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

BAA NIH-NIAID-DMID-07-20
NIAID Centers of Excellence for Influenza Research and Surveillance

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:** **March 6, 2006** **Time:** **4:00 p.m. , EST**	5. **Small Bus. Set-Aside:** [ ]Yes [X] No **8(a) Set-Aside:** [ ]Yes [X] No **NAICS #:** 541710 (See Part IV, Section L.)
October 18, 2005		

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	Number of Copies: See Part III, Section J (Packaging and Delivery of Proposal) Page Limits: See Appendix A.

9. **Issued By:**	10. [X] **NIAID reserves the right to make awards without discussion.**	
Carl A. Newman, Contracting Officer Contract Management Program, DEA NIH, NIAID 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	11. **Options:** **[X] No** **[ ] Yes (See Part IV, Section L.)**	12. **Period of Performance:** 7 years beginning on or about November 1, 2006

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : **Carl A. Newman** **Phone:** 301-496-8371 **Fax:** 301-480-2622 E-Mail: cnewman@niaid.nih.gov	**Name:** **Paul D. McFarlane** **Phone:** 301-496-0349 **Fax:** 301-480-2622 E-Mail: pmcfarlane@niaid.nih.gov	Charles W. Grewe Program Director, CMP **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)**

DELIVERY ADDRESS INFORMATION

18. Hand Delivery or Overnight Service:	19. **U.S. Postal Service or an Express Delivery Service**
Carl A. Newman Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Carl A. Newman Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

20. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

Updated thru FAC 2001-27 (3/28/2005)

DETAILED TABLE OF BAA CONTENTS

PART I - THE SCHEDULE
SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS 5
ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES 5
ARTICLE B.2. PRICES/COSTS 5
ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS....5
ARTICLE B.4. ADVANCE UNDERSTANDINGS....5
SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT 5
ARTICLE C.1. BROAD AGENCY ANNOUNCEMENT....5
ARTICLE C.2. REPORTING REQUIREMENTS 5
SECTION D - PACKAGING, MARKING AND SHIPPING....8
SECTION E - INSPECTION AND ACCEPTANCE....8
SECTION F - DELIVERIES OR PERFORMANCE....9
ARTICLE F. 1. DELIVERIES....9
ARTICLE F.2 CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)....10
SECTION G - CONTRACT ADMINISTRATION DATA 10
ARTICLE G.1. PROJECT OFFICER....10
ARTICLE G.2. KEY PERSONNEL....11
ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST AND CONTRACT FINANCIAL REPORT....11
ARTICLE G.4. GOVERNMENT PROPERTY....11
ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE....11
SECTION H – SPECIAL CONTRACT REQUIREMENTS....12
ARTICLE H.1. HUMAN SUBJECTS....12
ARTICLE H.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS ..12
ARTICLE H.3. HUMAN MATERIALS 13
ARTICLE H.4. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)....13
ARTICLE H.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH 13
ARTICLE H.6. NEEDLE EXCHANGE 13
ARTICLE H.7. PRIVACY ACT....14
ARTICLE H.8. SUBCONTRACTING PROVISIONS 14
ARTICLE H.9. ANIMAL WELFARE....15
ARTICLE H.10. OMB CLEARANCE 15
ARTICLE H.11. SALARY RATE LIMITATION LEGISLATION PROVISIONS....15
ARTICLE H.12. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL 15
ARTICLE H.13. CONFIDENTIALITY OF INFORMATION 16
ARTICLE H.14. PUBLICATION AND PUBLICITY 16
ARTICLE H.15. PRESS RELEASES 16
ARTICLE H.16. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE 16
ARTICLE H.17. YEAR 2000 COMPLIANCE....16
ARTICLE H.18. ANTI-LOBBYING....17
ARTICLE H.19. POSSESSION USE AND TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS....18
ARTICLE H.20. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391) 18
ARTICLE H.21. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES....19
ARTICLE H.22 . NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH....19
ARTICLE H.23. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES....19
ARTICLE H.24. SHARING RESEARCH DATA....19
SECTION I - CONTRACT CLAUSES....20
ARTICLE I.1. GENERAL CLAUSE LISTING....20
ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES 21
ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES....21
ARTICLE I.4. ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT 22
SECTION J - LIST OF ATTACHMENTS 25
SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS 27
SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS 28
SECTION M - EVALUATION FACTORS FOR AWARD....55

BROAD AGENCY ANNOUNCEMENT.....65
APPENDIX A-ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS.....75
APPENDIX B – ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS.....82

PART I - THE SCHEDULE

THE CONTRACT SCHEDULE SET FORTH IN SECTIONS B THROUGH H, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS **NOT** AN EXACT REPRESENTATION OF THE PROPOSED CONTRACT DOCUMENT. CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (I.E., THOSE RELATING TO THE ORGANIZATIONAL STRUCTURE [E.G., NON-PROFIT, COMMERCIAL] AND SPECIFIC COST AUTHORIZATIONS UNIQUE TO THE OFFEROR'S PROPOSAL AND REQUIRING CONTRACTING OFFICER PRIOR APPROVAL) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. HOWEVER, THE ENCLOSED CONTRACT SCHEDULE PROVIDES ALL THE NECESSARY INFORMATION FOR THE OFFEROR TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

Research Area 1: The Contractor shall carry out an international and/or domestic animal surveillance program focused on virologic, epidemiologic, and disease surveillance with emphasis on the rapid characterization of influenza viruses with pandemic potential.

Research Area 2: The Contractor shall carry out a research program focused on both of the following:
Part A. Determination of the molecular, ecologic and/or environmental factors that influence the evolution, emergence, transmission and pathogenicity of influenza viruses, including studies on animal influenza viruses with pandemic potential; and
Part B. Characterization of the immune response to influenza infection and/or vaccination to improve understanding of the immune correlates of protection and cross-protection.

ARTICLE B.2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. BROAD AGENCY ANNOUNCEMENT

a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work in response to the Broad Agency Announcement dated October 14, 2005 attached hereto and made a part of this Solicitation (See Section J - List of Attachments-Attachment 1)

ARTICLE C.2. REPORTING REQUIREMENTS

1. **Semi-Annual Reports**
   The Contractor shall submit four (4) copies of the Semi-Annual Report 15 days following the end of each 6 month period of performance (180 calendar days). The original shall be submitted to the NIAID Contracting Officer, with three (3) copies submitted to the NIAID Project Officer. Each Semi-Annual

Report shall include the following:

A. Face page to include the contract number, contract title, performance period covered Contractor's name and address, telephone number, fax number, email address and submission date.
B. 2-3 page Executive Summary to include: a listing of performance site(s), a brief overview of the work completed, and the major accomplishments achieved during the current reporting period.
C. Progress Report, to include a detailed description of:
    1) The work and accomplishments performed during the reporting period structured to follow the outline set forth in the Statement of Work. This includes the tasks noted in the Statement of Work.
    2) Any problems (technical or financial) that occurred or were identified during the reporting period, and how resolved.
    3) A listing of the transfer of all contact-supported materials, including but not limited to viruses, and reagents. Specify the Select Agent status, if applicable and include the recipients name and current permit number.
D. Copies of manuscripts (published and unpublished), abstracts, and any protocol or method developed specifically under the contract during the reporting period.
E. A full disclosure of any inventions developed during the course of this work, patent or copyright applications that have been submitted or are in the process of being drafted for submission at the time the report is due. Such inventions and copyrights shall include: procedures utilized, derived, or established by the work supported under this contract; and new materials generated or new properties of existing materials discovered in the course of carrying out work supported under this contract. The reports shall contain full disclosures of patent applications or copyrights filed, and copies of issued patents or copyright applications.
F. Semi-Annual Progress Reports are not required for the period in which the Final Report is due.

2. Final Report

The Contactor shall submit four (4) copies of the Final Report that documents and summarizes the results of the entire contract period of performance. This report shall be submitted on or before the completion date of the contract. The report shall conform to the following format:

A. Face page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.
B. Introduction covering the purpose and scope of the contract effort including a summary of the major accomplishments (not to exceed 500 words) during the performance of the contract
C. An executive summary to include fulfillment of the contract goals and the specific activities set forth in the Statement of Work.
D. A detailed description of the work performed (as described for the Semi-Annual Reports), the results obtained, and the impact of the results on the scientific and/or public health community.
E. A listing of all manuscripts (published and in preparation) and abstracts presenting work supported during the performance of the contract.

3. Transition Plan

The Contractor shall submit an original (paper and electronic) to the NIAID Contracting Officer and one (1) copy (paper and electronic) to the NIAID Project Officer of the Transition Plan six (6) months prior to the contract end date. The Transition Plan shall include the following:

A.. A cover page containing the contract umber and title; the period of performance being reported; the contractor's name, address, telephone, fax, and e-mail; the author(s); and date of submission;

B. A comprehensive list of all stored reagents, data, web sites, databases, bioinformatics software and tools, technologies, SOPs, unused supplies, Government-furnished equipment and any other resources generated under this contract; and

C. A plan for the transportation of these resources and deliverables to a subsequent contractor or the Government.

4. Other Deliverables

The Contractor shall provide to the Government or deliver to a successor contractor before the contract completion date as listed below and as instructed by the NIAID Project Officer.

A. All data, protocols, and lists of contract-generated reagents and products shall be submitted to the NIAID Project Officer within four (4) months of completion of their validation or as directed by the NIAID Project Officer.

B. Sufficient quantities for distribution of all reagents and products, including antibodies, primers, purified proteins, and viruses such as wild type isolates and vaccine reference viruses and all documents supporting their production and/or testing shall be submitted to the NIAID Biodefense and Emerging Infectious Diseases Research Repository within four (4) months of completion of validation studies or as directed by the NIAID Project Officer for distribution to the research community.

C. Invention Reporting Requirement

All reports and documentation required by FAR Clause 52.227-13 including, but not limited to, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040 A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the NIAID Contracting Officer. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted not later than the expiration date of the contract to the NIAID Contracting Officer.

The annual utilization report shall be submitted in accordance with ARTICLE F.1. DELIVERIES of this contract. Thereafter, reports shall be due on or before the 30th of the month following the anniversary reporting period. The final invention statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the expiration date of the contract to the following address:

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

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

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

D. Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in Section J of this contract. The contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report. The contractor shall submit the report in accordance with ARTICLE F.1. DELIVERIES of this contract. The report shall be due on or before the 30th day of the month following each anniversary of the contract. The final report shall be due on or before the completion date of the contract.

In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies. If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the annual progress report and the final report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, will suffice. The Government strongly encourages inclusion of the results of subset analysis in all publication submissions. In the final report, the contractor shall include all final analyses of the data on sex/gender and race/ethnicity.

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 NIAID 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 NIAID Project Officer is the authorized representative of the NIAID Contracting Officer.

c. Inspection and acceptance will be performed at:

DMID, NIAID, NIH
6610 Rockledge Drive
Room 6005, MSC 7630
Bethesda, MD 20892-7630 .

Acceptance may be presumed unless otherwise indicated in writing by the NIAID 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 NIAID Contracting Officer will make its full text available.

FAR Clause **52.246-5, Inspection of Services - Cost-Reimbursement** (April 1984).

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

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F. 1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in 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:

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

Item	Deliverable	No. of Hard Copies	Due Dates
1	Semi-Annual Reports (See ARTICLE C.2)	1 original to CO (paper and electronic) 3 copies to PO (paper and electronic)	15 days following the end of each semi-annual reporting period.
2	Annual Progress Report	1 original to CO (paper and electronic) 3 copies to PO(paper and electronic)	Due on/before the 30th of the month following each anniversary of the contract. The first report is due on November 30, 2006.
3	Final Reports (See ARTICLE C.2)	1 original to CO(paper and electronic) 3 copies to PO (paper and electronic)	Draft 30 days before the end of the contract period; final report due on or before completion date of the contract.
4	All data protocols and lists of contract-generated reagents and products	Supporting docs-1 original to CO and 1 to PO.	Within 4 months of completion of testing or at the direction of the Project Officer
5	Sufficient quantities for distribution of all reagents and products including but not limited to antibodies, primers, purified proteins and viruses and all documents supporting their production and or testing	N/A	Within 4 months of completion of validation studies or as directed by the NIAID Project Officer for distribution to the research community.
6	Transition Plan (See ARTICLE C.2)	1 Original to CO (paper and electronic) 1 copy to PO(paper and electronic)	Due 6 months prior to the completion date of the contract.
7	Annual Utilization Report (See ARTICLE C.2)	1 Original to OPERA 1 copy to CO	Due on/before the 30th of the month following each anniversary of the contract. The first report is due on November 30, 2006.
8	Final Invention Statement (See ARTICLE C.2.)	1 original to	Due on/before the completion date of

		OPERA 1 copy to CO	the contract.
9	Technical Progress Report for Clinical Research Study Populations (See ARTICLE C.2)	1 original to CO(paper and electronic) 3 copies to PO (paper and electronic)	Due on/before the 30th of the month following each anniversary of the contract. The first report is due on November 30, 2006.

b. The above items shall be addressed and delivered to the following in accordance with the delivery schedule above:

Project Officer (PO) DMID, NIAID, NIH 6610 Rockledge Drive Room (TBD) Bethesda, MD 20892	Contracting Officer (CO) CMP, DEA, NIAID, NIH 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	EITRB, Office of Biodefense Research Affairs, NIH 6705 Rockledge Drive Room 1040-A, MSC 7980 Bethesda, MD. 20892-7980
Item Nos. 1, 2, 3, 4, 5, 6 and 9	All above listed items.	Item Nos. 7 and 8.

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

Any contract awarded from this BAA will contain the following:

ARTICLE G.1. PROJECT OFFICER

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

[To be specified prior to award]

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

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

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

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

NAME	TITLE
[To be specified prior to award]	

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

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

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

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

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

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN2662006XXXXXC.)

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-XXXXX.)

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

Contracting Officer
Contract Management Program
National Institute of Allergy and Infectious Diseases, NIH, DHHS
Room 3214, MSC 7612
6700-B Rockledge Drive
BETHESDA MD 20892-7612

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

ARTICLE G.4. GOVERNMENT PROPERTY

If this BAA will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the DHHS Publication (OS) 686, entitled, **Contractor's Guide for Control of Government Property**, (1990) which can be found at:
http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm

ARTICLE G.5. 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 every two years to coincide with the anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H – SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by the NIAID and written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer 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. The human subject certification can be met by submission of the Contractor's 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.2. REQUIRED EDUCATION IN THE PROTECTION OF HUMAN RESEARCH PARTICIPANTS

NIH policy requires education on the protection of human subject participants for all investigators receiving NIH contract awards for research involving human subjects. For a complete description of the NIH Policy announcement on required education in the protection of human subject participants, the contractor should access the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. The information below is a summary of the NIH Policy Announcement:

The contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the Contracting

Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

ARTICLE H.3. HUMAN MATERIALS

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.

ARTICLE H.4. 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.5. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b. , below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

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

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

[Applicable information to be included at award]

ARTICLE H.6. 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.7. PRIVACY ACT

This procurement action requires the Contractor to do one or more of the following: design, develop, or operate a system of records on individuals to accomplish an agency function in accordance with the Privacy Act of 1974, Public Law 93-579, December 31, 1974 (5 USC 552a) and applicable agency regulations. Violation of the Act may involve the imposition of criminal penalties.

ARTICLE H.8. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

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

b. Subcontracting Reports

(1) Subcontracting Report for Individual Contracts, SF-294

The Contractor shall submit the original and one (1) copy of Subcontracting Report for Individual Contracts, SF-294 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. In addition to the information contained in the General Instructions on the back of this form for Block 17, "Remarks," the Contractor shall
provide an explanation for any category of small business subcontracting for which there were no dollars reported since the last reporting period.

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

The Report shall be sent to the Contracting Officer at following address:

Contracting Officer
Preclinical Research Contracts Branch
Contract Management Program, DEA
National Institute of Allergy and Infectious Diseases
6700-Rockledge Drive, Room 3214, MSC 7612
Bethesda, MD 20892-7612

(2) Summary Subcontract Report, SF-295

The Contractor shall submit two (2) copies of Summary Subcontract Report, SF-295 in accordance with the instructions on the report as referenced in Public Law 95-507, Section 211. 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

One (1) copy of this report shall be sent to the Contracting Officer at the address above. One (1) copy of this Report shall be mailed to the Office of Small and Disadvantaged Business Utilization, DHHS at the following addresses:

Office of Small and Disadvantaged Business Utilization

Department of Health and Human Services
Hubert H. Humphrey Bldg., Room 360G
200 Independence Avenue, S.W.
Washington, D.C. 20201

(3) The contractor shall also send an "Information Copy" of the SF-295 to the Cognizant Commercial Representative (CMR) at the address provided by the SBA. The Contractor should call SBA Headquarters in Washington, DC at (202) 690-7235 for the correct address if unknown.

ARTICLE H.9. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals. This policy may be accessed at:
http://grants1.nih.gov/grants/olaw/references/phspol.htm

ARTICLE H.10. OMB CLEARANCE

In accordance with HHSAR 352.270-7, Paperwork Reduction Act, the Contractor shall not proceed with surveys or interviews until such time as Office of Management and Budget (OMB) Clearance for conducting interviews has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed.

ARTICLE H.11. SALARY RATE LIMITATION LEGISLATION PROVISIONS

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

b.

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

[Applicable information to be included at award]

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

* For the period 10/1/04 - 12/30/04, the Executive Level I rate is $175,700. Effective January 1, 2005, the Executive Level I rate increased to $180,100 and will remain at that rate until it is revised. See the web site listed below for the Executive Schedule rates of pay:

FOR FY05 EXECUTIVE LEVEL SALARIES EFFECTIVE JANUARY 1, 2005:
http://www.opm.gov/oca/05tables/html/ex.asp
(NOTE: This site shows the CY 05 rates. For previous years, click on "salaries and wages" and then scroll down to the bottom of the page and click on the year to locate the desired Executive Level salary rates).

ARTICLE H.12. ACCESS TO NATIONAL INSTITUTES OF HEALTH (NIH) ELECTRONIC MAIL

All Contractor staff that have access to and use of NIH electronic mail (e-mail) must identify themselves as contractors on all outgoing e-mail messages, including those that are sent in reply or are forwarded to another user. To best

comply with this requirement, the contractor staff shall set up an e-mail signature ("AutoSignature") or an electronic business card ("V-card") on each contractor employee's computer system and/or Personal Digital Assistant (PDA) that will automatically display "Contractor" in the signature area of all e-mails sent.

ARTICLE H.13. CONFIDENTIALITY OF INFORMATION

The following information is covered by HHSAR 352.224-70, Confidentiality of Information (APR 1984); (Rev MARCH 2005):

ARTICLE H.14. 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 Cancer Institute, National Institutes of Health, Department of Health and Human Services, under Contract No. .

ARTICLE H.15. PRESS RELEASES

a. Pursuant to Public Law(s) cited in paragraph b., below, the contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

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

[Applicable information to be included at award]

ARTICLE H.16. 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.17. YEAR 2000 COMPLIANCE

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

1. Service Involving the Use of Information Technology

YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY

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

(End of Clause)

2. Noncommercial Supply Items Warranty

YEAR 2000 WARRANTY--NONCOMMERCIAL SUPPLY ITEMS

The contractor warrants that each noncommercial item of hardware, software, and firmware delivered or developed under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing and sequencing) from, into and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with the item documentation provided by the contractor, provided that all listed or unlisted items (e.g., hardware, software and firmware) used in combination with such listed item properly exchange date data with it. If the contract requires that specific listed items must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed items as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of any general warranty provisions of this contract provided that notwithstanding any provision to the contrary in such warranty provision(s), or in the absence of any such warranty provision(s), the remedies available to the Government under this warranty shall include repair or replacement of any listed item whose noncompliance is discovered and made known to the contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

YEAR 2000 COMPLIANT ITEMS

TO BE DETERMINED

(End of Clause)

3. Commercial Supply Products Warranty

YEAR 2000 WARRANTY--COMMERCIAL SUPPLY ITEMS

The contractor warrants that each hardware, software and firmware product delivered under this contract and listed below shall be able to accurately process date data (including, but not limited to, calculating, comparing, and sequencing) from, into, and between the twentieth and twenty-first centuries and the Year 1999 and the Year 2000 and leap year calculations, when used in accordance with the product documentation provided by the contractor, provided that all listed or unlisted products (e.g., hardware, software, firmware) used in combination with such listed product properly exchange date data with it. If the contract requires that specific listed products must perform as a system in accordance with the foregoing warranty, then that warranty shall apply to those listed products as a system. The duration of this warranty and the remedies available to the Government for breach of this warranty shall be as defined in, and subject to, the terms and limitations of the contractor's standard commercial warranty or warranties contained in this contract, provided that notwithstanding any provision to the contrary in such commercial warranty or warranties, the remedies available to the Government under this warranty shall include repair or replacement of any listed product whose non-compliance is discovered and made known to the contractor in writing within ninety (90) days after acceptance. Nothing in this warranty shall be construed to limit any rights or remedies the Government may otherwise have under this contract with respect to defects other than Year 2000 performance.

YEAR 2000 COMPLIANT ITEMS

TO BE DETERMINED

(End of Clause)

ARTICLE H.18. 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.19. 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.20. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting,

convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

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

ARTICLE H.21. 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.22 . 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.

ARTICLE H.23. 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.

ARTICLE H.24. SHARING RESEARCH DATA

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

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

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

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

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 BAA. 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 BAA:

ARTICLE I.1. GENERAL CLAUSE LISTING

General Clauses for a Cost-Reimbursement Research and Development Contract
General Clauses for a Cost-Reimbursement Contract with Educational Institutions
General Clauses for a Cost-Reimbursement Contract with Non-Profit Organizations Other Than Educational Institutions

The complete listing of these clauses may be accessed at:

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Any authorized substitutions and/or modifications other than the General Clauses which will be based on the type of contract/Contractor will be determined during negotiations.

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

FAR Clause **52.216-7, Allowable Cost And Payment** (December 2002), is modified in paragraph (a) to delete the words "subpart 31.2 of the Federal Acquisition Regulation (FAR)" and substitute the words "45 CFR part 74, appendix E".

FAR Clause **52.216-8, Fixed Fee** (March 1997), is deleted in its entirety and FAR Clause **52.216-11, Cost Contract--No Fee** (April 1984) is substituted therefor.

FAR Clause **52.249-14, Excusable Delays** (April 1984) is deleted and **HHSAR** Clause **352.249-14, Excusable Delays** (April 1984) is substituted therefor.

Alternate I of FAR Clause **52.216-11, Cost Contract--No Fee** (April 1984), 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 IV 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.

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 **52.211-11, Liquidated Damages--Supplies, Services, or Research and Development** (September 2000).

"(a) If the Contractor fails to deliver the supplies or perform the services within the time specified in this contract, the Contractor shall, in place of actual damages, pay to the government liquidated damages of $____ per calendar day of delay."

(2) FAR Clause **52.216-15, Predetermined Indirect Cost Rates** (April 1998).

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

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

[ ] Offeror elects to waive the evaluation preference."

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

(5) FAR Clause **52.223-3, Hazardous Material Identification and Material Safety Data** (January 1997), with Alternate **I** (July 1995).

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

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

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

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

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

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

(12) FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (April 1998).

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

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

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

(16) FAR Clause **52.246-23, Limitation of Liability** (February 1997).
AND/OR
(17) FAR Clause **52.246-24, Limitation of Liability - High-Value Items** (February 1997).

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

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

(2) HHSAR Clause **352.224-70, Confidentiality of Information** (April 1984) (Rev March 2005).

(3) HHSAR Clause **352.270-8, Protection of Human Subjects** (March 2005).

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

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

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

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

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

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

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Broad Agency Announcement	See Attachment Section at the end of this BAA
Attachment 2:	Appendix A and B	See Attachment Section at the end of this BAA
Attachment 3:	Proposal Intent Response Sheet	http://rcb.cancer.gov/rcb-internet/forms/intent.jsp
Attachment 4:	Packaging and Delivery of Proposal	http://www.niaid.nih.gov/contract/eproposal.htm#pack

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

Attachment No.	Title	Location
Attachment 5:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Attachment 6:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Attachment 7:	Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Attachment 8:	Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (formerly Optional Form 310	http://rcb.cancer.gov/rcb-internet/forms/of310.pdf
Attachment 9:	Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf
Attachment 10:	Targeted/Planned Enrollment Table	http://rcb.cancer.gov/rcb-internet/forms/enroll-table.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://www.niaid.nih.gov/contract/forms.htm http://ocm.od.nih.gov/contracts/spsh/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 BAA 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:	Privacy Act System of Records *System of Records No. 09-25-0200 is applicable to this BAA.*	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Attachment 18:	Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Attachment 19:	Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Attachment 20:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf
Attachment 21:	Inclusion Enrollment Report	http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.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

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 Order of Merit Ranking that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.

"In writing", *"writing"*, or *"written"* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

"*Proposal modification*" is a change made to a proposal before the solicitation's closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

"*Proposal revision*" is a change to a proposal made after the solicitation closing date, at the request of or as allowed by a Contracting Officer as the result of negotiations.

"*Time,*" if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to solicitations*. If this solicitation is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this solicitation by the date and time specified in the amendment(s).

(c) *Submission, modification, revision, and withdrawal of proposals*. (1) Unless other methods (*e.g.*, electronic commerce or facsimile) are permitted in the solicitation, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the solicitation, and (ii) showing the time and date specified for receipt, the solicitation number, and the name and address of the offeror. Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i) and (c)(1)(ii) of this provision.

(2) The first page of the proposal must show--
- (i) The solicitation number;
- (ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);
- (iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;
- (iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and
- (v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) *Submission, modification, revision, and withdrawal of proposals*. (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the solicitation by the time specified in the solicitation. If no time is specified in the solicitation, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines

that accepting the late offer would not unduly delay the acquisition; and--

(*1*) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(*2*) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(*3*) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.

(6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(d) *Offer expiration date*. Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be

disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

> Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
>
> The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
>
> If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
>
> The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

(2) In addition, the offeror should mark each page of data it wishes to restrict with the following statement:

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

(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

(f) *Contract award*. (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.

(2) The Government may reject any or all proposals if such action is in the Government's interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

(7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.

(8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(11) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.
(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.
(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iv) A summary of the rationale for award.
(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.
(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

Alternate I (October 1997). As prescribed in 15.209(a)(1), substitute the following paragraph (f)(4) for paragraph (f)(4) of the basic provision:

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors in the Order of Merit Ranking.

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 BAA), specifically in completing the provision entitled, SMALL BUSINESS PROGRAM REPRESENTATION, FAR Clause 52.219-1.

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.
(2) The small business size standard is 500 employees.

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

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

It is anticipated that multiple awards will be made from this solicitation and that the awards will be made on/about November 1, 2006. .

It is anticipated that the awards from this solicitation will be a multiple-year cost reimbursement completion type contract with duration of up to seven years and that incremental funding will be used. [See Section L.2.c. Business Proposal Instructions.]

d. **COMMITMENT OF PUBLIC FUNDS**

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

e. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

f. **RELEASE OF INFORMATION**

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

g. **COMPARATIVE IMPORTANCE OF PROPOSALS**

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

h. **PREPARATION COSTS**

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

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

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

Charles Grewe
Director, Contracts Management Program
National Institute of Allergy and Infectious Diseases, NIH, DHHS
6700 B Rockledge Drive, Room 3214 [MSC 7612]
BETHESDA MD 20892-7612

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

(End of Provision)

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

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

(End of provision)

INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

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

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

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

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this BAA. 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 BAA should be placed in the following order:

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments.

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments.

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

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

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

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS). 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**

Alternate 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 BAA, 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 BAA.

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

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

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

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

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

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

(8) **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.

(9) **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 of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
- a description of any euthanasia method to be used.

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

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

(10) **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.

(11) **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: The NIH Guide announcement referenced below states that this policy is applicable to "all investigator-initiated applications with direct costs greater than $500,000 in any single year." This is an overall grant policy which requires that an applicant must seek agreement by NIH to accept assignment of their application in advance of the submission date. As such, this policy has not correlation to the contract process, therefore, the threshold is not applicable to contracts. Thus, this article applies to ***any*** *contract that may 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 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 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)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.

(12) **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 BAA 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.

(13) **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 BAA, 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-

Communications will be held with offerors whose past performance information is the determining factor in preventing them from being placed within the Order of Merit Ranking. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond.

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 Order of Merit Ranking.

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 BAA. In addition, the BAA may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

(14) **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 11 to this BAA 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 BAA in SECTION J.

HHS expects each procuring activity to establish minimum subcontracting goals for all procurements. The anticipated minimum goals for this BAA 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.

(15) **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

(16) **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). The NAICS codes can be found at:
http://www.sba.gov/size

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

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

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Sub sector(s). The applicable authorized NAICS Sub sector(s) for this project is (are) identified elsewhere in this BAA. 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 sub factor 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 Sub sector 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.

(17) **Salary Rate Limitation in Fiscal Year 2005**

Offerors are advised that pursuant to P.L. 108-447, no NIH Fiscal Year 2005 (October 1, 2004 - September 30, 2005) 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. 108-447 applies only to Fiscal Year 2005 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. 108-447 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 extramural mechanism at a rate in excess of Executive Level I*."

LINK TO EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/05tables/html/ex.asp

***Note to Offerors:** The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award will be required to be in compliance with the current Fiscal Year 2005 Executive Level I Salary rates.*

(18) **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.

(19) **ROTC Access and Federal Military Recruiting on Campus**

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

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

(15) **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.

(16) **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) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

b) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

Part III. Technical Proposal Instructions for Broad Agency Announcements

1. **Technical Proposal**

The Technical Proposal consists of two major sections:

SECTION ONE - The **Statement of Work** which delineates each step or task to be carried out **after award of the contract** in order to accomplish the proposed research.

SECTION TWO - The **Detailed Proposal** which consists of three parts:

(1) **Part 1 - Technical Plan** - describes the proposed approach, methodology, and outcome in detail, including preliminary data and other documentation supporting the proposed research project;

(2) **Part 2 - Personnel** - a description of the experience and qualifications of proposed personnel and a discussion of how the project will be organized and managed; and,

(3) **Part 3 - Other Considerations.**

SECTION ONE - Offeror's Proposed Statement of Work ***(recommended limit-10 pages)***

In contracts awarded under this Broad Agency Announcement, the Statement of Work will be the Statement of Work proposed by the offeror and negotiated and accepted by the NIAID. This section of the offeror's Technical Proposal should outline the steps to be taken by the contractor during performance of the contract. The offeror's proposed Statement of Work should begin as follows:

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

The opening paragraph should be followed by a full Statement of Work describing each step that the contractor

shall perform **after the award of the contract**, including: the tasks that will be performed to carry out the research project; how these tasks will be accomplished; and the time frame within which each task will be accomplished. Each step described in the Statement of Work will begin with the words "The Contractor shall...." Where appropriate, divide the Statement of Work into separate tasks and subtasks. An outline format should be used. Briefly describe the work related to each task and describe the tasks in the sequence in which they will be carried out. More in depth descriptions of the proposed work should be provided in SECTION TWO of your Technical Proposal. The Statement of Work should also include a description of all items to be delivered to the Government during performance of the contract, such as progress reports, financial reports, end products, and deliverables.

SECTION TWO - Part 1-Technical Plan ***(recommended limit-25 pages)***

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and its relationship to comparable work in progress elsewhere or as part of your own studies. Review pertinent work already published which is relevant to this project and your proposed approach. Provide a list of references to document published work cited in the proposal. Place the list at the end of SECTION TWO, Part 1. This section of the Technical Plan should support the scope of the project as you propose it to be accomplished, and as outlined in your proposed Statement of Work.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly describe the general plan of work. Discuss phasing of research including rationale, experimental design, achievable milestones, and the possible or probable outcome(s) of the proposed approaches. Describe alternate approaches to be used if the primary approaches are unsuccessful. In addition, indicate the role of subcontractors in the plan of work, if applicable.

(3) Methods

Describe the methods 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 work and delivery of items specified in your proposed Statement of Work. Performance or delivery schedules should be indicated for phases or segments, as applicable, as well as for the overall project. Schedules should 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.

(5) Facilities

Describe facilities, equipment, and resources that will be used to perform all phases of the proposed project.

SECTION TWO - Part 2-Personnel-*(recommended limit-10 pages excluding letters of commitment and resumes)*

Describe the experience and qualifications of personnel who will be assigned for direct work on the project. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar research projects/programs and equipment/technologies. Special mention should be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for the project, as well as how the project will be organized and managed. If staff are to be hired, include a description of the qualifications that will be used to identify appropriate staff to fill the position(s). Include an organizational chart that clearly shows reporting relationships and lines of authority.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL

PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS AND OTHER SUPPORT FOR MORE THAN A TOTAL 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 who serves as the key contact for technical aspects of the project. Even though there may be co-investigators, identify the Prinicipal Investigator/Project Director who will be responsible for the overall implementation of any contract awarded. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project(s), his or her proposed duties, and the areas or phases of work 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 of each individual. 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 directly responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time and part-time employment, or on a subcontract or consultant basis. Describe the technical areas, character, and extent of subcontract or consultant activity and specify anticipated sources for all such services. 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 each of the following items of information:

* 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; and
* How rights to publications and patents will be handled.

Letters of commitment should be placed at the end of SECTION TWO, Part 2.

(4) Resumes ***(recommended limit–2 single-sided pages per person)***

Resumes of all key personnel are required. Each resume must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant recent publications. Resumes should be placed as the last documents in SECTION TWO, Part 2 of the proposal.

SECTION TWO -Part-3-Other Considerations

Record and discuss specific factors, not included elsewhere, that support your proposal using specifically titled subparagraphs. Items may include:

(1) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how your Statement of Work will be accomplished within this working relationship and how intellectual property issues will be treated (if applicable).

(2) Unique arrangements, equipment, procedures, etc. that no or few organizations are likely to have which will be advantageous for effective implementation of the project.

(3) Equipment, training and unusual operating procedures established to protect personnel from any hazards associated with your project.

(4) Other factors you feel important to support your proposed research.

(5) For additional requirements to be addressed in your Technical Proposal, refer to the following Sections of this BAA, as applicable:

a. Section L, Part II (General Instructions)
- Care of Live Vertebrate Animals
- Possession, Use and Transfer of Select Biological Agents or Toxins
- Sharing Research Data

b. Section L, Part III (Technical Proposal Instructions)
- Protection of Human Subjects
- Required Education in the Protection of Human Research Participants
- Inclusion of Women and Minorities in Research Involving Human Subjects
- Inclusion of Children in Research Involving Human Subjects
- Data and Safety Monitoring in Clinical Trials
- Information Technology Systems Security

Discussion of these subjects should be placed at the end of SECTION TWO, Part 3 of the technical proposal.

2. **Technical Evaluation**

Proposals will be technically evaluated by an initial review panel in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (see Section M.). This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

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) **Total Compensation Plan - Instructions**

a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as part of their business proposal will submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(4) **Total Compensation Plan - Evaluation**

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(5) **Qualifications of the Offeror**

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this BAA, 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 BAA**

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 BAA. 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 BAA.

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 BAA.

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 BAA; 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 BAA. 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 BAA 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.

(6) **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 BAA, 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.

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

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

(1) The solicitation number (or other procurement identification number).
(2) The offeror's name and remittance address, as stated in the offer.

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

d) **Financial Capacity**

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

e) **Incremental Funding**

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

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

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

(End of provision)

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

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

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

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

(End of Provision)

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

[ ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).

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

(7) **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 BAA 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

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

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

(9) **Representations and Certifications**

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

(10) **Travel Costs/Travel Policy**

a) **Travel Policy**

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

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

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

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against three factors. The factors in the order of importance are: technical, cost, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, 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 awards to that offeror whose proposal provides the best overall value to the Government.

All technical proposals will undergo evaluation by a peer review group also known as a Scientific Review Group (SRG).

The final stage of the evaluation is the establishment of an Order of Merit Ranking in which all competing proposals are ranked on the basis of their respective relevance and scientific merit evaluations. Final selection of awards will depend upon the availability of funds, scientific priority, and program balance that the NIAID determines to exist at the time of award selection.

The estimated cost of an offer must be reasonable for the tasks to be performed, and, in accordance with FAR 15.305, will be subject to a cost realism analysis by the Government.

Offerors must demonstrate in their proposals that they have the necessary expertise and capabilities for conducting the research as requested by this solicitation. Each proposal must document the feasibility of successful implementation of the requirements of the BAA.

2. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

(a) Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by the NIAID that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

(b) Data and Safety Monitoring

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data

and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers will rely on the Statement of Work and Section L in the solicitation, as well as any further technical evaluation criteria in this Section M, as applicable, for the solicitation's specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will consider the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for data and safety monitoring is still found to be unacceptable, then your proposal may not be considered further for award.

(c) Women and Minorities

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR

- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

Reviewers will consider the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:

- the purpose of the research constrains the offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
- overriding factors dictate selection of subjects); or
- gender representation of specimens or existing datasets cannot be accurately determined, and this does not

compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
    - inclusion of those groups would be inappropriate with respect to their health,; or
    - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research

Based on the evaluation of the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or "acceptable." See Section L of the solicitation for the requirements of women/minorities inclusion. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

(d) Children

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers' evaluation of the offeror's response, this section of the proposal may be rated "unacceptable" (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror's response regarding the inclusion of children; or the plan is not in accordance wit h NIH policy guidelines) or "acceptable." If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion of children is still found to be unacceptable, then your proposal may not be considered further for award.

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 order of merit ranking (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.

******* (NOTE: The plan shall be evaluated by program staff and shall not be scored. However, weaknesses in a plan should be part of discussions and should be resolved before 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 order of merit ranking (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 CRITERA

The technical evaluation criteria are used by the Scientific Review Group when reviewing the Technical Proposal, including the Offeror's Statement of Work. The criteria below are listed in order of relative importance with weights assigned for evaluation purposes.

Because Technical Proposals may contain Research Area 1 with the required Training/Career Development Program, Research Area 2 with the required Training/Career Development Program, the additional component for a Pilot Research Program, and the additional component for Animal Influenza Surveillance Capacity Building, the technical evaluation criteria have been organized according to these four components of the solicitation.

RESEARCH AREA 1: ANIMAL INFLUENZA SURVEILLANCE

CRITERIA

WEIGHT

A. Scientific and Technical Approach **45**

(1) The soundness, appropriateness, adequacy and feasibility of the scientific and technical approaches and methodologies for proposed animal influenza surveillance activities in the following areas:

- virologic, epidemiologic and disease surveillance; and
- biological and serological analysis and characterization of isolated influenza A viruses.

Proposals for Research Area 1 that incorporate limited surveillance activities for Severe Acute Respiratory Syndrome (SARS)-associated coronavirus in international settings will be evaluated according to item 1. above.

(2) Where applicable, the soundness, appropriateness, adequacy and feasibility of the scientific and technical approaches and methodologies for additional proposed animal influenza surveillance activities.

(3) Surveillance Sites and Collaborative Arrangements: The appropriateness and adequacy of the proposed surveillance sites and collaborative arrangements to enable the conduct of the surveillance activities proposed, and to enable the development and maintenance of a network capable of rapid biological, molecular and serological characterization of influenza viruses. This includes the number of surveillance sites, the geographic location(s) of the surveillance sites, and the scope of animal influenza virus infection.

(4) Provision of Contract-Generated Materials and Data:

- Adequacy and appropriateness of the methods and procedures to be used to provide contract-generated materials to an NIAID repository for further distribution to the influenza research community, including characterized viruses suitable for possible use in human vaccine development, accompanying data (e.g., pathogenicity, antigenicanalysis, and passage history) and reagents, ensuring the suitability for potential use of the viruses or reassortment of the viruses in human vaccines.
- Adequacy and appropriateness of plans to provide information, including antigenic and genetic characterization of influenza viruses conducted under the contract, contract-generated reagents and other materials and tools, to a publicly accessible database.

(5) Where applicable, the soundness, appropriateness, adequacy and feasibility of studies proposing the collection and evaluation of human specimens, including the adequacy of the agreement with the Principal Investigator of the clinical study from which human specimens will be obtained.

(6) Contributions to the NIAID Pandemic Public Health Research Response Plan

Suitability and feasibility of the proposed contributions to the NIAID Pandemic Public Health Research Response Plan, and the potential for the proposed activities to provide critical expertise and resources to complement public health efforts for the control of influenza viruses in humans.

B. Qualifications of Personnel **25**

(1) Appropriateness and relevance of the documented training, experience, expertise and availability of proposed scientific and technical staff in relation to their specific duties and responsibilities. This includes:

a) Qualifications of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract either directly or indirectly through subcontracts. This includes: scientific and technical expertise in animal influenza surveillance; experience in the development and maintenance of collaborations with other organizations/institutions; and the capacity to monitor progress, assess performance, identify performance problems and implement corrective actions for Contractor staff and the staff of any proposed subcontractors.

b) Qualifications of all other scientific and technical staff, including subcontractors, with respect to conducting the range of animal influenza surveillance activities proposed, including a proven track record in infectious disease surveillance and related areas.

(2) Appropriateness of the proposed mix and balance of key personnel in relation to their specific responsibilities and time commitments.

C. Training/Career Development Program **10**

(1) Quality and appropriateness of the technical and scientific expertise, mentoring experience, and availability of the faculty and staff to conduct the proposed training/career development.

(2) Merit and feasibility of the proposed approaches to increase the human resources available for animal influenza surveillance, including recruitment of outstanding candidates, and the relevance of the proposed training/career development to the Center's activities and goals.

(3) Suitability of plans for evaluation of the training/career development program and documenting success.

D. Project Management **10**

(1) Appropriateness and clarity of the organizational structure and lines of authority for all proposed activities and personnel, including any proposed subcontractors, and strength and appropriateness of plans for managing, coordinating and overseeing the entire range of Center activities; monitoring progress; and ensuring the effective and efficient implementation and conduct of all proposed activities, including any proposed subcontractors.

(2) Adequacy and appropriateness of the plan the management and quality control of all data resulting from the Center's activities, including validation, storage, retrieval, confidentiality and transmission.

E. Facilities and Resources **10**

(1) Adequacy and availability of appropriate facilities, equipment, and other resources necessary to safely and efficiently accomplish the work proposed either directly or indirectly through subcontracts. This includes, where applicable, the adequacy of the Biocontainment Plan to ensure the necessary level of biosafety and appropriate safety procedures.

(2) Capacity to perform required work in a timely and efficient manner (resources dedicated to this project).

TOTAL POINTS FOR RESEARCH AREA 1 **100**

RESEARCH AREA 2: PATHOGENESIS AND HOST RESPONSE RESEARCH

CRITERIA

WEIGHT

A. Scientific and Technical Approach **45**

(1) The soundness, appropriateness, adequacy and feasibility of the scientific and technical approaches and methodologies for proposed research projects in pathogenesis and host response. This includes the potential for the proposed research projects to contribute to the development of improved methods of control and prevention.

(2) Where applicable, the soundness, appropriateness, adequacy and feasibility of studies proposing the collection and evaluation of human specimens, including the adequacy of the agreement with the Principal Investigator of the clinical study from which human specimens will be obtained.

(3) Contributions to the NIAID Pandemic Public Health Research Response Plan

Suitability and feasibility of the proposed contributions to the NIAID Pandemic Public Health Research Response Plan, and the potential for the proposed activities to provide critical expertise and resources to complement public health efforts for the control of influenza viruses in humans.

B. Qualifications of Personnel **25**

(1) Appropriateness and relevance of the documented training, experience, expertise and availability of proposed scientific and technical staff in relation to their specific duties and responsibilities. This includes:

a) Qualifications of the proposed Principal Investigator to lead and direct the activities to be carried out under this contract either directly or indirectly through subcontracts. This includes: scientific and technical expertise in pathogenesis and host response research, and the capacity to monitor progress, assess performance, identify performance problems and implement corrective actions for Contractor staff and the staff of any proposed subcontractors.

b) Qualifications of all other scientific and technical staff, including subcontractors, with respect to conducting the range of research projects proposed, including a proven track record in infectious disease research and related areas.

(2) Appropriateness of the proposed mix and balance of key personnel in relation to their specific responsibilities and time commitments.

C. Training/Career Development Program **10**

(1) Quality and appropriateness of the technical and scientific expertise, mentoring experience, and availability of the faculty and staff to conduct the proposed training/career development.

(2) Merit and feasibility of the proposed approaches to increase the human resources available for pathogenesis and host response research, including recruitment of outstanding candidates, and the relevance of the proposed training/career development to the Center's activities and goals.

(3) Suitability of plans for evaluation of the training/career development programs and documenting success in designing and carrying out training/career development programs.

D. Project Management **10**

(a) Appropriateness and clarity of the organizational structure and lines of authority for all proposed activities and personnel, including any proposed subcontractors, and the strength and appropriateness of plans for managing, coordinating and overseeing the entire range of Center activities; monitoring progress; and ensuring the effective and efficient implementation and conduct of all proposed activities, including any proposed subcontractors.

(b) Adequacy and appropriateness of the plan for the management and quality control of all data resulting from the Center's activities, including validation, storage, retrieval, confidentiality and transmission.

E. Facilities and Resources **10**

(1) Adequacy and availability of appropriate facilities, equipment, and other resources necessary to safely and

efficiently accomplish the work proposed either directly or indirectly through subcontracts. This includes, where applicable, the adequacy of the Biocontainment Plan to ensure the necessary level of biosafety and appropriate safety procedures.

(2) Capacity to perform required work in a timely and efficient manner (resources dedicated to this project).

TOTAL POINTS FOR RESEARCH AREA 2 **100**

ADDITIONAL COMPONENTS

The two additional components will be evaluated by the Scientific Review Group using a qualitative, adjectival approach. Each additional component will be rated as: excellent; good; fair; or poor.

1. PILOT RESEARCH PROGRAM-RESEARCH AREAS 1 AND OR 2:

CRITERIA

(a) The innovation and originality of the proposed pilot research projects.

(b) The potential for the proposed pilot research projects to lead to breakthroughs in a particular area, or to the development of novel techniques, methodologies, models or applications.

2. ANIMAL INFLUENZA SURVEILLANCE CAPACITY BUILDING-RESEARCH AREA 2 ONLY:

CRITERIA

A. Scientific and Technical Approach

(1) Strength, appropriateness, adequacy and feasibility of the proposed surveillance sites and adequacy and feasibility of plans to develop collaborations with surveillance site-specific institutions/organizations capable of participating in surveillance activities and providing access to animal populations.

(2) Appropriateness, adequacy and feasibility of plans for establishing the laboratory capability necessary for the rapid analysis, characterization and distribution of influenza viruses from animals, including available laboratory facilities.

B. Recruitment and Training of Scientific & Technical Staff

Merit and feasibility of the proposed approaches to recruit and train scientific and technical staff to conduct animal influenza surveillance activities, including plans for building the appropriate technical and scientific expertise and mentoring experience of the faculty and staff to conduct the proposed training.

C. Timelines for Capacity Building Activities

Appropriateness and feasibility of the proposed timelines for the initiation and completion of each step in the capacity building process.

6. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before the Order of Merit of Ranking is completed. 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 of commitment to use SDB concerns
(b) Realism of the proposal
(c) Extent of participation of SDB concerns in terms of the value of the total acquisition.

SOLICITATION ATTACHMENTS INCLUDED WITH THE BAA

The following pages include Attachments 1 through 2 applicable to this BAA as specified in SECTION J - List of Attachments

BROAD AGENCY ANNOUNCEMENT
"NIAID CENTERS OF EXCELLENCE FOR INFLUENZA RESEARCH AND SURVEILLANCE"
BAA NIH-NIAID-DMID-07-20

BROAD AGENCY ANNOUNCEMENT DESCRIPTION

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUCEMENT (BAA), NIH-NIAID-DMID-07-20, entitled: "NIAID Centers of Excellence for Influenza Research and Surveillance." The Broad Agency Announcement is authorized by FAR 6.102 and further described in FAR 35.016 as well as the NIH Manual Issuance 6035, Broad Agency Announcements. A BAA is a general announcement of an agency's research interest and constitutes a solicitation. The intent of a BAA is to encourage the submission of creative and innovative approaches to specific research areas identified by the Government.

A proposal submitted in response to this BAA must present a detailed technical and cost proposal designed to meet the Research and Technical Objectives described in this announcement. The proposal must be signed by an official authorized to contractually commit the submitting organization.

The Statement of Work, including the specific work requirements and performance specifications, is developed and defined by the Offeror, not the Government. The Statement of Work should not exceed ten (10) single spaced-pages in length within the technical proposal.

Proposals are not evaluated against a specific Government need, as in the case of a conventional Request for Proposal (RFP), since they are not submitted in accordance with a common Statement of Work issued by the Government. Instead, Research and Technical Objectives are provided in the BAA that describe the research areas in which the Government is interested. Proposals received as a result of the BAA are evaluated by a Scientific Review Group (SRG) in accordance with the Evaluation Criteria specified in the BAA.

There is no Source Selection Determination utilized under the BAA process. All the competing proposals are ranked on the basis of their respective relevance and scientific merit. The scores assigned by the SRG is considered the final scores. An Order of Merit Ranking is established by the Contracting Officer in lieu of a Competitive Range.

Negotiations are conducted with those Offerors selected from the Order of Merit Ranking whose proposals would comprise the best group of contractors to fill NIAID's needs for this research program based on technical merit, scientific priority, programmatic balance and the availability of funds. During negotiations, there is an opportunity to refine the proposed Statement of Work in consultation with the Project Officer, including the incorporation of the comments of the SRG, as appropriate. At the conclusion of negotiations with the Offerors selected from the Order of Merit Ranking, those Offerors are allowed the opportunity to submit a Final Proposal Revision (FPR) to address weaknesses in the proposal, based on issues identified by the SRG and to revise costs as may be appropriate.

It is anticipated that multiple awards will result from this announcement and these awards will be multi-year, cost-reimbursement, completion type contracts. The NIAID anticipates awarding up to four (4) contracts based on technical merit, scientific priority, programmatic balance and the availability of funds. Awards are expected to be made on or about November 9, 2006. The NIAID estimates that the annual total costs (direct and indirect cost combined) will range from $2.5 million to $5.0 million per contract. However, it is anticipated that the total costs of each award may vary substantially depending upon the scope of the project and the technical objectives of the award. The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. The maximum period of performance is limited to seven (7) years.

The award document will be tailored to the final negotiations with the selected Offeror(s) and modified as appropriate for the type of contractor organization, cost and/or fee arrangements, and other elements as negotiated prior to award.

BACKGROUND

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), strives to understand, treat and ultimately prevent the myriad infectious, immunologic, and allergic diseases that threaten millions of human lives. The NIAID Division of Microbiology and Infectious Diseases (DMID) supports extramural research to control and prevent diseases caused by virtually all infectious agents. This includes basic and applied research to develop and evaluate therapeutics, vaccines, and diagnostics, which are funded through a variety of research grants and contracts.

Influenza A viruses are major pathogens of both humans and animals and are responsible for an estimated 500,000 deaths worldwide each year. In the U.S. alone, it is estimated that as many as 36,000 deaths due to influenza and influenza-related complications occur annually, with 90% of those deaths occurring in the elderly and in individuals with chronic underlying health conditions. In addition to the morbidity and mortality associated with annual influenza epidemics, there is an ever present threat of the emergence of a global epidemic or pandemic if a new subtype of influenza virus emerges for which humans have no prior immunity. The influenza pandemic of 1918 – 1919 is believed to be one of the worst epidemics of an infectious disease ever recorded, with an estimated world death toll of 20-25 million. Five major influenza pandemics have occurred since 1889, the most recent in 1968 (Hong Kong flu). The current outbreak of highly pathogenic H5N1 influenza A viruses in Asia, which was first identified in early 2004, is unprecedented in terms of the number of human cases (108 confirmed human cases with 54 deaths as of June 8, 2005), the lethality (50% mortality rate), and size of the outbreak (at least 9 countries in Asia have reported one or more outbreaks in poultry over the last 15 months). Recent reports suggest that the virus may now be able to infect other mammals, including cats, and may be endemic in birds in multiple regions in Asia. While sustained human to human transmission has not yet been documented, several probable clusters of limited human to human transmission have been identified.

The annual mortality associated with epidemic influenza, the ongoing unprecedented outbreaks of the H5N1 virus in humans and in animals, and the recent identification of a number of other avian influenza virus subtypes in humans and in animals, underscore the need to support high priority research areas aimed at developing information and tools needed to decrease the mortality and morbidity associated with both interpandemic and the emergence of pandemic influenza.

INTRODUCTION

The NIAID has had a long history of supporting research activities to provide more effective approaches to controlling influenza virus infections. These activities include both basic and applied research on influenza virus basic biology and replication, pathogenesis, immunology, epidemiology, and clinical research to develop new and improved diagnostics, antiviral drugs, and vaccines. Due to the ever present threat of an influenza pandemic, the Institute is initiating this program to establish NIAID Centers of Excellence for Influenza Research and Surveillance to support the research agenda of the DHHS Pandemic Influenza Response and Preparedness Plan (http://www.hhs.gov/nvpo/pandemicplan/). Other NIAID pandemic preparedness activities include supporting the production and clinical testing of pandemic influenza vaccines, the development of screening assays for the identification of new influenza therapeutics, and a recently initiated program to fully sequence several thousand human and animal influenza viruses.

Following the 1997 outbreak of highly pathogenic avian influenza in humans in Hong Kong, NIAID awarded a contract to St. Jude Children's Research Hospital in 1999 (N01-AI-95357), entitled "Pandemic Preparedness in Asia." Through this program, virologic surveillance in aquatic birds and in live bird markets in Hong Kong has been established and other activities to elucidate the natural history of influenza viruses with pandemic potential have been carried out. In addition, scientists have conducted training courses in animal influenza surveillance, and developed reagents to detect these viruses which are available to the influenza research community. This contract also has provided characterized viruses suitable for use in human vaccine development and production.

Through this solicitation, NIAID seeks to continue and expand its animal influenza surveillance program internationally and domestically, as well as establish additional Centers of Excellence focused on several high priority areas in influenza research. The overall goal of this program is to provide the Government with information and public health tools and strategies needed to control and lessen the impact of epidemic influenza and the increasing threat of pandemic influenza. The activities undertaken by the NIAID Centers of Excellence for Influenza Research and Surveillance will lay the groundwork for the development of new and improved control measures for emerging and reemerging influenza viruses, including determining the prevalence of avian influenza viruses in animals in close contact with humans, understanding how influenza viruses evolve, adapt and transmit, and identifying immunological factors that determine disease outcome. In the event of an urgent public health emergency involving the emergence and rapid spread of an influenza pandemic in humans, the Network of Centers shall also develop and implement a NIAID Pandemic Public Health Research Response Plan.

Each NIAID Center of Excellence for Influenza Research and Surveillance shall have a focus on one or both of the following research areas:

Research Area 1: Animal Influenza Surveillance
Research Area 2: Pathogenesis and Host Response Research

Specific information on Research Area 1, Research Area 2, the required Training/Career Development Program, and two additional components is provided below.

Research Area 1: Animal Influenza Surveillance - Conduct prospective international and/or domestic animal influenza surveillance for the rapid detection and characterization of influenza viruses with pandemic potential.

Proposals for Research Area 1 must have a primary focus on influenza viruses; however, Offerors may also choose to propose limited animal surveillance activities for Severe Acute Respiratory Syndrome (SARS)-associated coronavirus in international settings.

Research Area 2: Pathogenesis and Host Response Research – Conduct research to enhance understanding of the molecular, ecological, and/or environmental factors that influence pathogenesis, transmission, and evolution of influenza viruses; and characterize the protective immune response, including immune correlates of protection and cross protection among different influenza virus subtypes, and develop methods to assess immunity.

Required Training/Career Development Component: Each Center shall develop and carry out a Training Program to increase the number of qualified scientific and technical personnel capable of conducting research directly related to the scope of the Center's activities. A minimum of two (2) career development projects must be carried out at each Center as an integral part of the Center's activities.

Additional Components:

1. **Pilot Research Program-Research Areas 1 and or 2:** In order to facilitate the development of innovative, high risk concepts, Offerors for Research Area 1 and Research Area 2 have the option to incorporate in their

proposals a Pilot Research Program. Each Center will be provided with support for up to two (2) pilot research projects per Research Area, focused on short-term, high risk investigations of novel approaches or applications. Pilot research projects shall be limited to a project period of up to two years ending at or before the expiration of the contract.

2.**Animal Influenza Surveillance Capacity Building: Research Area 2 Only:** Offerors submitting proposals for Research Area 2 have the option to incorporate in their proposal an Animal Influenza Surveillance Capacity Building component to establish the expertise, resources and collaborations necessary for the actual conduct of prospective animal influenza surveillance internationally and/or domestically. The contracts awarded under this solicitation will not support animal surveillance capacity building for SARS.

Summary of Alternative Scenarios for Proposal Submission: Proposals may be submitted as follows:

1. Research Area 1 – Animal Influenza Surveillance alone with required Training/Career Development Program
2. Research Area 2 – Pathogenesis and Host Response Research alone with required Training/Career Development Program; or
3. Research Areas 1 and 2 combined with required Training/Career Development Program; and potentially, at offerors discretion,
4. Additional Components:

   Pilot Research Program (Required for Research Areas 1 and 2)
   Animal Influenza Surveillance Capacity Building (Required for Research Area 2)

The NIAID reserves the right to award all or any portion of the projects/activities proposed based on technical merit, scientific priority, programmatic balance and the availability of funds.

Contracts awarded under this BAA will not support development of new vaccines, drugs, or diagnostic products. Product development for the NIAID biodefense priority pathogens is being accomplished through other initiatives (see the NIAID Biodefense web site http://www.niaid.nih.gov/biodefense).

The NIAID Biodefense and Emerging Infections Research Resources Program

The NIAID Biodefense and Emerging Infections Research Resource Program was established in FY 2003 through a contract awarded to the American Type Culture Collection in Manassas, Virginia (Contract N01-AI-30067).

This contract: (1) makes unique, quality-assured reagents and resources available to the research community to investigate pathogenesis of the NIAID Category A, B and C Priority Pathogens and emerging pathogens; (2) aids in the development and evaluation of vaccine, therapeutics and diagnostics; and (3) initiates research and development to add value to the reagents and assays. In addition, the contract provides oversight of access to and use of the materials.

Additional information on the NIAID Biodefense and Emerging Infections Research Resource Program can be found at http://www.beiresources.org/.

RESEARCH AND TECHNICAL OBJECTIVES

This section presents the technical objectives that the Government seeks to achieve through this BAA. Proposals should explain how the Offeror will contribute to these objectives. In contracts awarded as a result of this BAA, the Statement of Work will be proposed by the Offeror and negotiated and accepted by the Government.

When preparing proposals in response to this BAA, Offerors must review the "Technical Proposal Instructions for Broad Agency Announcements" included in Section L, the "Additional Technical Proposal Instructions" contained in Appendix A, and the "Evaluation Factors for Award" included in Section M of this BAA for additional information.

The purpose of this solicitation is to establish multiple Centers of Excellence for Influenza Research and Surveillance (hereinafter referred to as "Centers") to conduct prospective animal influenza surveillance, internationally and domestically, and/or research on pathogenesis and host response. Proposals may be submitted in one or both of the following Research Areas:

RESEARCH AREA 1 – ANIMAL INFLUENZA SURVEILLANCE

The Contractor shall carry out an international and/or domestic animal surveillance program focused on virologic, epidemiologic, and disease surveillance with emphasis on the rapid characterization of influenza viruses with pandemic potential. This includes the development and/or maintenance of a network capable of rapid biological, molecular and serological characterization of influenza viruses identified in animals, including but not limited to aquatic and land-based birds, wild birds, live animal markets, and other settings that provide enhanced opportunities for the reassortment of influenza A virus subtypes and close contact with humans. Additional areas of interest include, but are not limited to, serosurveillance studies of humans in close contact with animals, pathogenicity studies in animals, the role of migratory birds in the spread of influenza viruses, and the effectiveness of animal control measures.

Examples of activities that are responsive to Research Area 1 include, but are not limited to, the following:

- Establishment and maintenance of a laboratory capability for the rapid analysis, characterization, and distribution of influenza viruses isolated from animals;
- Provision of characterized viruses (wild type and reassortants) suitable for possible use in human vaccine development;
- Determination of the natural history of influenza A viruses in wild birds in Asia;
- Determination of the role of wild migrating birds and/or current agricultural practices in the spread of avian influenza viruses to domestic poultry and humans;
- Evaluation of the effectiveness of strategies for controlling the spread of animal influenza viruses, including studies in animal models;
- Determination of susceptibility of avian influenza viruses to currently available antiviral agents; and
- Production, characterization, and provision of reagent materials to support research activities.

Research projects involving the use of human specimens will be initiated based on prior written approval of the NIAID Project Officer.

Proposals for Research Area 1 must have a primary focus on influenza viruses; however, Offerors have the option of proposing limited animal surveillance activities for Severe Acute Respiratory Syndrome (SARS)-associated coronavirus in international settings.

Proposals for Research Area 1 may be submitted for:

- international animal influenza surveillance alone;
- domestic animal influenza surveillance alone; or
- international and domestic animal influenza surveillance combined.

Proposals for international SARS surveillance alone will not be accepted.

International Surveillance Sites and Minimum Sample Requirements: Offers containing or comprising international animal influenza surveillance activities must include at least one key sentinel site located in Asia with sufficient infrastructure to serve other surveillance areas within the geographic region. In addition, contracts for international animal influenza surveillance alone must collect and analyze a minimum of ten thousand (10,000) samples per year.

Domestic Surveillance Sites and Minimum Sample Requirements: Contracts containing or comprising domestic animal influenza surveillance activities must include a minimum of two states within the U.S. In addition, contracts for domestic animal influenza surveillance alone must collect and analyze a minimum of ten thousand (10,000) samples per year.

Surveillance Sites and Minimum Sample Requirements for International and Domestic Animal Influenza Surveillance Combined: Contracts for international and domestic animal influenza surveillance combined must: (1) include at least one key sentinel site located in Asia with sufficient infrastructure to serve other surveillance areas within the geographic region; (2) include a minimum of two states within the U.S.; and (3) collect and analyze a minimum of fifteen thousand (15,000) samples per year.

Contracts awarded under this BAA will not support development of new vaccines, drugs, or diagnostic products. Product development for the NIAID BioDefense priority pathogens is being accomplished through other initiatives (see the NIAID Biodefense web site http://www.niaid.nih.gov/biodefense).

RESEARCH AREA 2: PATHOGENESIS AND HOST RESPONSE RESEARCH

The Contractor shall carry out a research program focused on both of the following:

Part A. Determination of the molecular, ecologic and/or environmental factors that influence the evolution, emergence, transmission and pathogenicity of influenza viruses, including studies on animal influenza viruses with pandemic potential; and

Part B: Characterization of the immune response to influenza infection and/or vaccination to improve understanding of the immune correlates of protection and cross-protection.

A minimum of three (3) and a maximum of five (5) research projects must be proposed for Research Area 2, at least one for Part A and at least one for Part B.

Examples of research topics that are responsive to Part A include, but are not limited to, the following:

- Evaluation of the role of mutations on drug-resistant strains and interpandemic strains or strains with pandemic potential;
- Determination of the molecular mechanisms responsible for the transmission of influenza viruses between animals, between humans, and from animals to humans;
- Identification of the molecular factors influencing viral adaptation, including antigenic drift;
- Conduct of pathogenicity studies in animals including infected bird populations to assess virulence; and
- Elucidation of the molecular mechanisms by which influenza viruses acquire increased pathogenicity for humans and animals.

Examples of research topics that are responsive to Part B include, but are not limited to, the following:

- Improved definition or validation of correlates of protection that will facilitate testing and licensure of candidate vaccines;
- Determination of the mechanisms of T cell priming and memory T cell immunity against influenza;
- Determination of the role of immunosenescence in flu vaccine failures in the elderly;
- Investigations on the role of immune mechanisms in the prevention of mortality by H5N1 animal influenza viruses;
- Investigatations of the potential cross protection provided by human anti-HA or anti-NA antibodies against avian influenza strains;
- Identification of mechanisms by which influenza viruses evade adaptive immunity;
- Determination of the importance of cellular immunity following influenza disease or the potential importance of cellular immunity in response to vaccination;
- Development of improved serological tools for assessing the immune response to pandemic influenza vaccines (e.g., neutralization assays, HAI, ELISA, NI, etc.); and
- Development of new methods to probe the human immune response to primary and secondary influenza infection (e.g., characteristics of influenza specific memory T cells and B cells, trafficking of immune cells to lung, mucosa, cross protective immunity by T cells against flu proteins, etc.).

Research projects involving the use of human specimens will be initiated based on prior written approval of the NIAID

Project Officer.

Under Research Area 2, support will NOT be provided for research in the following areas:

- Clinical trials, although clinical research that uses human samples and/or clinical data obtained from independent clinical trials or studies is responsive (see the NIH definition of a clinical trial vs. clinical research at http://grants.nih.gov/grants/funding/phs398/instructions2/phs398instructions.htm#p2_human_subjects_definitions.htm).
- Research on influenza viruses containing one or more genes from the 1918 pandemic influenza virus.
- Development of new vaccines, drugs, or diagnostic products for influenza.

REQUIRED TRAINING/CAREER DEVELOPMENT COMPONENT: Each Center shall develop and carry out a Training/Career Development Program to increase the number of qualified scientific and technical personnel capable of conducting animal influenza surveillance and/or pathogenesis and host response research. A minimum of two (2) career development projects will be carried out by each Center as an integral part of the Center's activities. Career development projects for individuals may focus on advanced post-doctoral candidates, junior faculty, or established investigators who wish to develop or refocus their careers on animal influenza surveillance and/or pathogenesis and host response research. Each candidate must have a mentor and each candidate must devote at least 50% of his/her effort to the project.

The Training/Career Development Program should support the salary and costs of candidates with outstanding potential, as well as other reasonable costs for career development and training activities.

Additional career development and training activities may be directed to groups of individuals; for example, there may be training programs for graduate students, technicians and others to learn specific skills.

ADDITIONAL COMPONENTS:

RESEARCH AREAS 1 AND 2: ADDITIONAL COMPONENT – PILOT RESEARCH PROGRAM

Each Center will be provided with support for up to two (2) pilot research projects for each Research Area to conduct investigations of innovative, high risk concepts. Each pilot research project shall be limited to no more than $200,000 in total costs for a project period of up to two years.

RESEARCH AREA 2: ADDITIONAL COMPONENT – ANIMAL INFLUENZA SURVEILLANCE CAPACITY BUILDING

Offerors submitting proposals for Research Area 2 may choose to incorporate an Animal Influenza Surveillance Capacity Building component in order to develop the expertise, resources and collaborations necessary for the actual conduct of prospective animal influenza surveillance internationally and/or domestically. Support to develop an animal influenza surveillance capacity may include, but is not limited to, the following:

(1) The recruitment and training of technical and scientific personnel with respect to animal surveillance/detection techniques and strategies, analysis and characterization of influenza viruses isolated from animals, natural history studies, reagent production and characterization, etc.
(2) The development of collaborations with other domestic and foreign institutions/sites.
(3) The establishment of laboratory capability for the rapid analysis, characterization and distribution of influenza viruses isolated from animals, including up to a total of $300,000 in year 1 of the contract for the purchase of equipment at one or more sites.

Support under this additional component will not be provided for alterations and renovations. In addition, support will not be provided for SARS surveillance capacity building.

SUMMARY OF SCENARIOS FOR PROPOSAL SUBMISSION: Proposals may be submitted as follows:

1. Research Area 1 – Animal Influenza Surveillance alone with required Training/Career Development Program; or
2. Research Area 2 – Pathogenesis and Host Response Research alone with required Training/Career Development Program; or
3. Research Areas 1 and 2 combined with required Training/Career Development Program; and potentially, at offerors discretion,
4. Additional Components:

- Pilot Research Program (Required for Research Areas 1 and 2);
- Animal Influenza Surveillance Capacity Building (Required if Pilot Research Program(s) is submitted for Research Area 2)

ADDITIONAL TECHNICAL REQUIREMENTS FOR CENTERS

Contracts awarded as part of this BAA must also meet the following technical requirements:

1. Research Area 1 - Animal Influenza Surveillance: Contracts comprising or containing animal influenza surveillance activities must provide characterized viruses suitable for possible use in human vaccine development, as well as accompanying characterization data that includes pathogenicity, antigenic analysis, and passage history ensuring suitability for the potential use of the virus or a reassortant of the virus in human vaccines. Reagents that may be prepared include but are not limited to wild type viral isolates and reassortants, reference monospecific sheep and/or goat antisera for selected hemagglutinin (HA) and neuraminidase (NA) subtypes for influenza, purified proteins for the production of reference sera and for use in serologic assays, monoclonal antibodies and antibody panels, and plasmids. Initiation of reagent preparation will be at the direction of the NIAID Project Officer. In addition, at the discretion of the NIAID Project Officer, contractors conducting activities in Research Area 1 shall be required to ship viruses and accompanying reagents and documents to an NIAID repository for further distribution to the research community for information on the NIAID Biodefense and Emerging Infections Research Resources Program), and must provide surveillance information, including antigenic and genetic characterization of influenza viruses conducted under the contract, to a publicly accessible database.

The same requirements specified above shall pertain to contracts that incorporate limited SARS surveillance activities in addition to influenza surveillance activities.

2. Biocontainment Plan: When appropriate and necessary, Centers shall develop and implement a Biocontainment Plan to address the biocontainment level for working with avian influenza and genetically modified and/or reassortant viruses. A copy of the current interim CDC/NIH DRAFT guidelines in the *Biosafety in Microbiology and Biomedical Laboratories, 5th edition* is available at: .http://www.cdc.gov/flu/h2n2bsl3.htm. These interim biocontainment guidelines, and the final guidelines (when available), shall apply to all studies supported under this BAA. In addition, Contractors shall be expected to obtain and provide copies of all required permits for working with avian influenza viruses, as appropriate. Information can be found at http://www.aphis.usda.gov/vs/ncie/.

3. Select Agents: Contractors conducting research on highly pathogenic avian influenza strains must be in compliance with CDC Select Agent requirements which can be found at http://www.cdc.gov/od/sap.

4. Institutional Biosafety Committee Review and Approval: Contractors will be expected to provide documentation of materials submitted for Institutional Biosafety Committee Review and approval of experiments at the request of the NIAID Project Officer.

5. Statistical Design and Analysis: All Centers shall be responsible for the statistical design and analysis of data resulting from the projects undertaken, including the provision of appropriate statistical expertise.

6. Data Management and Quality Control: All Centers shall be responsible for the development and implementation of data management and quality control systems/procedures, including the transmission, storage, confidentiality, and retrieval of all study data.

7. Network of Centers of Excellence for Influenza Research and Surveillance:
The contracts awarded under this solicitation will comprise the Network of Centers of Excellence for Influenza Research and Surveillance (hereinafter referred to as the Network). A **Network Executive Committee** will be established to serve as an advisory body to the NIAID for the activities carried out by the Centers. The members of the Network Executive Committee will include the Principal Investigator for each Center, the NIAID Project Officer, and other NIAID scientific staff. Additional Federal and non-Federal experts, selected by the NIAID Project Officer, may participate in selected Executive Committee activities in an advisory capacity, when appropriate. A Network Executive Committee Chair shall be selected from among the non-Federal members of the Committee shortly after award. The Network Executive Committee shall meet annually and shall conduct conference calls on a biannual basis.

The Network Executive Committee shall be responsible for the following activities:

(a) **Collaborative Activities:** The Network Executive Committee shall be responsible for defining areas of collaboration among the Centers. This shall include determining how the expertise, facilities and other resources of the Centers engaged in pathogenesis and host response research can contribute to critical public health information needs through the analysis of samples, the sharing of reagents and assays, and other collaborative activities.

(b) **The NIAID Pandemic Public Health Research Response Plan:** The Network Executive Committee shall be responsible for the development of the NIAID Pandemic Public Health Research Response Plan and for the implementation of that Plan in the event of an urgent public health emergency involving the emergence and rapid spread of an influenza pandemic in humans. At the direction of the NIAID Project Officer and/or the NIAID Contracting Officer, each Center must be capable of contributing to the NIAID Pandemic Public Health Research Response Plan to rapidly redirect funds and other resources to perform activities to complement public health efforts and responsibilities, as appropriate.

(c) **Annual Network Meetings:** The Network Executive Committee shall be responsible for planning and conducting an annual two-day meeting to be held in the Bethesda, Maryland area. Annual meeting participants shall include: the Principal Investigators and key scientific staff of the Centers, the NIAID contract and program staff, as well as representatives from other U.S. Federal agencies, including the Centers of Disease Control and Prevention, the U.S. Food and Drug Administration, the U.S. Department of Agriculture, and the NIAID scientific advisors as appropriate. These annual meetings shall provide for presentations on progress, study results and future plans of the Centers. In addition, these meetings shall serve as a means of identifying opportunities for collaboration among Centers.

8. Annual Site Visits: Each Center shall plan and host an annual site visit for the NIAID contract and program staff. The Center's Principal Investigator and key technical and scientific staff shall present an update on progress and a summary of results generated on each Center project, including a discussion of problems/obstacles encountered and proposed approaches taken or planned to overcome problems/obstacles. Annual site visits shall also address the application of policies and procedures for monitoring the direction of specific projects.

9. Publications: Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted for NIAID Project Officer review no less than sixty (60) calendar days before submission for public presentation or publication. Contract support shall be acknowledged in all such publications. A "publication' is defined as an issue of printed material offered for distribution or any communication or oral presentation of information. The NIAID Project Officer will review all manuscripts/abstracts in a period of time not to exceed sixty (60) calendar days from receipt, and will either agree to the publication/disclosure or recommend changes.

Additionally, after the contract is awarded, the following shall be required:

1. Intellectual Property Rights

To be successful, these contracts are likely to involve collaborations with multiple organizations, including academic and/or non-profit research institutions. It is the intent of this BAA to support the formation of the appropriate partnerships that are essential to meet these critical public health needs. The NIAID recognizes that intellectual property rights are likely to play an important role in achieving the goals of this program. To this end, all Contractors understand and acknowledge the following:

- The Contractor is solely responsible for the timely acquisition of all appropriate proprietary rights, including intellectual property rights, and all materials needed to perform the project.
- Before, during, and subsequent to the award, the U.S. Government is not required to obtain for the Contractor any proprietary rights, including intellectual property rights, or any materials needed by Contractor to perform the project.
- The Contractor is required to report to the U.S. Government all inventions made in the performance of the project, as specified at 35 U.S.C. Sect. 202 (Bayh-Dole Act).

In addition, Contractors are expected to exercise their Bayh-Dole rights in a manner that does not conflict with the goals of the contract or the intent of the Bayh-Dole Act to promote the utilization, commercialization and availability of U.S. Government-funded inventions for public benefit.

2. Transition Plan

The Contractor shall:

1. Provide for an orderly transition at the end of the contract.

a. Submit a written transition plan to be reviewed and approved by the NIAID PO six months prior to the completion date of the contract to ensure an orderly transition of this project to a subsequent contractor or to the Government.

b. Transfer electronic files as requested by the NIAID PO on/before the completion date of the contract.

c. Maintain full operational capacity until the completion date of the contract.

APPENDIX A
"The NIAID CENTERS OF EXCELLENCE FOR INFLUENZA RESEARCH AND SURVEILLANCE"
BAA-NIH-NIAID-DMID-07-20

APPENDIX A-ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS
FORMAT FOR TECHNICAL PROPOSAL-TABLE OF CONTENTS

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

The following additional technical proposal instructions reflect the requirements of the BAA and are meant to provide additional instructions as well as a uniform format for technical proposals. The information requested in these instructions should be used as a guide for formatting and preparing the proposal. Offerors should follow the instructions in Section L of the solicitation, include the information requested in this appendix, as well as **any other** information which will benefit the proposal and assist in the evaluation of the offer.

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Background, Introduction, Research and Technical Objectives, all reference material, appendices and attachments, the technical evaluation criteria, and, the BAA as a whole, in the development of your proposal.

Offerors who propose subcontracts to perform portions of the statement of work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration between the prime and subcontractor(s), and the expected advantages of such an approach.

THE MAXIMUM NUMBER OF PAGES INCLUDING THE APPENDIX AND ADDITIONAL COMPONENTS EXCLUDING REFERENCES ARE 170 PAGES FOR RESEARCH AREA 1 AND 210 PAGES FOR RESEARCH AREA 2. THE TOTAL PAGE LIMIT FOR THE TECHNICAL PROPOSAL PACKAGE IS 360 PAGES FOR THE TECHNICAL PROPOSAL AND ADDITIONAL COMPONENTS FOR RESEARCH AREAS 1 AND 2.

COSTING SCENARIOS

I. Scenario 1-Animal Influenza Surveillance Domestic and International-Elect a. or b., or if electing a and b, elect c.
   a. Research Area 1-Animal Influenza Surveillance International (10,000 samples)
   b. Research Area 1-Animal Influenza Surveillance Domestic (10,000 samples)
   c. Research Area 1-Animal Influenza Surveillance Domestic and International (15,000 samples)

II. Scenario 2-Pathogenesis and Host Response Research-Elect a. or b.
   a. Research Area 2-Pathogenesis and Host Response Research-Present a minimum of three research projects, at least one for Part A and one for Part B.
   b. Research Area 2-Pathogenesis and Host Response Research-Present a maximum of five research projects, at least one for Part A and one for Part B.

III. Scenario 3-Required Training (Pilot Research Program)
   Applicable for both Research Areas 1 or 2: Required Training (Pilot Research Program)

IV. Additional Component 4-Pilot Research Program (per project)
   Applicable for both Research Areas 1 and 2: Support of up to two pilot research projects for each Research Area to conduct investigations of innovative, high risk concepts. Each pilot research project shall be limited to no more than $200,000 in total costs for a project period of up to two years.

V. Additional Component 5-Capacity Building
   Applicable only for Research Area 2: If the offeror submits a proposal for Research Area 2, the offeror may choose to increase their capacity.

NOTE 1: Offerors submitting proposals for Research Areas 1 alone and 2 alone and Research Areas 1 and 2 combined have the option of proposing a Pilot Research Program specific to the Research Area proposed (i.e. if

the offeror submits a proposal for Research Area 1 alone, the offeror can submit a Pilot Research Program for Research Area 1, but that offeror cannot submit a Pilot Research Program for Research Area 2).

NOTE 2: If an offeror submits a proposal for one Research Area that is considered for award, the offeror would be awarded a contract representing that Research Area. If an offeror submits a proposal that includes two Research Areas and each Research Area is considered for award, the offeror would be awarded a single contract representing both Research Areas.

NOTE 3: Each proposed Research Area will be evaluated separately. As a result, a proposal representing one Research Area plus a Pilot Research Program component (if applicable) must be submitted as a separate and distinct proposal. If an offeror submits a proposal for Research Area 1 and Research Area 2, one distinct proposal for each Research Area must be submitted.

TECHNICAL PROPOSAL-TABLE OF CONTENTS

A. RESEARCH AREA 1: ANIMAL INFLUENZA SURVEILLANCE

SECTION 1: PROPOSED STATEMENT OF WORK (not to exceed10 pages)

Provide a full Statement of Work describing each step that the contractor shall perform **after award of the contract**, including: the tasks that shall be performed to carry out the research projects/activities; how these tasks will be accomplished; and the time frame within which each task will be accomplished. Describe the work related to each task and describe the tasks in the sequence in which they will be carried out. The Statement of Work must also include a description of all items to be delivered to the Government during performance of the contract.

SECTION 2: CENTER PROGRAM OVERVIEW (suggested page length – 4 pages total)

Provide a brief description of the proposed Center Program, including:

a) A 1-2 sentence summary stating: the scope of activities proposed and, if applicable, the additional component for the Pilot Research Program; the titles of each proposed surveillance activity/project; and an organizational chart including personnel for the Offeror and any proposed subcontractors.

b) The specific surveillance activities and sites to be undertaken by the Offeror and any proposed subcontractors, including the contribution of each to the Center Program;

c) A synopsis of the proposed Training/Career Development Program;

d) A list of key personnel of the Offeror and any proposed subcontractors with degrees, titles, institutional affiliation, and role within the Center;

e) A brief description of the facilities and other resources to be made available by the Offeror and any proposed subcontractors; and

f) If applicable, a synopsis of the proposed Pilot Research Program.

Offerors for Research Area 1 are eligible to incorporate the additional component, the Pilot Research Program, in their Technical Proposal. Offerors for Research Area 1 are <u>not</u> eligible to incorporate the additional component, Animal Influenza Surveillance Capacity Building.

SECTION 3: CENTER PLAN FOR SURVEILLANCE (suggested page length – 40-50 pages total)

Provide a detailed plan for the design and conduct of prospective international and/or domestic animal influenza surveillance for the rapid detection and characterization of influenza viruses with pandemic potential. The plan must include:

a) Surveillance Sites – List all proposed surveillance sites and discuss the history of these sites with respect to influenza A virus infection and surveillance in animals and humans; describe the nature and scope of proposed collaborations with site-specific participating institutions/organizations to ensure access to appropriate animal populations, including live markets and other settings that will provide opportunities for the reassortment of influenza virus subtypes and close contact

with humans; and describe the site-specific resources to be made available for the proposed surveillance activities. The Technical Proposal must demonstrate the Offeror's ability to develop and maintain a network capable of rapid biological, molecular and serological characterization of influenza viruses.

Proposals for international animal influenza surveillance alone must: (1) have at least one sentinel site located in Asia with sufficient infrastructure to serve other surveillance areas within the geographic region; and (2) collect and analyze a minimum of ten thousand (10,000) samples per year.. Proposals for domestic animal influenza surveillance alone must: (1) include a minimum of two states within the U.S.; and (2) collect and analyze a minimum of ten thousand (10,000) samples per year. Proposals for international and domestic surveillance combined must: (1) have at least one sentinel site located in Asia with sufficient infrastructure to serve other surveillance areas within the geographic region; (2) include a minimum of two states in the U.S.; and (3) collect and analyze a minimum of fifteen thousand (15,000) samples per year.

b) Surveillance Activities - Provide a detailed plan for the design and conduct of all proposed animal influenza surveillance activities, including:

(i) virologic, epidemiologic and disease surveillance; and
(ii) biological and serological analysis and characterization of isolated influenza A viruses.

If additional surveillance activities and studies are proposed, such as: (i) studies to determine the natural history of influenza A viruses; (ii) serosurveillance studies of humans in close contact with animals; (iii) pathogenicity studies in animals; (iv) studies of the role of migratory birds in the spread of influenza viruses; and (v) studies to assess the effectives of control measures, this section of the Technical Proposal must also include a detailed description of their design and conduct.

Include the methods, techniques and technologies to be employed in conducting all proposed surveillance activities, statistical analysis plans, a discussion of potential problems/obstacles in carrying out surveillance activities, and proposed alternative approaches/methods to overcome potential problems/obstacles. Identify all activities to be undertaken by the Offeror and any proposed subcontractors.

c) Surveillance Studies Using Human Samples – Offerors for Research Area 1 have the option to propose surveillance studies using human samples. Proposed studies involving the collection and evaluation of human samples must include a written agreement between the Offeror and the Principal Investigator of the study through which clinical specimens will be obtained outlining the nature of the human specimens, the manner of collection and access, and ownership, analysis and release of data resulting from the proposed studies.

Contractors shall be required to adhere to the NIAID clinical terms of award for all funded studies involving the collection and evaluation of human clinical specimens (see http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf).

d) Plan for the Provision of Center Resources – Include a plan that delineates the methods and procedures to be used to provide: (i) Center-generated materials to an NIAID repository for further distribution to the influenza research community, including characterized viruses suitable for possible use in human vaccine development, reagents, and supporting data; and (ii) surveillance information, including antigenic and genetic characterization of influenza viruses conducted under the contract, contract-generated reagents and other materials and tools, to a publicly accessible database.

SECTION 4: DATA MANAGEMENT AND QUALITY ASSURANCE (suggested page length – 5 pages)

Provide a plan for the management of all data resulting from the Center's activities, including validation, storage, retrieval, confidentiality and transmission.

SECTION 5: CONTRIBUTIONS TO THE NIAID PANDEMIC PUBLIC HEALTH RESEARCH RESPONSE PLAN
(suggested page length – 3 pages total)

Provide a brief description of potential activities/research that could be undertaken in the event of an urgent public health emergency involving the emergence and rapid spread of an influenza pandemic in humans, including the provision of scientific and technical expertise to the Government.

SECTION 6: TRAINING/CAREER DEVELOPMENT PROGRAM (suggested page length – 5-10 pages total)

Provide a plan for the design, development and implementation of the Center's Training/Career Development Program. The plan must: (i) include a minimum of two career development projects as an integral part of the Center's activities; (ii) identify the types of individuals to receive training (e.g., advanced post-doctoral candidates, junior faculty, established

investigators, graduate students, etc.); (iii) describe the policies, processes and criteria for recruiting and selecting candidates and monitoring their progress; and (iv) describe plans for following the impact of the training on the careers of the participating trainees.

SECTION 7: CENTER PROGRAM ORGANIZATION AND MANAGEMENT PLAN (suggested page length – 5 pages total)

a) Provide a plan for the organization and staffing of the Center, including delineation of clear lines of authority and responsibility for all proposed activities.

b) Provide a plan for managing, coordinating and overseeing the entire range of Center activities; monitoring progress; and ensuring the effective and efficient implementation and conduct of all proposed activities.

SECTION 8: PERSONNEL (limit CVs to 2-3 pages)

Document the training, expertise, related experience, leadership skills and availability of key personnel with scientific, technical and managerial competence in animal influenza surveillance. Describe ongoing and completed projects of a similar nature. Documentation of personnel qualifications must be provided for the Offeror and any proposed subcontractors. Documentation supporting the expertise and related experience may include a list of up to five (5) publications relevant to the proposed Center program for the Principal Investigator and lead investigators for any proposed subcontracts.

SECTION 9: CENTER FACILITIES AND RESOURCES (suggested page length – 10 pages total)

a) Facilities and Resources: Provide a description of the facilities and other scientific/technical resources to be made available for the proposed activities of the Center by the Offeror and any proposed subcontractors, and how they will be utilized to support the conduct of the proposed activities.

b) Biocontainment Plan: If applicable, the Technical Proposal must provide a Biocontainment Plan that addresses the appropriate level of biosafety for working with avian influenza viruses and genetically modified or reassortant viruses, and documents the availability of suitable biocontainment facilities, equipment and safety procedures for the conduct of the proposed work. A copy of the current interim CDC/NIH DRAFT guidelines in the *Biosafety in Microbiology and Biomedical Laboratories, 5th edition* is available at: .http://www.cdc.gov/flu/h2n2bsl3.htm.

B. RESEARCH AREA 2 – PATHOGENESIS AND HOST RESPONSE RESEARCH

SECTION 1: PROPOSED STATEMENT OF WORK (not to exceed10 pages)

Provide a full Statement of Work describing each step that the contractor shall perform **after award of the contract**, including: the tasks that shall be performed to carry out the research projects/activities; how these tasks will be accomplished; and the time frame within which each task will be accomplished. Describe the work related to each task and describe the tasks in the sequence in which they will be carried out. The Statement of Work must also include a description of all items to be delivered to the Government during performance of the contract.

SECTION 2: CENTER PROGRAM OVERVIEW (suggested page length – 4 pages total)

Provide a brief description of the proposed Center Program, including:

a) A 1-2 sentence summary stating: the scope of proposed research activities included in the proposal and, if applicable, any additional components proposed; the titles of each proposed research project; and an organizational chart including personnel for the Offeror and any proposed subcontractors;

b) The research projects to be undertaken by the Offeror and any proposed subcontractors, including the contribution of each to the Center Program;

c) A synopsis of the proposed Training/Career Development Program;

d) A list of key personnel of the Offeror and any proposed subcontractors with degrees, titles, institutional affiliation, and role within the Center;

e) The facilities and other resources to be made available by the Offeror and any proposed subcontractors;

f) If applicable, a synopsis of the proposed Pilot Research Program; and

g) If applicable, a synopsis of proposed surveillance capacity building activities, including surveillance sites, collaborations to be developed, recruitment and training of scientific and technical staff, available laboratory facilities, and equipment needed.

Offerors for Research Area 2 may incorporate the additional components for both the Pilot Research Program and Animal Influenza Surveillance Capacity Building.

SECTION 3: RESEARCH PLAN (suggested page length – 15 pages for <u>each</u> proposed research project)

All proposals for Research Area 2 must include a minimum of three (3) and a maximum of five (5) proposed research projects. At least one research project must address Part A of Research Area 2 - determination of the molecular, ecologic and/or environmental factors that influence the evolution, emergence, transmission and pathogenicity of influenza viruses. At least one project must address Part B of Research Area 2 - characterization of the immune response to influenza infection and/or vaccination to improve understanding of the immune correlates of protection and cross-protection.

Provide a detailed plan for the design and conduct of each proposed research project, including: the scientific and technical methods, approaches and technologies to be utilized; statistical analysis plans; the anticipated contributions of each proposed research project to achieving the goals of the Center Program; and anticipated problems/obstacles to achieving the aims of the research projects and proposed approaches to overcome them.

Studies Using Human Samples – Offerors for Research Area 2 have the option to propose studies using human samples. Proposed studies involving the collection and evaluation of human samples must include:

(i) a synopsis of the clinical study through which human samples will be obtained;
(ii) a copy of the consent form for the clinical study through which human samples will be obtained;
(iii) a written agreement between the Offeror and the Principal Investigator of the clinical study through which clinical specimens will be obtained outlining:
- the nature of the human specimens and the manner of collection and access;
- the timing and manner of access to data produced by the clinical study, including procedures to maintain confidentiality; and
- ownership, analysis and release of data resulting from the proposed studies;

(iv) where appropriate, documentation of data and safety monitoring procedures for the clinical study.

Contractors shall be required to adhere to the NIAID clinical terms of award for all funded studies involving the collection and evaluation of human clinical specimens (see http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf).

SECTION 4: DATA MANAGEMENT AND QUALITY ASSURANCE (suggested page length – 5 pages)

Provide a plan for the management of all data resulting from the Center's activities, including validation, storage, retrieval, confidentiality and transmission.

SECTION 5: CONTRIBUTIONS TO THE NIAID PANDEMIC PUBLIC HEALTH RESEARCH RESPONSE PLAN (suggested page length – 3 pages total)

Provide a brief description of potential activities/research that could be undertaken in the event of an urgent public health emergency involving the emergence and rapid spread of an influenza pandemic in humans, including the provision of scientific and technical expertise to the Government.

SECTION 6: TRAINING/CAREER DEVELOPMENT PROGRAM (suggested page length – 5-10 pages total)

Provide a plan for the design, development and implementation of the Center's Training/Career Development Program. The plan must: (i) include a minimum of two career development projects as an integral part of the Center's activities; (ii) identify the types of individuals to receive training (e.g., advanced post-doctoral candidates, junior faculty, established investigators, graduate students, etc.); (iii) describe the policies, processes and criteria for recruiting and selecting candidates and monitoring their progress; and (iv) describe plans for following the impact of the training on the careers of the participating trainees.

SECTION 7: CENTER PROGRAM ORGANIZATION AND MANAGEMENT PLAN (suggested page length – 5 pages total)

a) Provide a plan for the organization and staffing of the Center, including delineation of clear lines of authority and responsibility for all proposed activities.

b) Provide a plan for managing, coordinating and overseeing the entire range of Center activities; monitoring progress; and ensuring the effective and efficient implementation and conduct of all proposed activities.

SECTION 8: PERSONNEL (limit CVs to 2-3 pages)

Document the training, expertise, related experience, leadership skills and availability of key personnel with scientific, technical and managerial competence pathogenesis and host response research. Describe ongoing and completed projects of a similar nature. Documentation of personnel qualifications must be provided for the Offeror and any proposed subcontractors. Documentation supporting the expertise and related experience may include a list of up to five (5) publications relevant to the proposed Center program for the Principal Investigator and lead investigators for any proposed subcontracts.

SECTION 9: CENTER FACILITIES AND RESOURCES (suggested page length – 10 pages total)

a) Facilities and Resources: Provide a description of the facilities and other scientific/technical resources to be made available for the proposed activities of the Center by the Offeror and any proposed subcontractors, and how they will be utilized to support the conduct of the proposed activities.

b) Biocontainment Plan: If applicable, the Technical Proposal must provide a Biocontainment Plan that addresses the appropriate level of biosafety for working with avian influenza viruses and genetically modified or reassortant viruses, and documents the availability of suitable biocontainment facilities, equipment and safety procedures for the conduct of the proposed work. A copy of the current interim CDC/NIH DRAFT guidelines in the *Biosafety in Microbiology and Biomedical Laboratories, 5th edition* is available at: .http://www.cdc.gov/flu/h2n2bsl3.htm

TECHNICAL PROPOSAL INSTRUCTIONS FOR ADDITIONAL COMPONENTS

SECTION 10: RESEARCH AREAS 1 AND 2 – ADDITIONAL COMPONENT: PILOT RESEARCH PROGRAM
(suggested page length – 10 pages total)

Offerors submitting proposals for Research Areas 1 alone and 2 alone and Research Areas 1 and 2 combined have the option of proposing a Pilot Research Program. Technical Proposals incorporating this additional component must describe up to two (2) pilot research projects for innovative, high risk concepts relating to influenza surveillance and/or pathogenesis and host response research. Offerors must include the specific aims of the project(s), their significance, the approach, and the contribution of the project(s) to achieving the overall goals of the Center.

SECTION 11: RESEARCH AREA 2 – ADDITIONAL COMPONENT: ANIMAL INFLUENZA SURVEILLANCE CAPACITY BUILDING (suggested page length – 10 pages total)

Offerors submitting proposals for Research Area 2 have the option of proposing an animal surveillance capacity building component in order to develop the expertise, resources and collaborations necessary for the actual conduct of prospective animal influenza surveillance in international and/or domestic settings. Technical Proposals incorporating an animal influenza capacity building component must provide a detailed plan describing the following:

a) A description of the surveillance sites and activities, and plans for the development of appropriate collaborations;
b) The number and type of scientific and technical staff required;
c) Plans for the recruitment of scientific and technical staff;
d) Plans for the training of scientific and technical staff;
e) Plans for establishing laboratory capability for the rapid analysis, characterization and distribution of influenza viruses from animals; and
f) Milestones and a timeline for the establishment and implementation of the program.

APPENDIX B:
THE NIAID CENTERS OF EXCELLENCE FOR INFLUENZA RESEARCH AND SURVEILLANCE
BAA-NIH-NIAID-DMID-07-20

APPENDIX B – ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSMPTIONS

In addition to the format requirements for the business proposal that are contained in Section L of the solicitation, the information provided in this Appendix is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Background, Introduction, Research and Technical Objectives, all reference material provided as appendices and attachments, the technical evaluation criteria, and the BAA 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.

All questions regarding this Broad Agency Announcement shall be submitted to the Contracts Management Program no later than 90 days after the BAA is issued.

1. **Budget Presentation**

   Composite Budget: Provide a one-page composite budget itemizing the costs for all proposed activities.

   Individual Budgets: Provide individual budget breakdowns for each component being proposed, including:

   (a) Research Area 1 – Animal Influenza Surveillance
   (b) Research Area 2 – Pathogenesis and Host Response Research
   (c) Training/Career Development Program
   (d) Research Areas 1 and 2: Additional Component- Pilot Research Program
   (e) Research Area 2: Additional Component- Animal Influenza Capacity Building

   The estimated costs associated with subcontractors and collaborative arrangements with surveillance site-specific institutions/organizations must be shown separately within each individual budget breakdown as well as within the composite budget.

2. **Contract Period**
   All proposals submitted shall have a performance period no greater than seven years.

3. **Purchase of Equipment:** Support for the purchase of equipment will be provided only for proposals for Research Area 2 which incorporate the additional component for Animal Influenza Surveillance Capacity Building. Support for the purchase of equipment for Animal Influenza Capacity Building will be provided in year 1 only and may not exceed $300,000.

4. **Alterations and Renovations:** Support will not be provided for alternations and renovations for any proposals submitted under this solicitation.

5. **Research Area 1:** Assume the following for each year of the contract: (1) the production of three (3) to five (5) monoclonal antibodies, five (5) monospecific polyclonal sheep antisera, and three (3) recombinant proteins in sufficient quantities to provide to an NIAID-supported repository for distribution to the research community.

   In addition, include in the Business Proposal support for the packaging and shipping of 2,000 samples within the U.S. and up to 500 samples abroad. The receiving and storage of up to 2,000 samples per year should also be included in the Business Proposal.

6. **Annual Network Meetings:**

(a) Assume that a total of five (5) Center staff, including subcontractor staff, will attend two-day annual Network meetings to be held in the Bethesda, Maryland area.

(b) Assume travel support for four (4) technical advisors to attend annual Network meetings, two from the U.S. and two from outside of the U.S.

7. **Annual Site Visits:** Assume travel support for four (4) advisors to attend annual site visits, two (2) from the U.S. and two (2) from outside of the U.S.

8. **Scientific Meetings:** Assume travel costs for up to 6 individuals to attend one (1) scientific meeting per year to present data generated under this contract.

9. **Note Regarding Indemnification:** The NIAID cautions that all risks related to any indemnification included in all sub-agreements under a contract resulting from this solicitation is the responsibility of the prime contractor and in no way constitutes any form of indemnification on behalf of the Federal Government. You are advised that NIAID does not have the authority to grant indemnification to a prime contractor or a subcontractor/consultant at any level under the prime agreement. For the purposes of a contract arising from this solicitation, indemnification by the Federal Government can only be authorized by the Secretary of Department of Health and Human Services.

10. **Proposal Estimates:** For proposal preparation purposes, possible Year-1 estimate scenarios follow:

Research Area 1 with International and Domestic Surveillance (15,000 samples)	$3,630,000
Research Area 2 with a maximum of 5 Research Projects	$2,160,000
Training Component	$ 392,800
Additional Research Component (Each Pilot Research Program shall not exceed 2-years)	$ 200,000
Capacity Building for Research Area 2	$ 776,000