 calendar days after the effective date of the contract. Update as necessary.
23.	Draft and Final Technology Transfer Plans	Task 10	1 hard copy to PO 1 elec. Copy to PO	At the request of the Project Officer or 6 months prior to the completion date of the contract.
24.	Software	Task 10	1 Copy to PO	Submit with signed, final Study Reports for each applicable Task.
25.	Draft and Final Strategic Work Plan	Task 11.3	1 hard copy to PO 1 elec. Copy to PO	Draft due within 30 calendar days after the effective date of the contract. Final due 15 calendar days after receipt of PO comments on draft. Update monthly.
26.	Meeting and Teleconference Agendas	Task 11.4	Electronic copy to PO	Submit 2 business days prior to each meeting
27.	Meeting and Teleconference Minutes	Task 11.4	Electronic copy to PO	Submit 3 calendar days after each meeting.
28.	Read-ahead Documents	Task 11.4	Electronic copy to PO	Submit 2 business days prior to each meeting. Submit 2 weeks prior to each site visit and audit and assessment.
29.	Site Visit Reports	Task 11.4	Electronic copy to PO	Within 14 calendar days after completing site visit.
30.	Publications	Task 11.6	1 hard copy to PO 1 elec. Copy to PO	30 calendar days prior to submission for publication.
31.	Meeting Abstracts and Oral Presentations	Task 11.6	1 hard copy to PO 1 elec. Copy to PO	15 calendar days in advance of each meeting.
32.	Transition Plan (Draft and Final)	Task 11.7	1 hard copy to PO 1 elec. Copy to PO	Draft plan due 12 months prior to completion date of contract. Final Plan due 6 months prior to completion date of contract.

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

RFP NIH-NIAID-DMID-07-06
Development of Animal Models and Assays for Plague Vaccines

It is strongly recommended that Offerors use the following template as the Table of Contents for the Technical Proposal. All information presented in the Technical Proposal should be presented in the order specified below.

These additional Technical Proposal instructions reflect the requirements of the RFP and provide specific instructions and formatting for the Technical Proposal. The information requested in these instructions should be used to format and prepare the Technical Proposal, and should be used as a Table of Contents for your Technical Proposal. Offerors should follow the instructions in Section L of the solicitation, and include the information requested in this Appendix.

Offerors are advised to give careful consideration to the Statement of Work, all reference materials, appendices and attachments, the Technical Evaluation Criteria in Section M, and the RFP as a whole in the development of their Technical Proposals.

Offerors proposing subcontracts to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration/coordination between the prime contractor and all proposed subcontractors, and the expected advantages of such an approach.

Offerors are reminded that the total page limitation for the entire Technical Proposal (Base and Options) is 200 pages including all appendices and attachments. Any pages in excess of this limit will be expunged from the proposal and will not be provided to the peer review panel for consideration in the technical review.

Documentation that is excluded from the total page count includes:
1) the SOPs requested in Section 3, paragraph A.4., below,
2) audit and assessment reports, and
3) responses to audit and assessment reports.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

GENERAL

NIAID anticipates making one or more awards under this RFP for a base period of three years and an Option period of up to 1 year for the completion of up to three Options.

NIAID is aware that no single organization or institution may have the expertise and facilities required to perform all parts of the Statement of Work; therefore, it may be necessary for the offeror to subcontract portions of the work. It is expected that prospective awardees and their proposed subcontractors will have applied for all applicable permits and Select Agent Clearance by the time of proposal submission.

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 1688-1)
C. GOVERNMENT NOTICE FOR HANDLING PROPOSALS
D. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)
E. TABLE OF CONTENTS

SECTION 2: TECHNICAL APPROACH

NIAID will provide directly or ensure the provision of vaccine candidates, challenge strains, and clinical samples.

A. **KEY SOW ACTIVITY: Animal Model Development**

1. Describe the current status of the offeror's plague animal model development, and provide related preliminary data.

2. Describe a proposed technical approach and rationale for the development of animal efficacy models for both the pneumonic and bubonic forms of plague in a small animals and nonhuman primates. Provide related preliminary data.

3. Describe the proposed technical approach and rationale for performing validation studies for the procedures that ensure the reproducibility of the small animal and NHP models.

B. **KEY SOW ACTIVITY: Correlates of Protection**

1. Describe the scientific rationale, including bridging studies, for identifying correlates of protection to *Y. pestis* infections and vaccination.

2. Propose a rationale for the selection of specific assays that will enable the analyses of correlates of protection.

C. **KEY SOW ACTIVITY: Immunoassay Development**

1. Describe the proposed technical approaches and methods to develop immunoassays that enable identification of correlates of protection and can be used to assess the effectiveness of plague vaccines. Provide related preliminary data.

2. Describe the proposed technical approach and rationale for performing validation studies for the proposed immunoassays.

D. **KEY SOW ACTIVITY: Potency Assay Development**

1. Describe the proposed technical approaches and methods to develop potency assays that can be used to assess the effectiveness of plague vaccines. Provide related preliminary data.

2. Describe the proposed technical approach and rationale for performing validation studies for the proposed potency assay(s).

E. **KEY SOW ACTIVITY: Critical Assay Components**

1. Describe the proposed technical approach and rationale for identifying critical assay components and developing specifications and Certificates of Analyses.

2. Describe the proposed technical approach and rationale for manufacturing critical assay components not available commercially.

3. Describe the technical approach and rationale for performing stability testing and determining shelf life for critical assay components.

SECTION 3: QUALITY SYSTEM

Describe your Quality System and your ability to ensure compliance for the successful performance of Validation Studies and the completion the contract Tasks under GLP, GMP, and GCP as appropriate.

A. **KEY SOW ACTIVITY: GLP, GMP, and GCP Compliant Quality System Plan**

1. For all proposed facilities, provide a brief description of the chronology of the Quality System(s) and Quality Assurance (QA) Unit(s). Include information such as the date of the implementation of the QA unit and experiences and achievements of the offeror(s) under the Quality System (i.e. validation).

2. Provide an organization chart that shows:

   a) the reporting structure within the QA Unit
   b) the relationship between the QA Unit and management
   c) the titles of QA personnel and their roles and responsibilities.

   The organization chart shall serve as the basis for one of the elements of the Quality System Plan required in Task 8.1 of the Statement of Work.

3. For all proposed facilities, provide a list of the titles of all implemented quality Standard Operating Procedures.

   The list of titles of implemented quality SOPs shall serve as the basis for one of the elements of the Quality System Plan required in Task 8.1 of the Statement of Work.

4. For all proposed facilities, provide a copy of:

   a) a QA SOP addressing the procedure for writing and reviewing study reports, and
   b) a technical SOP for a validated procedure.

5. For all proposed facilities, provide evidence of a recent (within the last year) Quality System audit performed by an external organization, including the responses to any audit observations.

6. For all proposed facilities, provide copies of two internal audits and/or assessments performed in the last year, including the responses to audit observations.

B. **KEY SOW ACTIVITY: Draft and Final Quality Agreements**

1. Provide a Quality Agreement outlining the quality commitments the offeror proposes to make with NIAID regarding materials and analytical activities, stability programs, sample storage, archiving, documentation and records, change management, investigations, validations, technology and process transfers, and right to audit. Clearly define scope and delineate the roles and responsibilities of NIAID and the offeror.

   The Quality Agreement shall serve as the basis for the draft Quality Agreement required in Task 9.1 of the Statement of Work.

2. Provide a Quality Agreement outlining the quality commitments the offeror proposes to make with subcontractors. Clearly define the scope and delineate the roles and responsibilities of both parties.

   The Quality Agreement shall serve as the basis for the draft Quality Agreement required in Task 9.2 of the Statement of Work.

C. **KEY SOW ACTIVITY: Technology Transfer Plan**

1. Provide a general Technology Transfer Plan for the animal models, immunoassays, and potency assays proposed in your Technical Proposal. Include anticipated critical implementation requirements, circumstances that will lead to successful implementation, and the efforts that would be put forth by the offeror to support implementation. Identify the knowledge, methodology, processes and procedures, and critical assay components that the offeror anticipates transferring.

2. Provide a Gantt chart that clearly defines the activities and timelines associated with the Technology Transfer Plan and its implementation.

3. Provide a general Technology Transfer Plan for the acceptance and transfer of established models and assays into the offeror's laboratories and facilities.

SECTION 4: PERSONNEL

Describe your ability to provide all expertise needed to complete the contract tasks. Provide the following documentation and information for the Principal Investigator and all proposed scientific and technical personnel, including personnel of the offeror and any proposed subcontractors.

A. Key Personnel

1. Principal Investigator (PI)

   a) Describe the training, education, experience and qualifications of the PI for providing:
      1) leadership, overall project management, communications, and scientific decision making;
      2) assessing and balancing effort and progress;
      3) tracking, monitoring and reporting on project status and progress;
      4) recommending modifications to project requirements and timelines, including projects undertaken by subcontractors; and
      5) contract deliverables within negotiated timeframes.

b) Provide the following documentation:
   1) CV (up to 3 pages);
   2) Qualifications and relevant training;
   3) Previous experience with projects of similar size and complexity (limited to the past 5 years);
   4) References to relevant publications;
   5) Availability for the proposed project; and
   6) Summary of related activities.

2. Project Manager (PM)

   a) Describe the training, education, experience and qualifications of the PM with:
      1) monitoring and tracking day-to-day progress and timelines;
      2) coordinating communication and project activities; and
      3) tracking cost incurred for effort expended and progress achieved.

   b) Provide the following documentation:
      1) CV (up to 3 pages);
      2) Qualifications and relevant training;
      3) Previous experience with projects of similar size and complexity (limited to the past 5 years);
      4) References to relevant publications;
      5) Availability for the proposed project; and
      6) Summary of related activities.

B. Quality Assurance Unit

1. Describe the training, education, experience and qualification of the Quality Assurance personnel proposed, as well as the percentage of the total time each will be committed to the project. This includes staff of the offeror and all proposed subcontractors.

2. Provide the following documentation:

   a) CVs of key Quality Assurance Personnel (limit CVs to 2 pages);
   b) Qualifications, certifications, and relevant training;
   c) Previous experience with projects of similar size and complexity (within the past 5 years) within the biomedical field;
   d) Availability for the proposed project; and
   e) Summary of related activities.

C. Senior Scientific and Technical Personnel

1. Describe the training, education, experience and qualifications of the senior scientific and technical personnel proposed for the offeror and all proposed subcontractors, as well as the percentage of the total time each will be committed to the project. This includes scientific and technical personnel with the qualifications and abilities to conduct animal studies and a range of assays.

2. Provide documentation to describe:

   a) Senior Scientific and Technical Personnel (limit CVs to 2 pages each);
   b) Qualifications and relevant training;
   c) Previous experience with projects of similar size and complexity (limited to the past 5 years);
   d) References to relevant publications;
   e) Availability for the proposed project; and
   f) Summary of related activities.

D. Other Personnel

   Offeror(s) should demonstrate the related experience and the role of other personnel as needed to address the requirements of the Statement of Work. CVs for other personnel are not required to be submitted with the Technical Proposal. They can be included with the Business Proposal.

E. Training

   1. Describe the offeror's and potential subcontractors current procedures for training, implementing, and monitoring procedures associated with:
      a) safety
      b) biohazards
      c) animal handling
      d) GLP, GMP, and GCP

   2. Provide a summary of training records for technical personnel in the areas outlined in E.1.

SECTION 5: PROJECT MANAGEMENT

A. Discuss your plan for project organization, staffing, and management in relation to the planning, initiation, implementation, conduct, monitoring and completion of tasks identified in the Statement of Work. Describe in detail the responsibilities and level of effort for all proposed personnel who will be assigned to the contract, including proposed subcontractors and consultants, and an administrative and technical framework indicating clear lines of authority and responsibility for all proposed personnel.

B. Describe the experience and education of the contract management staff in the acquisition and management of subcontracts under Federal contracts.

C. Provide a Strategic Plan, as outlined in Task 11.3, including a Gantt chart that clearly defines the Tasks and timelines for each task to be performed.

   This Strategic Work Plan shall serve as the basis for the draft Strategic Work Plan required in Task 11.3.

D. Describe how the PI shall ensure adherence to a comprehensive Quality System plan.

E. Outline how the PI will communicate with the Project Officer and Contracting Officer and how the PI will communicate, monitor, and manage the project both internally and externally at subcontractor facilities.

F. Discuss your organizations understanding of the process for soliciting, evaluating, negotiating, awarding and managing subcontracts in accordance with FAR Clause 52.244-2.

G. Describe experience with identification and remediation of subcontractor performance or noncompliance with subcontract terms and conditions.

H. Provide a Letter of Understanding (LOU) signed by persons with authority to bind each collaborating party involved in the proposed work. The LOU must describe how the collaborating parties will coordinate their efforts to:

1) protect intellectual property arising in the performance of the contract;
2) facilitate the development and technology transfer of the models and assays;
3) ensure GLP, GMP, and GCP compliance and quality assurance; and
4) resolve disputes among the collaborating parties should such disputes arise in performance of the contract.

I. Describe how the offeror will safeguard confidentiality of intellectual property, data and material provided to them by third parties of the United State Government, and data generated during the performance of the contract.

SECTION 6: FACILITIES, OTHER RESOURCES, SAFETY AND TRAINING

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

A. Location and features of the biocontainment facilities including a floor plan and a list of equipment and resources dedicated to the project for the prime contractor and any proposed subcontractors (lease or ownership information should be provided).

B. For all proposed sites working with *Y. pestis*, evidence of Select Agent Approval from the CDC (Select Agent Approval Certificate and letter from CDC indicating approval has been granted for *Y. pestis*) or evidence that an application for Select Agent Approval has been submitted (copies of Sections 1,2,3, and 4 from the Application for Laboratory Registration for Possession, Use and Transfer of Select Agents and Toxins Approval and copies of letters from the Responsible Official at all proposed sites verifying that the above application has been submitted to the CDC).

C. Location and features of the animal facilities including floor plans and a list of equipment and resources dedicated to the project for the prime contractor and any proposed subcontractors (lease or ownership information should be provided).

D. Provide a thorough summary of safe practices and facilities that will be available to assure a safe working environment for all personnel handling or in contact with animals and/or pathogenic microorganisms. Describe the level of training required for proposed staff working with animals and pathogenic microorganisms.

E. Provide a floor plan for all proposed GLP, GMP, and GCP facilities and laboratories where assays will be performed. Describe the level of training required for proposed staff working in GLP, GMP, and GCP environments.

F. Provide a description of the facilities and practices for receiving, shipping, storing, tracking and archiving of clinical and non-clinical samples, samples for stability testing, and storing critical reagents.

G. Identification and description of ALL support resources (including Information Technology systems) which will be required to effectively complete the SOW.

SECTION 7: OPTIONS

Each Option should be presented as a separate part of your Technical Proposal and clearly identified as such. This portion of the Technical Proposal will be included in the total page limitation.

A. Option 1:
Describe how you will assess vaccine candidates by performing efficacy studies for both pneumonic and bubonic plague in one small animal and one NHP model following the SOPs to be developed in Tasks 1 and 2 and analyzing the associated samples following the SOPs to be developed in Task 5 during the Base Period.

B. Option 2:
Describe your approach to analyzing clinical trial samples using the validated immunoassay procedures and SOPs to be developed in Task 5 during the Base Period.

C. Option 3:
Describe your approach for analyzing lots of vaccine candidates using the validated potency assay(s) procedures and SOPS to be developed in Task 6 during the Base Period.

SECTION 8: TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

A. 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.

B. Sharing Research Data (Plan)

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

C. Sharing of Model Organisms for Biomedical Research (Plan)

Section L of the RFP specifies the minimum documentation requirements for Model Organism sharing. All related documentation should be included in the proposal in this clearly marked section. The Technical Proposal should include a plan for sharing Model Organisms as required by this RFP.

D. Biohazard Safety

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

E. Information Technology (IT) Systems Security

Section L of the RFP specifies the minimum documentation requirements for IT Systems security. All related documentation should be included in the Technical Proposal in this clearly marked section. The Technical Proposal should include a plan for IT Systems security as required by this RFP.

ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM BUDGET ASSUMPTIONS

RFP NIH-NIAID-DMID-07-06
Development of Animal Models and Assays for Plague Vaccines

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 budget assumptions and business clarifications.

Offerors are advised to give careful consideration to the Statement of Work, all reference material provided as appendices and attachments, the Technical Evaluation Criteria, and, the RFP as a whole, in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your business proposal. Offerors should consider and include the information requested in this appendix, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL – TABLE OF CONTENTS

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

SECTION 2 – COST OR PRICE SUPPORT

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

SECTION 3 – UNIFORM BUDGET ASSUMPTIONS

A. **Technical Cost Assumptions**

1. **Overall Budget and Budgets by Tasks:**

   Business Proposals must include a breakdown by line item cost to include, for example, Direct Labor, Direct Materials, Animal costs (including housing), Subcontracts, Consultants, Travel (refer to the instructions in Section L.2.c, Business Proposal Instructions, of this solicitation).

   The Business Proposal must include a detailed Gantt chart that provides timelines delineating each Task with associated sub-tasks and budget. Your cost estimate should be based on budget linked to Task activities contained in the Strategic Work Plan and timeline. The Task linked budget will be spread by month and by annual contact years.

2. **Special Shipping and Packaging**

   Offerors should include a uniform assumption of $5,000 per year for the first 2 years and $15,000 for the third year of the base contract period for shipping.

3. **Storage**

Offerors should include a uniform assumption of 20,000 specimens to be stored for each year of the base period of the contract.

4. **GLP/GMP/GCP Audits**

Offerors should include a uniform assumption of two GLP/GMP/GCP audits annually.

B. **Budgets for Options Establishing Central Reference Laboratories -- (Tasks 12, 13, and 14):**

1. **Technical Cost Assumptions:**

The offeror should assume the following:

Option 1: efficacy studies shall be performed for both pneumonic and bubonic plague in one small animal and one NHP model for two vaccine candidates following the procedures and SOPs developed in Tasks 1 and 2. The associated samples will be analyzed following the procedures and SOPs developed in Task 5.

Option 2: samples from 3,000 clinical trial subjects shall be analyzed following the procedures and SOPs developed in Task 5.

Option 3: six lots of vaccine shall be assayed following the procedures and SOPs developed in Task 6.

2. **Specimens**

Offerors should include a uniform assumption of $15,000 for packaging and marking of specimens in the Option year of the contract.

3. **Storage**

Offerors should include a uniform assumption of 50,000 specimens to be stored during the Option year.

SECTION 4 - DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

1) Small Business Subcontracting Plan

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

2) Extent of Small Disadvantaged Business Participation

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

3) Past Performance Data, including references

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

4) Other Documentation

Include any other documentation to support your business proposal.