SOLICITATION

SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended			
2. **Request for Proposal (RFP) Number:** DMIDNIAIDNIHAI20080022BARDA	3. **Issue Date:** February 15, 2008	4. **Just in Time:** [X]No [ ]Yes See Part IV Section L	5. **Set Aside:** [X]No [ ]Yes See Part IV Section L
6. Title : Application of Platform Technologies for the Development of Therapeutic for Biodefense			
7. ISSUED BY: Office of Acquisitions National Institute of Allergy and Infectious Diseases National Institutes of Health 6700 B Rockledge Drive Room, 3214 Bethesda, Maryland 20892-7612		8. SUBMIT OFFERS TO: See Part III, Section J, "Packaging and Delivery of the Proposal," ATTACHMENT 1 of this Solicitation.	
9. Proposals for furnishing the supplies and/or services in THE SCHEDULE will be received at the place specified in, and in the number of copies specified in Attachment 1, "Packaging and Delivery of the Proposal," until 3:00 PM local time on June 4, 2008. Offers will be valid for 120 days unless a different period is specified by the offeror on the Attachment entitled, "Proposal Summary and Data Record, NIH 2043.			
10. THIS SOLICITATION REQUIRES DELIVERY OF PROPOSALS TO TWO DIFFERENT LOCATIONS. THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY IS THE ADDRESS PROVIDED FOR THE OFFICE OF ACQUISITIONS AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR HIS DESIGNEE AT THE PLACE AND TIME SPECIFIED FOR THE OFFICE OF ACQUISITIONS, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR CLAUSE 352.215-70, ENTITLED, "LATE PROPOSALS, AND REVISIONS" LOCATED IN SECTION L.1. OF THIS SOLICITATION.			
11. Offeror must be registered in the Central Contractor Registry (CCR) prior to award of a contract. http://www.ccr.gov			
12. FOR INFORMATION CALL: Suzanne Dawkins PHONE: (301) 451-3698 e-MAIL: sd33r@nih.gov COLLECT CALLS WILL NOT BE ACCEPTED.			
		Robert Singman Contracting Officer e-Mail: rsingman@niaid.nih.gov Phone: (301) 451-2607	

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PART I - THE SCHEDULE

THE INFORMATION SET FORTH IN **SECTION A - SOLICITATION/CONTRACT FORM**, HEREIN CONTAINS IMPORTANT INFORMATION FOR ANY OFFEROR INTERESTED IN RESPONDING TO THIS SOLICITATION. ANY CONTRACT RESULTING FROM THIS SOLICITATION WILL INCLUDE IN ITS **SECTION A - SOLICITATION/ CONTRACT FORM**, ACCOUNTING, APPROPRIATION AND GENERAL INFORMATION APPLICABLE TO THE CONTRACT AWARD.

THE CONTRACT SCHEDULE SET FORTH IN **SECTIONS B THROUGH H**, HEREIN, CONTAINS CONTRACTUAL INFORMATION PERTINENT TO THIS SOLICITATION. IT IS NOT AN EXACT REPRESENTATION OF THE CONTRACT DOCUMENT THAT WILL BE AWARDED AS A RESULT OF THIS SOLICITATION. THE CONTRACT COST OR PRICE AND OTHER CONTRACTUAL PROVISIONS PERTINENT TO THE OFFEROR (i.e., those relating to the organizational structure [e.g., Non-Profit, Commercial] and specific cost authorizations unique to the Offeror's proposal and requiring Contracting Officer Prior Approval) WILL BE DISCUSSED IN THE NEGOTIATION PROCESS AND WILL BE INCLUDED IN THE RESULTANT CONTRACT. THE ENCLOSED CONTRACT SCHEDULE IS INTENDED TO PROVIDE THE OFFEROR WITH THE NECESSARY INFORMATION TO UNDERSTAND THE TERMS AND CONDITIONS OF THE RESULTANT CONTRACT.

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose is to fund organizations with expertise in product development, including regulatory submissions, to advance the development and evaluation of innovative broad spectrum technologies and/or platforms to progress candidate therapeutics against select biothreat pathogens and toxins toward licensure.

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

A. NIAID Review of Press Releases Under Contracts

The contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. In accordance with NIH Manual Chapter 1754, misrepresenting contract results or releasing information that is injurious to the integrity of NIH may be construed as improper conduct. The complete text of NIH Manual Chapter 1754 can be found at: http://www1.od.nih.gov/oma/manualchapters/management/1754/. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the project officer has received an advance copy of any press release related to this contract not less than four (4) working days prior to the issuance of the press release.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. BROAD AGENCY ANNOUNCEMENT (BAA)

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 February 15, 2008 attached hereto and made a part of this Solicitation (See Section J - List of Attachments-Attachment 1).

ARTICLE C.2. REPORTING REQUIREMENTS

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

a. Technical Reports

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

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to technical inspection and requests for clarification by the Project Officer. These reports shall be brief and factual and prepared in accordance with the format described below:

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

- Contract number and project title
- Period of performance being reported
- Contractor's name and address
- Author(s)
- Date of submission
- Delivery address

(1) Monthly Progress Report

This report shall include a description of the activities during the reporting period and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

(2) Annual Progress Report

This report includes a summation of the results of the entire contract work for the period covered. An Annual Progress Report will not be required for the period when the Final Report is due. A Monthly Report shall not be submitted when an annual Report is due.

(3) 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

the 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 the DELIVERIES Article in SECTION F of this 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 3 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.

(4) Draft and Final Report

This report is to include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An Annual Progress Report will not be required for the period when the Final Report is due.

The Contractor shall provide the Contracting Officer with 2 copies of the Final Report in draft form in accordance with the DELIVERIES Article in SECTION F of this contract sixty (60) calendar days prior to the completion date of this contract. The Project Officer will review the draft Final Report and provide the Contracting Officer with comments within thirty (30) calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary, and the final version delivered as specified in the above paragraph.

(5) Summary of Salient Results

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

b. Other Reports and Deliverables

In addition to the above reports, the following are considered other reports and deliverables under this contract and are identified in the Statement of Work. A listing is included in the DELIVERIES Article in SECTION F.

Human Subjects IRB Annual Report (Form OMB No. 0990-0263-formerly Optional Form 310)

Invention Report Requirement

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

OTHER TECHNICAL REPORTS

1) Decision Gate Report

A Decision Gate Report shall be submitted when the Contractor has completed a stage of product development and has reached a Go/No Go decision point, as defined in the approved Strategic Staged Product Development Plan. These reports shall be in sufficient detail to explain comprehensively the results achieved. The description shall also include pertinent data and/or conclusions resulting from the analysis and scientific evaluation of data accumulated to date under the project.

Decision Gate Reports shall include the following specific information:
a) Cover page that lists the contract number and title, the period of performance being reported, the Contractor's name and address, telephone number, fax number, email address, and the date of submission.

b) An introduction covering the purpose and scope of the contract effort, and the specific Decision Gate that has been reached.
c) Document and summarize the results of work undertaken that supports the completion of the stage of product development, including an analysis of the data as it relates to the qualitative and quantitative criteria established for Go/No Go decision-making.
d) Actual costs incurred in relation to costs estimated in the original approved budget.
e) A description of the next stage of product development to be initiated and a request for Project Officer approval to proceed to the next stage of product development.

2) Decision Gate and Work Plan Change Request

The Contractor shall submit a written request for a change in the approved Strategic Staged Product Development Plan and WorkPlan. This request shall include the following:
a. A discussion of the justification/rationale for the request based on current data and a description of those data.
b. Options for addressing the needed change/deviation from the approved timelines and/or decision gates, including a cost-benefit analysis of each option.
c. A recommendation for the preferred option that includes a full analysis and discussion of the effects of the change on the entire product development program, timelines, and budget.

3) Audit Reports

Within thirty (30) calendar days of completion of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP or GCP guidelines, the Contractor shall provide copies of the audit report and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

4) Clinical Trial Protocols

The NIAID has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in NIAID-funded clinical trials. Therefore, as described in the NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf), the Contractor shall develop a protocol for each clinical trial and submit all protocols and protocol amendments for approval by the Project Officer. Protocols must be submitted using the approved DMID template and include a sample Informed Consent and Clinical Trials Monitoring Plan. The DMID templates and other important information regarding performing human subjects research are available at http://www.niaid.nih.gov/dmid/clinresearch/.

5) Final Clinical Study Report

For each clinical study performed with contract support, a Final Clinical Study Report shall be provided within thirty (30) calendar days of the completion of the analysis of all data generated in the clinical trial. Final Clinical Study Reports shall follow the ICH guidelines on Structure and Content of Clinical Study Reports E3 (http://www.pharmacontract.ch/support/su_ich_liste.htm).

6) Draft and Final Animal Efficacy Report

For each animal efficacy study performed with contract support, a Draft Animal Efficacy Study Report and a Final Animal Efficacy Study Report shall be submitted within thirty (30) and sixty (60) calendar days (unless otherwise approved by the Project Officer), respectively, of the completion of the analysis of all data generated in the animal study. The Animal Efficacy Study Reports shall include a complete description of the experimental design, protocol, methods, reagents, data analysis, and conclusions of studies performed to demonstrate efficacy of therapeutic product for the indication (i.e., post-exposure prophylaxis or treatment) being sought. For GLP studies the Draft and Final Animal Efficacy Study Report shall have been audited for quality assurance by the Contractor or subcontractor.

7) Strategic Staged Product Development Plan and Work Plan

The Contractor shall be required to update the Strategic Staged Product Development Plan and the Work Plan to incorporate progress since the effective date of the contract. Within fourteen (14) calendar days of the effective date of the contract and prior to initiation of product development activities, unless otherwise negotiated with the Project Officer and the Contracting Officer, the Contractor shall submit an updated Strategic Staged Product Development Plan and Work Plan for approval. This updated Strategic Staged Product Development Plan shall include:

a) Clearly defined goals, product development stages and product development activities.
b) Go/No Go decision gates.
c) Quantitative and qualitative criteria and associated data elements for assessing the scientific merit and feasibility of moving to the next stage of product development.
d) A detailed timeline for each stage covering the initiation, conduct and completion of product development activities and a budget linked to each stage.

The Work Plan shall include a description of the studies to be performed within each stage of the project.

The Contractor shall also be required to submit a revised Strategic Staged Product Development Plan and associated Work Plan when a change to the approved plans is requested. At any time during the contract period the Project Officer may request additional detail from the Contractor regarding the Strategic Staged Product Development Plan and the Work Plan.

8) External Advisory Board Approval Request

The Contractor shall submit the following to the Project Officer and the Contracting Officer to request approval of External Advisory Group membership within six (6) months of the effective date of the contract:
a) A brief biosketch for each member being proposed.
b) A description of the roles and duties of each member.
c) The proposed compensation for each member.

9) Contract Meeting Reports

A report of the Post-Award Contract Initiation Meeting, Annual Review Meetings and External Advisory Group meetings shall be prepared by the Contractor and submitted within twenty-one (21) calendar days following the date of the meetings. These reports shall include the slide presentations and all other meeting materials as well as summaries of all discussions.

Minutes of regular, as well as, ad hoc teleconferences and meetings shall be provided by the Contractor within seven (7) calendar days following the date of the teleconference or meeting.

10) Copies of FDA Correspondence and Meeting Summaries

Within thirty (30) calendar days of receiving correspondence from or meeting with the FDA, submit copies of the correspondence or meeting minutes/summaries to the Project Officer.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

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

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

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

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

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
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 ***52.246-9, 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 the Article in SECTION C, Article C.1. of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

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

Type of Report	Addresses/Distribution	Due Date
PROGRESS		
Monthly Progress Report	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	The 15 th of each month. First report is due following the first full month of contract performance, including any portion of the prior month since award. The Monthly Progress Report shall not be required on months when an Annual Progress Report is due.
Annual Technical Progress Report	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	15 th of the month following the end of each 12 months of the performance period. The Annual Progress Report shall not be required when the Final Progress Report is due.
DRAFT Final Progress Report	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	60 calendar days prior to completion date of the contract
Final Progress Report	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	15 calendar days before completion of the contract period
Summary of Salient Results (to be submitted with Final Report)	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	15 calendar days before completion of the contract period
TECHNICAL		
Decision Gate Report	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	Following completion of a pre-defined stage of product development and prior to initiation of a new stage.
Decision Gate Change and Work Plan Change Request	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	As soon as the Contractor has sufficient data to support the need for a change from the approved Strategic Staged Product Development Plan.
Audit Reports	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	Within 30 calendar days of the audit.
Clinical Trials Protocols	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	To be negotiated with the NIAID Project Officer and prior to IND submission or enrollment of human subjects.
Final Clinical Study Report	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	30 calendar days after completion of analysis of clinical trial data.

Draft Animal Efficacy Study Reports	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	30 calendar days after completion of all analysis of animal efficacy study data, unless otherwise approved by the PO.
Final Animal Efficacy Study Reports	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	60 calendar days after completion of all analysis of animal efficacy study data, unless otherwise approved by the CO.
OTHER REPORTS		
Strategic Staged Product Development Plan and Work Plan	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	Within 14 calendar days after contract award and prior to initiation of product development activities, when a Decision Gate/Workplan Change Request is submitted or as requested by the PO.
External Advisory Group Approval Request	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	Within 6 months after contract award.
Annual Review Meeting Report	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	Within 21 calendar days following the date of the Annual Review Meeting.
External Advisory Group Meeting	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	Within 21 calendar days following the date of the Annual Review Meeting.
FDA Correspondence and Meeting Summaries	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	Within 30 calendar days of receiving correspondence or meeting with the FDA.
Teleconference and Meeting Minutes	1 Original hardcopy to CO 2 Hardcopies to PO 1 electronic copy to CO and PO	Within 7 calendar days of the teleconference or meeting.
Human Subjects IRB Annual Report	1 Hardcopy to CO 3 Hardcopies to PO	Annually; submitted 30 days after the anniversary date.
Invention Report Requirement	1 Hardcopy to CO 3 Hardcopies to PO 1 Hardcopy to OPERA	As required.

D. Other Deliverables

1) Samples of Therapeutics: The Contractor shall submit samples of non-GMP candidate therapeutics and GMP material manufactured with contract funding. The type of material and the amount will be specified in the contract. The Contractor will be advised by the Project Officer how samples are to be packaged and where samples are to be shipped. It is acceptable to label material "Not for Clinical Use".

2) Animal Model: Technology Transfer packages that include complete protocols and critical reagents for animal models developed and/or improved with contract funding must be submitted at the request of the Project Officer.

3) Copies of other reports generated during the contract period related to performance of the contract, including: Process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis at the request of the Project Officer.

4) Institutional Biosafety Approval: The Contractor shall provide documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments at the request of the Project Officer.

5) Data: Provide raw data or specific analysis of data generated with contract funding at the request of the Project Officer and in sufficient detail as specified by the Project Officer.

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. PROJECT OFFICER

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

To be specified at award.

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

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

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL, HHSAR 352.270-5 (January 2006)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

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

Name	Title
To be specified at award	

ARTICLE G.3. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

a. Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts NIH(RC)-1 are attached and made part of this contract. The Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

1. Payment requests shall be submitted as follows:

   a. One original to the following designated billing office:

      National Institutes of Health
      Office of Financial Management
      Commercial Accounts
      2115 East Jefferson Street, Room 4B-432, MSC 8500
      Bethesda, MD 20892-8500

b. One copy to the following approving official:

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

E-Mail:

The Contractor shall submit an electronic copy of the payment request to the approving official in lieu of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in a format compatible with the computer systems at NIH [e.g., MS Word, MS Excel, or Adobe Portable Document Format (PDF). ***[Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]***

2. In addition to the requirements specified in FAR Subpart 32.9 for a proper invoice, the Contractor shall include the following information on all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is the National Institute of Allergy and Infectious Diseases Office of Acquisitions.

   b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAID OA Invoices.

   c. Vendor Identification Number. This is the 7 digit number that appears after the Contractor's name in Block 7 of Standard Form 26.

   d. DUNS number or DUNS+4 that identifies the Contractor's name and address exactly as stated on the face page of the contract.

   e. Identification of whether payment is to be made using a two-way or three-way match. This contract requires a Two-Way match.

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 Contractor shall follow the attached instructions and submission procedures specified below to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment.

   1. Payment requests shall be submitted as follows:

      a. One original to the following designated billing office:

      National Institutes of Health
      Office of Financial Management
      Commercial Accounts
      2115 East Jefferson Street, Room 4B-432, MSC 8500
      Bethesda, MD 20892-8500

      b. The Contractor shall submit an electronic copy of the payment request to E-Mail: NIAIDOAInvoices@niaid.nih.gov for the approving official in lieu of a paper copy. The payment request shall be transmitted as an attachment via e-mail to the address listed above in a format

compatible with the computer systems at NIH [e.g., MS Word, MS Excel, or Adobe Portable Document Format (PDF). [Note: The original payment request must still be submitted in hard copy and mailed to the designated billing office to meet the requirements of a "proper invoice."]

2. In addition to the requirements specified in FAR Subpart 32.9 for a proper invoice, the Contractor shall include the following information on all payment requests:

   a. Name of the Office of Acquisitions. The Office of Acquisitions for this contract is National Institute of Allergy and Infectious Diseases .

   b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAID OA Invoices .

   c. Vendor Identification Number. This is the 7 digit number that appears after the Contractor's name in Block 7 of Standard Form 26.

   d. DUNS number or DUNS+4 that identifies the Contractor's name and address exactly as stated on the face page of the contract.

   e. Identification of whether payment is to be made using a two-way or three-way match. This contract requires a Two-Way match.

a. Inquiries regarding payment of invoices shall be directed to the designated billing office, (301) - 496-6088.

ARTICLE G.4. INDIRECT COST RATES

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

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

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

ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be prepared as neccessary, but every two years at a minimum.

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 NIAID, 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).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, 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 research.

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. DATA AND SAFETY MONITORING IN CLINICAL TRIALS

The contractor is directed to the full text of the NIH Policy regarding Data and Safety Monitoring and Reporting of Adverse Events, which may be found at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

The contractor must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this contract.

Data and Safety Monitoring shall be performed in accordance with the approved Data and Safety Monitoring Plan.

The Data and Safety Monitoring Board shall be established and approved prior to beginning the conduct of the clinical trial.

ARTICLE H.4. 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.5. 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.6. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to Public Law(s) cited in paragraph b., below, NIH is prohibited from using appropriated funds to support human embryo research. Contract funds may not be used for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

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

b.

Public Law and Section No.	Fiscal Year	Period Covered
[applicable information to be included at award]		

ARTICLE H.7. 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.8. 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.9. 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.10. PRIVACY ACT, HHSAR 352.270-11 (January 2006)

This contract requires the Contractor to perform one or more of the following: (a) Design; (b) develop; or (c) operate a Federal agency system of records to accomplish an agency function in accordance with the Privacy Act of 1974 (Act) (5 U.S.C. 552a(m)(1)) and applicable agency regulations. The term "system of records" means a group of any records under the control of any agency from which information is retrieved by the name of the individual or by some identifying number, symbol, or other identifying particular assigned to the individual.

Violations of the Act by the Contractor and/or its employees may result in the imposition of criminal penalties (5 U.S.C. 552a(i)). The Contractor shall ensure that each of its employees knows the prescribed rules of conduct and that each employee is aware that he/she is subject to criminal penalties for violation of the Act to the same extent as HHS employees. These provisions also apply to all subcontracts awarded under this contract which require the design, development or operation of the designated system(s) of records (5 U.S.C. 552a(m)(1)).

The contract work statement: (a) Identifies the system(s) of records and the design, development, or operation work to be performed by the Contractor; and (b) specifies the disposition to be made of such records upon completion of contract performance.

45 CFR Part 5b contains additional information which includes the rules of conduct and other Privacy Act requirements and can be found at: http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html.

The Privacy Act System of Records applicable to this project is Number 0925-0216. This document is incorporated into this contract as an Attachment in SECTION J of this contract. This document is also available at: http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm.

ARTICLE H.11. 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.12. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

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

http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/

ARTICLE H.13. 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.14. SUBCONTRACTING PROVISIONS

a. **Small Business Subcontracting Plan**

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

b. **Subcontracting Reports**

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

1. Individual Subcontract Reports (ISR)

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

   April 30th
   October 30th

2. Summary Subcontract Report (SSR)

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

October 30th

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

ARTICLE H.15. 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 annual salary rate limitation also applies to individuals proposed under subcontracts. It does not apply to fees paid to consultants. If this is a multiple year contract, it may be subject to unilateral modifications by the Government if an individual's salary rate used to establish contract funding exceeds any salary rate limitation subsequently established in future HHS appropriation acts.

b.

Public Law and Section No.	Fiscal Year	Dollar Amount of Salary Limitation
110-161	2008	$191,300

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

ARTICLE H.16. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.270-19(b) (January 2006)

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d) as amended by Public Law 105-220 under Title IV (Rehabilitation Act Amendments of 1998), all Electronic and Information Technology (EIT) developed, procured, maintained, and/or used under this contract shall be in compliance with the "Electronic and Information Technology Accessibility Standards" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. The complete text of Section 508 Final Standards can be accessed at http://www.access-board.gov/sec508/standards.htm.

The standards applicable to this requirement are [identified in the Statement of Work/listed below]:

Vendors may document conformance using [attached documentation/industry-standard Voluntary Product Accessibility Template at http://www.itic.org/archives/articles/20040506/faq_voluntary_product_accessibility_template_vpat.php]. Vendors should provide detailed information necessary for determining compliance, including defined contractor-incidental exceptions.

ARTICLE H.17. ENERGY STAR REQUIREMENTS

Executive Order 13123, "Greening the Government Through Efficient Energy Management" and FAR 23.203 require that when Federal Agencies acquire energy using products, they select, where life-cycle cost-effective, and available, ENERGY STAR® or other energy efficient products.

Unless the Contracting Officer determines otherwise, all energy-using products acquired under this contract must be either an ENERGY STAR® or other energy efficient product designated by the Department of Energy's Federal Energy Management Program (FEMP).

For more information about ENERGY STAR® see http://www.energystar.gov/
For more information about FEMP see http://www.eere.energy.gov/

ARTICLE H.18. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.270-6, Publications and Publicity** incorporated by reference in SECTION I of this contract, the contractor shall acknowledge the support of the National Institutes of Health whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the National Institutes of Allergy and Infectious Diseases National Institutes of Health, Department of Health and Human Services, in conjunction with the Biomedical Advanced Research and Development Authority, Department of Health and Human Services, under Contract No. (to be determined)."

ARTICLE H.19. SHARING RESEARCH DATA

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

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

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

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

ARTICLE H.20. 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.21. 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.22. 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.23. 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.24. CONSTITUTION DAY

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

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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

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

General Clauses for a Cost-Reimbursement Research and Development Contract

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

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

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

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

d. *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.]***

e. *FAR Clause **52.216-11, Cost Contract--No Fee** (April 1984) is deleted in its entirety and FAR Clause **52.216-8 Fixed Fee** (March1997) is substituted therefor.*

   *FAR Clause **52.232-17, Interest** (June 1996) is added.*

   *FAR Clause **52.249-5, Termination For Convenience Of the Government (Educational And Other Non-Profit Institutions)** (April 1984) is deleted in its entirety and FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (May 1986) is substituted therefor.*

   *HHSAR Clause **352.249-14, Excusable Delays** (January 2006) is deleted in its entirety and FAR Clause **52.249-14, Excusable Delays** (April 1984) is substituted therefor.*

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

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

   "(c) Waiver of evaluation preference.....
   ***[ ]** Offeror elects to waive the evaluation preference."*

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

4. *FAR Clause **52.224-1, Privacy Act Notification** (April 1984).*

5. *FAR Clause **52.224-2, Privacy Act** (April 1984).*

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

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

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

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

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

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

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

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

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

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

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

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

1. *HHSAR Clause **352.223-70, Safety and Health** (January 2006).*

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

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

4. *HHSAR Clause **352.270-9(b), Care of Live Vertebrate Animals** (January 2006).*

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

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

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

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

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

This contract incorporates the following clauses in full text.

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

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

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

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

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

Notice to Employees

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

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

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

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

To locate the nearest NLRB office, see NLRB's website at http://www.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 2021, 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.

(End of Clause)

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 1: Packaging and Delivery of Proposal http://www.niaid.nih.gov/contract/eproposal.htm#pack

Attachment 2: Proposal Intent Response www.niaid.nih.gov/contractform1.htm

Attachment 3: Background and Introduction

Attachment 4: Statement of Objectives

Attachment 5: Reporting Requirements and Deliverables

Attachment 6: Additional Technical Proposal Instructions

TECHNICAL PROPOSAL ATTACHMENTS

Attachment 7: Technical Proposal Cost Summary http://www.niaid.gov/contract/forms.htm

Attachment 8: Summary of Related Activities http://www.niaid.gov/contract/forms.htm

Attachment 9: Government Notice of Handling of Proposals http://www.niaid.gov/contract/form7.pdf

Attachment 10: Project Objectives, NIH 1688-1 http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

BUSINESS PROPOSAL ATTACHMENTS

Attachment 11: Small Business Subcontracting Plan
http://rcb.cancer.gov/rcbinternetforms/SBAPlanNov2005

Attachment 12: Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet http://oamp.od.nih.gov/Division/contractsBUSCOST.HTM http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls

Attachment 13: Offerors Point of Contacts http://www.niaid.nih.gov/contract/forms.htm

Attachment 14: Additional Business Proposal Instructions

INFORMATIONAL ATTACHMENTS

Attachment 15: Invoice/ Financing Request amd Contract Financial Reporting Instructions-Cost Reimbursement, NIH (RC)-4 http://www.niaid.nih.gov/contract/forms/NIH-RC-4.rtf

Attachment 16:Privacy Act System of Records http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm

Attachment 17: Safety and Health, HHSAR Clause 352.223-70 http://www.niaid.nih.gov/contract/forms/form10.rtf

Attachment 18: Procurement of Certain Equipment, NIH (RC)-7 http://www.niaid.nih.gov/contract/forms/NIH/RC-7.pdf

Attachment 19: Disclosure of Lobbying Activities, OMB Form SF-LLL http://www.niaid.nih.gov/contract/forms/sf-lll.rtf

Attachment 20: Inclusion Enrollment Report http://www.niaid.nih.gov/contract/forms/inclusion_enrollment_report.doc

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST :

1. Go to the Online Representations and Certifications Application (ORCA) at: https://orca.bpn.gov/ and complete the Representations and Certifications; and
2. Complete, and include as part of your BUSINESS PROPOSAL, SECTION K which can be accessed electronically from the INTERNET at the following address: http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

If you are unable to access this document electronically, you may request a copy from the Contracting Officer identified on the cover page of this solicitation.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. **GENERAL INFORMATION**

a. **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 541711.
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 System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

b. **TYPE OF CONTRACT AND NUMBER OF AWARDS**
It is anticipated that multiple award(s) will be made from this solicitation and that the award(s) will be made on/ about May 15, 2009.

It is anticipated that the award(s) from this solicitation will be a multiple-year Cost-Reimbursement type Completion contract with a 5 Year Period of Performance, and that incremental funding will be used (See Section L.2.c. Business Proposal Instructions).

c. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this BAA. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 5-8 FTEs per year. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

d. **COMMITMENT OF PUBLIC FUNDS**

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

e. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**
Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this 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 is 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** (SEPTEMBER 2006) - FAR 52.233-2

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

Contracting Officer
Office of Acquisitions, Division of Extramural Activities
National Institute of Allergy and Infectious Diseases
Room 3214
6700 B Rockledge Drive MSC 7612
BETHESDA MD 20892- 7612

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

j. ***LATE PROPOSALS AND REVISIONS****, HHSAR 352.215-70 (January 2006)*

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

(End of provision)

2. **INSTRUCTIONS TO OFFERORS**

a. **GENERAL INSTRUCTIONS**

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

1. **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement 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 addressees, 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 SECTION J, Attachment entitled, TECHNICAL PROPOSAL COST SUMMARY.) However, the technical proposal should not include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

5. **Alternate Proposals**
   You may, at your discretion, submit alternate proposals, or proposals which deviate from the requirements; provided, that you also submit a proposal for performance of the work as specified in the statement of work. Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this 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. **Potential Award Without Discussions**

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

8. **Use of the Metric System of Measurement**

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

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

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

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

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

9. **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.

10. **Institutional Responsibility Regarding Conflicting Interests of Investigators**

- **EACH INSTITUTION MUST:**

a. Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

b. Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

c. Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

e. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

f. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

g. Certify, in each application/proposal for funding to which the regulations applies, that:

1. there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

2. prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

3. the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

4. the Institution will otherwise comply with the regulations.

- **Institutional Management of Conflicting Interests**

a. The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research.**
Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

i. public disclosure of significant financial interests;

ii. monitoring of research by independent reviewers;

iii. modification of the research plan;

iv. disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;

v. divestiture of significant financial interests; or

vi. severance of relationships that create actual or potential conflicts of interests.

b. An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

11. **ROTC Access and Federal Military Recruiting on Campus**

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

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

12. **Past Performance Information**

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

A list of the last 5 contracts completed during the past three years and the last (3) contracts currently being performed that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior

contracts and subcontracts may also submit past performance information regarding key personnel who have relevant experience.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. Standard Industrial Code

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

b. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

13. **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.

14. ***Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998)***

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a. *Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).*

b. *Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).*

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

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

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

A detailed work plan must be submitted indicating how each aspect of the statement of work is to be accomplished. Your technical approach should be in as much detail as you consider necessary to fully explain your proposed technical approach or method. The technical proposal should reflect a clear understanding of the nature of the work being undertaken. The technical proposal must include information on how the project is to be organized, staffed, and managed. Information should be provided which will demonstrate your understanding and management of important events or tasks.

1. **Technical Discussions**

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

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

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

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

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

b. **Statement of Work**

1. Objectives

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

2. Approach

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

3. Methods

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

4. Schedule

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

c. **Personnel**

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

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

1. Single Principal Investigator/Project Director

   List the name of the Principal Investigator/Project Director responsible for overall implementation of the contract and key contact for technical aspects of the project. Even though there may be co-investigators, identify the Principal Investigator/Project Director who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project, his/her proposed duties, and the areas or phases for which he/she will be responsible.

2. Other Investigators

   List all other investigators/professional personnel who will be participating in the project. Discuss the qualifications, experience, and accomplishments. State the estimated time each will spend on the project, proposed duties on the project, and the areas or phases for which each will be responsible.

3. Additional Personnel

   List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment, or on a subcontract or consultant basis. The technical areas, character, and extent of subcontract or consultant activity will be indicated and the anticipated sources will be specified and qualified. For all proposed personnel who are not currently members of the offeror's staff, a letter of commitment or other evidence of availability is required. A resume does not meet this requirement. Commitment letters for use of consultants and other personnel to be hired must include:

- The specific items or expertise they will provide.
- Their availability to the project and the amount of time anticipated.
- Willingness to act as a consultant.
- How rights to publications and patents will be handled.

4. Resumes

   Resumes of all key personnel are required. Each must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant publications.

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

3. **Additional Technical Proposal Information**

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

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

4. **Other Considerations**

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

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

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

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

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

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

<u>IMPORTANT NOTE TO OFFERORS</u>: The following 8 paragraphs (5 through 12) shall be addressed, as applicable, in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

5. ***Human Subjects***
   The following notice is applicable when contract performance is expected to involve risk to human subjects: ***Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects, HHSAR 352.270-8(a) (January 2006)***

(a) Copies of the Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Bethesda, Maryland 20892. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the HHS.

(b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information. The regulations extend to the use of human organs, tissue, and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR Part 46.

(c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1 6) are exempt from coverage.

(d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The OPDIV will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consultation with OHRP, (telephone: 301-496-7014), is recommended.

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. The contracting officer will direct the offeror/contractor to the OHRP IRB Registration and Assurance Filing website, found at http://www.hhs.gov/ohrp/ or to the physical address if the offeror/contractor cannot access the Internet. HHS regulations for the protection of human subjects (45 CFR Part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information can be accessed at the OHRP Web site:
http://www.hhs.gov/ohrp/.

(f) It is recommended that OHRP be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects."

(End of provision)

6. **Instructions to Offerors Regarding Protection of Human Subjects**
   Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

   a. Risks to the subjects

      - Human Subjects Involvement and Characteristics:

        - Describe the proposed involvement of human subjects in response to the solicitation.

- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

- Sources of Materials:
  - Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.
- Potential Risks:
  - Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
  - Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

b. Adequacy of Protection Against Risks

- Recruitment and Informed Consent:
  - Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.
- Protection Against Risk:
  - Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
  - Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
  - In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

c. Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

d. Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

Note: If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

Collaborating Site(s)
When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

7. **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in 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. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the 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.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. You may download the information at this site at no cost and modify it, if desired. The University of Rochester has made its training program available for individual investigators. Completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at
http://www.centerwatch.com/order/pubs_profs_protect.html.
In addition, the NIAID sponsors an online training course at:
http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp
If an institution already has developed educational programs on the protection of research participants, completion of these programs also will satisfy the educational requirement.

In addition, prior to the 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 contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

8. **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), **and applies to research subjects of all ages.**
All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

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

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research," at:

(http://www.nih.gov/news/crp/97report/execsum.htm).

Information Required for ALL Clinical Research Proposals

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

NOTE 1: *For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at*: http://www.whitehouse.gov/OMB/fedreg/ombdir15.html .

NOTE 2: *If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in FAR 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.*

Standards for Collecting Data. When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple responses, you shall make available, at a minimum, the total number of respondents reporting "more than one race." Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials *** require that: a) all proposals and/or protocols 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).
*The definition of an " **NIH-Defined Phase III clinical trial**" can also be found at this website.)

by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal 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,

  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.

Use the form entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities. (See Section J-List of Documents, Exhibits and Other Attachments of the RFP)
Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

Use the form entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.

9. **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are clear and compelling reasons not to include them. (See examples of Justifications for Exclusion of Children below). For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

All offerors proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors also may obtain copies from the contact person listed in the BAA.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. The "Human Subjects" section of your technical proposal should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

Justifications for Exclusion of Children
It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.
    - There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
    - The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
    - A separate, age-specific study in children is warranted and preferable. Examples include:
        - The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
        - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or

- Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
- Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
- Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
- Other special cases justified by the offeror and found acceptable to the review group and the Institute Director

Definition of a Child

For the purpose of this solicitation, a child is defined as an individual under the age of 21 years.

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a "child," and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of "child" for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

10. **Human Embryonic Germ Cell (HEGC) Research**

1. Guidelines.

Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://stemcells.nih.gov/policy/guidelines.asp) (only the information regarding human embryonic germ cells is relevant). Embryonic germ cells are pluripotent stem cells derived from human embryos. See NIH Guide for Grants and Contracts Notice NOT OD 02 049, requiring that offerors/contractors submit certain documents to the Human Pluripotent Stem Cell Review Group (HPSCRG), which will be reviewed in a public meeting. Research using human embryonic germ cells may not be performed prior to approval by the HPSCRG.

All offerors should read the "NIH Guidelines" (http://stemcells.nih.gov/policy/guidelines.asp) if they either: (1) propose to respond to the Statement of Work requirements by conducting research that uses human embryonic germ cells or, (2) are responding to a Statement of Work that requires the use of human embryonic germ cells.

Offerors may obtain copies of these Guidelines from the website above or from the contact person listed in this solicitation.

2. Procedure for Required Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

If the offeror intends to fulfill the requirements of the Statement of Work by performing research using human embryonic germ cells, it must so state in its proposal.

If the offeror's proposal includes research using human embryonic germ cells and it receives a contract award, the contractor may not perform any research using these human embryonic germ cells until the Human Pluripotent Stem Cell Review Group (HPSCRG) has reviewed and approved the documentation furnished as prescribed in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) and the contracting officer has notified the contractor of the approval in writing.

If the HPSCRG disapproves the documentation presented by the contractor, the Contracting Officer may elect to either terminate the contract in accordance with the Termination for Convenience clause of the contract OR determine not to exercise subsequent option(s) as appropriate based the terms of the specific contract. Otherwise, when the HPSCRG approves the documentation, the contracting officer will notify the contractor in writing that research using the human embryonic germ cells may commence.

Research involving the use of human embryonic germ cells shall not be conducted under the contract until the HPSCRG review and approval have been obtained, and the contracting officer has provided written notice of such approval to the contractor.

11. **Human Embryonic Stem Cell (HESC) Research**

On August 9, 2001, the President announced the criteria that must be met for Federal funds to be used for research on existing human embryonic stem cell lines. These criteria were subsequently published by the NIH at: http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-005.html. The following eligibility criteria must be met:

1. The derivation process (which commences with the removal of the inner cell mass from the blastocyst) must have already been initiated prior to August 9, 2001;
2. Prior to August 9, 2001, the embryo from which the stem cell line was derived no longer had the possibility of development as a human being;
3. The stem cells must have been derived from an embryo that was created for reproductive purposes;
4. The embryo was no longer needed for these purposes;
5. Informed consent must have been obtained for the donation of the embryo;
6. No financial inducements were provided for the donation of the embryo.

To facilitate research using human embryonic stem cells, the NIH has established a Human Embryonic Stem Cell Registry ("the NIH Registry") that lists the human embryonic stem cells that meet the eligibility criteria. This registry is available at: http://stemcells.nih.gov/registry/.

Research involving the derivation of new stem cells from human embryos or the use of human embryonic stem cells that are not listed on the NIH Human Embryonic Stem Cell Registry may not be conducted with Federal funding.

If a particular human embryonic stem cell line has not been required by the Statement of Work, an offeror proposing research involving human embryonic stem cells must cite a human embryonic stem cell line that is listed in the NIH Registry in its proposal.

12. **Data and Safety Monitoring in Clinical Trials**

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the NIH Guide for Grants and Contracts Announcements at the following web sites:

http://grants.nih.gov/grants/guide/notice-files/not98-084.html
http://grants.nih.gov/grants/guide/notice-files/not99-107.html
http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan you should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. The NIH Policy for Data and Safety Monitoring at http://grants.nih.gov/grants/guide/notice-files/not98-084.html describes examples of monitoring activities to be considered.

The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual /Safety Officer
- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multisite trials)
- Institutional Review Board (IRB - required)

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

13. **Care of Live Vertebrate Animals**

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

Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals, HHSAR 352.270-9(a) (January 2006)

The PHS Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before award may be made to an applicant organization, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No award involving the use of animals shall be made unless OLAW approves the Animal Welfare Assurance. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information contact OLAW,at NIH, Bethesda, Maryland 20892 (301-496-7163).

The following specific address for OLAW is provided for ease of contact:

Office of Laboratory Animal Welfare
National Institutes of Health
RKL 1 - Suite 360, MSC 7982
6705 Rockledge Drive
Bethesda, MD 20892-7982 (For Hand-delivered/express mail use Zip code 20817)

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, if required by the SOW contained in this solicitation.

14. **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.

15. **Obtaining and Disseminating Biomedical Research Resources**

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

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

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

http://ott.od.nih.gov/NewPages/64FR72090.pdf

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

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

b. **Sharing of Model Organisms for Biomedical Research**

The NIH Research Tools Policy (http://www.ott.nih.gov/policy/research_tool.html) also referred to as NIH Principles and Guidelines for Sharing of Biomedical 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 at:
(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html), dated May 7, 2004, and the September 10, 2004 extension of this policy NOT-OD-04-066 at:
(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-04-066.html),
the NIH provides further sharing guidance with particular attention on model organisms for biomedical research. Such organisms include, but are not limited to: mammalian models such as the mouse and rat, and non-mammalian models, such as budding yeast, social amoebae, round worm, fruit fly, zebra fish, and frog. Research resources to be shared include genetically modified or mutant organisms, sperm, embryos, protocols for genetic and phenotypic screens, mutagenesis protocols, and genetic and phenotypic data for all mutant strains.

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

- Will material transfers be made with no more restrictive terms than in a Simple Letter Agreement (SLA) at:
  (http://ott.od.nih.gov/forms_model_agreements/forms_model_agreements.html#MTACTA)
  for the transfer of materials or the Uniform Biological Material Transfer Agreement (UBMTA) (http://www.autm.net/aboutTT/ , then search "Implementing Letter")
- 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.

c. **BUSINESS PROPOSAL INSTRUCTIONS**

1. **Basic Cost/Price Information**

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

2. **Proposal Cover Sheet**
   The following information shall be provided on the first page of your pricing proposal:

   1. Solicitation, contract, and/or modification number;
   2. Name and address of Offeror;

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

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

3. **Information Other than Cost or Pricing Data**

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

      1. **Direct Labor**

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

      2. **Materials**

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

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

      4. **Raw Materials**

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

      5. **Purchased Parts**
         Includes material items not covered above. Provide priced quantities of items required for the proposal.

      6. **Fringe Benefits**

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

7. **Indirect Costs**

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

8. **Special Equipment**
   If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

9. **Travel**

   If direct charge, list any equipment in accordance with Item (13) Other Administrative Data, subparagraph (2) Government Property of this Section L.2.c of this solicitation.

10. **Other Costs**

    List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing.

4. **Salary Rate Limitation in Fiscal Year 2008**

Offerors are advised that pursuant to P.L. 110-161**, no NIH Fiscal Year 2008 (October 1, 2008 - September 30, 2009) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 110-161** applies only to Fiscal Year 2008 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 110-161** states in pertinent part:

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

LINK TO EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/07tables/html/ex.asp

***Note to Offerors**: The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year 2008 Executive Level I Salary rates.

***Public Law 110-161: The Executive Level I annual salary rate was $186,600 for the period January 1 through December 31, 2007. Effective January 1, 2008, the Executive Level I salary rate increased to $191,300.*

5. **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $550,000 for the entire period of performance, the offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, See SECTION J - LIST OF ATTACHMENTS, BUSINESS PROPOSAL ATTACHMENTS of this BAA for an example of such a plan.

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

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

c. The offeror understands that:

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

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

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

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

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

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

d. Each plan must contain the following:

1. Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
2. A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
3. A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
4. A description of the method used to develop the subcontracting goals.
5. A description of the method used to identify potential sources for solicitation purposes.
6. A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
7. The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
8. A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
9. Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of $550,000 adopt a plan similar to the plan agreed upon by the offeror.
10. Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.
11. List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

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

6. **HUBZone Small Business Concerns**

Small Business offerors located in underutilized business zones, called "HUBZones," will be evaluated in accordance with FAR Clause 52.219-4, NOTICE OF PRICE EVALUATION

PREFERENCE FOR HUBZONE SMALL BUSINESS CONCERNS, which is incorporated by reference in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone.

7. **Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $550,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

The factor entitled "Extent of Small Disadvantaged Business Participation" as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes.

The Department of Commerce determines, on an annual basis, by Subsectors, as contained in the North American Industry Classification System (NAICS) codes, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.sba.gov/size

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

* *Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*
Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Industry Subsector(s). The applicable authorized NAICS Industry Subsector(s) for this project is (are) identified elsewhere in this 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 subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	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		

	SDB Percentage of Total Contract Value	SDB Dollars
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.

8. **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.

9. **Other Administrative Data**

a. **Property**

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below , the proposal must include a comprehensive justification addressing the following items:

    a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.

    b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. Government Property

    The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

    a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the contracting officer having cognizance of the property);

    b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;

    c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and

    d. The voluntary consensus standard or industry leading practices and standards to be used in the management of Government property, or existing property management plans, methods, practices, or procedures for accounting for property.

    NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from the contractor possessing Government property, and for evaluation purposes only, adjust the offers using a rental equivalent evaluation factor, as appropriate.

b. **Royalties**

The offeror shall furnish information concerning royalties which are anticipated to be paid in connection with performance of work under the proposed contract.

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.

(End of Provision)

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 provision is applicable:

Incremental Funding, HHSAR 352.232-75 (January 2006)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds as specified in FAR 52.232-22. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. The Government intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modifications. However, the Government is not obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor is the Contractor obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract, as specified in FAR 52.232-22, shall supersede the Limitation of Cost clause found in the Section I, Contract Clauses.

(End of provision)

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.

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

[ ]Fac Cap Cost of Money (Has Not) ***has not*** *specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.*

10. **Subcontractors**

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

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

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

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

d. Information on their cognizant field audit offices.

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

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

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this 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

11. **Proposer's Annual Financial Report**

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

12. **Representations and Certifications - SECTION K**
One copy of SECTION K (which includes FAR Clause 52.204-8 Annual Representations and Certifications) shall be completed and be signed by an official authorized to bind your organization.

Additionally, a completed copy of SECTION K shall be submitted from any proposed subcontractor. SECTION K can be found at: http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

13. **Travel Costs/Travel Policy**

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

    b. **Travel Policy**

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

14. **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 four factors. The factors in the order of importance are: technical, cost, past performance, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, cost/ price, past performance 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 and BARDA determine 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.

Offerors determined, upon completion of the scientific/technical peer review, to be in the Order of Merit Ranking may be subject to auditing of their facilities and Quality Assurance and Quality Control (QA/QC) and security capabilities. The decision to audit specific facilities will be made by the Project Officer. If audits are performed during the negotiations, the results of the audits will be a factor in final selection for award of a contract. Offerors, including proposed subcontractors, will be requested to make all non-proprietary records, including previous regulatory inspection records, and staff available in response to a pre-award site visit or audit by the NIAID or its designee. Due to timeline requirements, pre-award site visits may be made with short notice. Offerors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.

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

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 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 includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to 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. **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 includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to 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.

c. **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 includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to 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.

d. **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 includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to 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.

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.

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

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

5. **TECHNICAL EVALUATION CRITERIA**

The 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 and BARDA determines to exist at the time of award selection.

PRE-AWARD SITE VISIT OR SITE AUDIT

Offerors may be subject to auditing of their facilities and Quality Assurance/Quality Control (QA/QC) capabilities. The decision to audit specific facilities will be made by the Project Officer. If audits are performed during the negotiations, the results of the audits will be a factor in final selection for award of a contract. Offerors, including proposed subcontractors, will be requested to make all non-proprietary records, including previous regulatory inspection records, and staff available in response to a pre-award site visit or audit by the NIAID or its designee. Due to timeline requirements, pre-award site visits may be made with short notice. Offerors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.

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

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

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO - Additional Technical Proposal Instructions - OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF TECHNICAL PROPOSALS.

CRITERIA WEIGHT

CRITERION 1: INNOVATION AND PRODUCT POTENTIAL 100

A. Innovation of Broad Spectrum Technology and/or Broad Spectrum Platform (50)

(1) The potential of the proposed broad spectrum technology or platform to advance the product development process for the proposed therapeutic candidate/product or lead series, and contribute overall to "state-of-the-art" drug development technologies.
(2) The suitability of the plan to develop and evaluate the performance of the broad spectrum technology and/or platform.

B. Therapeutic Candidate Suitability and Comprehensive Product Development Plan Feasibility (50)

1) The suitability of the proposed therapeutic candidate/product or lead series for further development as described in the Comprehensive Product Development Plan (e.g. the biodefense/public health gap this is being addressed, potential for licensure for a treatment indication, for formulation with long term stability, oral bioavailability, simple dosing regiment, safety in diverse populations, broad spectrum activity).
2) The soundness of the assays used and the data to support therapeutic activity of the proposed candidate/product or lead series.
3) The soundness and feasibility of the Comprehensive Product Development Plan for advancing the therapeutic candidate/product toward a licensed product for the proposed indication.

CRITERION 2: TECHNICAL PLAN/APPROACH 50

A. Implementation of the Strategic Staged Product Development Plan and Work Plan (40)

1) The soundness and feasibility of the Strategic Staged Product Development Plan for advancing the therapeutic candidate/product toward a licensed product for the proposed indication within the requested period of funding.
2) The soundness, feasibility, suitability and completeness of the proposed decision gates for the Go/No Go evaluation of the therapeutic candidate/product or lead series, including the qualitative and quantitative criteria to be used to reach Go/No Go decisions at the various stages of product development and the budget for each stage of product development.
3) The feasibility of completing a Phase 1 clinical trial and the Final Clinical Study Report within the 5-year contract period (if a Phase I clinical trial has not already been completed at the time of review).
4) The soundness, appropriateness and feasibility of the technical methods proposed in the Work Plan (e.g. non-clinical studies, medicinal chemistry, manufacturing, assay development, animal model development, performance of animal studies, clinical evaluation, NDA- or BLA-enabling activities).
5) The suitability and adequacy of the plans for quality control, quality assurance, and data management for the conduct of activities proposed under the Work Plan.
6) The feasibility of performing the proposed activities within the stated timelines for initiation, conduct, completion and analysis of data.
7) The suitability and feasibility of the plans for modifying the Strategic Staged Product Development Plan/Work Plan based on adverse experimental or production results, or new scientific findings.
8) The adequacy of the clinical trial Protocol Synopsis and documented experience in performing human subjects research in accordance with Federal regulations for the conduct of clinical trials.
9) Adequacy of the plan to communicate and meet with the FDA and to share FDA communication with the Project Officer.
10) Adequacy of previous experience of the Offeror and any proposed subcontractors in conducting studies in compliance with GLP, cGMP and GCP guidelines as documented by the Offeror and provision of audit history and reports.

B. Proposed Statement of Work (10)

1) The adequacy of the Statement of Work to describe the necessary activities, services, personnel, materials, equipment and facilities to be provided by the Offeror and any proposed subcontractors to perform the proposed Work Plan
2) The suitability, completeness and timeliness of the list of Deliverables provided in the Statement of Work and the description of the deliverables to be provided to the Government during the performance of the contract.

CRITERION 3: QUALIFICATIONS/AVAILABILITY OF PROPOSED PERSONNEL 20

As required and/or appropriate for the Offeror's Statement of Work and Work Plan, the appropriatness/adequacy of the following:

1) Documented qualifications, knowledge, experience, education, competence, and availability of the PI to carry out the proposed Statement of Work and Work Plan.
2) Documented qualifications, knowledge, experience, education, competence and availability of the Project Manager to carry out the proposed Statement of Work and Work Plan.
3) Documented qualifications, knowledge, experience, education, competence and availability of other key personnel, provided by the Contractor or by subcontractors or consultants to carry out the proposed Statement of Work and Work Plan.
4) The responsibilities and level of effort of all proposed staff of the Offeror and any proposed subcontractors and consultants.
5) The proposed mix of staff, expertise, experience and training (e.g. research, manufacturing, clinical, regulatory, statistical, management, administrative) to carry out the proposed Statement of Work and Work Plan.

CRITERION 4: FACILITIES, EQUIPMENT AND OTHER RESOURCES 20

As required and/or appropriate for the Offeror's proposed Statement of Work and Work Plan, the availability and adequacy/suitability:

1) Facilities, equipment, and other resources to effectively and safely perform all phases of the proposed project.
2) Biocontainment facilities, as needed.
3) Facilities to: conduct assays and animal studies in accordance with FDA regulations and guidelines, including GLP guidelines; manufacture therapeutic candidate/products according to cGMP guidelines; and perform clinical trials in accordance with GCP guidelines.
4) The plan for obtaining, adding or deleting facilities as necessary due to progress during the course of product development.
5) The provisions for the conduct of work in accordance with the DHHS regulations regarding the transfer of Select Agents.
6) Occupancy of facility, including documentation of lease or ownership for the period of performance of the contract.

CRITERION 5: PROJECT MANAGEMENT 10

1) Adequacy of the Project Management Plan in terms of staffing, organization, responsibilities, leadership and lines of authority.
2) Suitability of systems proposed for tracking project activities and monitoring progress, timelines and budgets.
3) Suitability of the plan for how the PI will communicate with the Project Officer and the Contracting Officer, as well as establish lines of communication between all performance sites and activities.
4) Suitability of the plan for soliciting, evaluating, negotiating, awarding and managing any proposed subcontractor in accordance with Federal regulations.
5) Adequacy of plan to identify and remediate problems in subcontractor performance.
6) Completeness of Letters of Understanding between collaborating parties to address intellectual property, facilitate development of commercialization, and resolve disputes.
7) Adequacy of plan to protect and share confidential information with External Advisory Group members.
8) Suitability of plan to organize Annual Review Meetings and provide for a thorough assessment of contract status, problems and approaches to their resolution, and future plans.

TOTAL POSSIBLE POINTS: 200

6. **PAST PERFORMANCE FACTOR**

An evaluation of offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal would not be selected for award based on the results of the evaluation of factors other than past performance.

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

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

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

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

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

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

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

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

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before determination of the order of merit ranking. 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. Complexity and variety of the work SDB concerns are to perform

ATTACHMENT 3

BROAD AGENCY ANNOUNCEMENT INFORMATION, BACKGROUND and INTRODUCTION

Application of Platform Technologies for the Development of Therapeutics for Biodefense

DMID-NIAID-NIHAI20080022BARDA

BROAD AGENCY ANNOUNCEMENT INFORMATION

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA) solicitation, DMID-NIAID-NIHAI20080022BARDA entitled "**Application of Platform Technologies for the Development of Therapeutic Agents for Biodefense**". The BAA is authorized by Federal Acquisition Regulation (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. 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.

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 describes 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 Technical Evaluation Criteria specified in the BAA. NIAID reserves the right to convene multiple SRGs to evaluate proposals.

An Order of Merit Ranking is established by the Contracting Officer in lieu of a Competitive Range. The competing proposals are ranked on the basis of scientific merit, NIAID and BARDA programmatic balance and the availability of funds. Negotiations are conducted with offerors selected from the Order of Merit Ranking based on their scientific merit and those specific considerations set forth in this solicitation under Section M, Evaluation Factors. During negotiations, there is an opportunity to refine the proposed Statement of Work in consultation with the Project Officer including the incorporation of 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 and questions identified by the SRG.

It is anticipated that multiple awards will result from this announcement, and these awards will be multi-year, cost reimbursement, completion type contracts. 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 5 years. It is anticipated that the total cost for each award may vary depending on the scope and capacity of the technical objectives of the award.

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 AND INTRODUCTION

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), Department of Health and Human Services (DHHS) 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, with the exception of the human immunodeficiency virus (HIV). 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. The NIAID also has a mission to advance the development of new medical countermeasures against the biological agents that are most likely to be used in a terror attack on civilian populations.

The Pandemic and All-Hazards Preparedness Act (PAHPA) established the Biomedical Advanced Research and Development Authority (BARDA) in the Department of Health and Human Services (HHS) to facilitate the research, development, and acquisition of medical countermeasures for chemical, biological, radiological, and nuclear (CBRN) agents and emerging infectious disease, including pandemic influenza, that threaten the U.S. civilian population. One of the central responsibilities of BARDA is to lead the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE), which provides an integrated approach to the development, purchase and utilization of medical countermeasures for public health medical emergencies. The HHS PHEMCE consists of NIH, Assistant Secretary for Preparedness Response (ASPR), Food and Drug Administration (FDA), and Centers for Disease Control and Proevention (CDC), along with ex officio participation from other federal agencies. To guide progress toward the goal of public health preparedness, the HHS PHEMCE Implementation Plan for CBRN Threats (http://www.hhs.gov/aspr/barda/phemce/enterprise/strategy/index.html) provides insight into the current priorities for medical countermeasure development against advanced, enhanced, and emerging threats.

Through this solicitation NIAID and BARDA are partnering to support the development and evaluation of innovative technologies and platforms for the development of therapeutics with either single-pathogen or broad spectrum activity against select NIAID Category A, B and C (http://www2.niaid.nih.gov/Biodefense/bandc_priority.htm) biothreat pathogens and toxins.

Homeland Security Presidential Directive (HSPD)-18 (www.whitehouse.gov/news/releases/2007/02/print/20070207-2.html) expands on the traditional classification of Category A, B, and C biological threats to include

- Enhanced agents – traditional agents that have been modified or selected to enhance their ability to harm human populations or circumvent available countermeasures. (e.g. extensively drug-resistant *Mycobacterium tuberculosis*).
- Emerging agents – previously unrecognized pathogens that might be naturally occurring and represent a serious risk to human populations (e.g. Severe Acute Respiratory Syndrome Virus).
- Advanced agents – novel pathogens or other biological materials that have been artificially engineered in the laboratory to bypass traditional countermeasures or produce a more severe or otherwise enhanced spectrum of disease (e.g. multi-drug resistant *Bacillus anthracis*).

These designations highlight the fact that advanced, enhanced, and emerging threats are likely to be unanticipated and ill-defined in comparison to traditional threat agents. To more effectively address these lesser known and ill-defined threat agents and to encourage overall innovation in the product development process, NIAID and BARDA are supporting product development strategies that include:

- **Development and evaluation of treatments with broad spectrum activity.** There are a number of traditional threats for which effective treatments are either non-existent, of limited usefulness, or vulnerable to both naturally emerging and intentionally engineered antibacterial and antiviral resistance. A limited number of anti-infectives with broad spectrum activity directed at common, invariable, and essential components of different classes of microbes could potentially be effective against both traditional and non-traditional threats. This approach would allow a small number of drugs to replace dozens of pathogen-specific drugs for emergency use. Additionally, strategies to overcome bacterial and viral drug resistance could extend the clinical utility of existing broad spectrum anti-infectives and have immediate benefits. Treatments that target host immune responses have the potential to be effective against multiple diseases. These immunomodulators reduce morbidity and mortality by controlling host responses that contribute to disease or non-specifically activating the host's natural immune defenses to induce a faster, more potent protective response.

- **Development and evaluation of broad spectrum technologies.** Broad spectrum technologies refer to technologies with the potential to enhance product performance, such as:
    - Delivery systems (e.g. extended release drug depot systems to assure treatment completion and adequate drug release to target systems);
    - Stability (e.g. independent of cold chain, humidity, etc);
    - Potency/efficacy (e.g. broad therapeutic margin);
    - Bioavailability (e.g. independent of co-morbidities and host factors); and
    - Safety (e.g. can be administered in emergencies to population independent of existing co-morbidities and age groups).

- **Development and evaluation of broad spectrum platforms.** Broad spectrum platform refers to standardized methods that can be used to reduce the time and cost required to bring medical countermeasures to market, such as:
    - Universal expression frameworks (e.g. RNAi, monoclonal antibody frameworks);
    - Manufacturing platforms (e.g. microwave technology for chemical synthesis); and

- Preclinical/nonclinical drug evaluation technologies.

The limited resources available for the development of biodefense countermeasures are most efficiently deployed when they address broad spectrum drugs, broad spectrum technologies and broad spectrum platforms. Through this solicitation, NIAID and BARDA seek to support development of specific products in which one or more innovative broad spectrum technologies and/or platforms are proposed to be used and evaluated in the development of one of the following broad spectrum (e.g. inhibiting conserved, universal bacterial and/or viral targets) or narrow spectrum (single-agent) biodefense countermeasures:

Broad spectrum therapeutic:

- Broad spectrum anti-bacterial – therapeutic with activity against more than one genera of bacterial pathogen, including at least one of the following: *Bacillus anthracis*, *Francisella tularensis*, *Yersinia pestis*, *Burkholderia pseudomallei*, *B. mallei*, and *Rickettsia prowazeki*. Broad spectrum anti-bacterials that target other Category A, B and C bacterial threat agents will be considered on the basis of the overall innovation of the strategies proposed for their development.

- Broad spectrum anti-viral – therapeutic with activity against more than one genera of viral pathogen, including at least one of the following: Ebola virus, Marburg virus, Junin virus, *Varioloa major*, and influenza. Proposals for broad spectrum anti-virals that target other Category A, B and C viral threat agents will be considered on the basis of the overall innovation of the strategies proposed for their development.

- Broad spectrum anti-toxins – NIAID and BARDA are particularly interested in therapeutics with activity against multiple serotypes of botulinum neurotoxin. Proposals for broad spectrum anti-toxins that target other Category A, B and C toxins will be considered on the basis of the overall innovation of the strategies proposed for their development.

- Broad spectrum anti-disease – therapeutic directed at a host response that reduces morbidity and mortality from exposure/infection and is effective against more than one Category A, B or C priority threat agent.

Narrow spectrum or single-pathogen therapeutic:

- Treatment for *Bacillus anthracis and multi-drug resistant Bacillus anthracis*
- Post-exposure prophylactic for *multi-drug resistant Bacillus anthracis*
- Treatment and post-exposure prophylactic for *Variola major*
- Treatment and post-exposure prophylactic for Marburg virus
- Treatment and post-exposure prophylactic for Ebola virus
- Treatment and post-exposure prophylactic for Influenza

- Treatment for dengue virus

Offerors shall propose a well-defined product development path that must include completion of a Phase 1 clinical trial prior to or within the 5-year of contract period of performance. The performance of studies in vertebrate animals and clinical studies must be consistent with all applicable Federal regulations and the DMID, NIAID, and NIH policies and guidelines for the conduct and oversight of research in vertebrate animals and human subjects. This solicitation will also support post-Phase 1 product development activities which are enabling for a biologic license application (BLA) or a new drug application (NDA), including:

a) Manufacturing scale-up leading to consistency lot manufacturing.
b) Phase 2 clinical trials.
c) Animal studies leading to pivotal animal efficacy studies required to support licensure under the U.S. Food and Drug Administration (FDA) "Animal Rule" (New Drug and Biological Drug Products; Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible: http://www.fda.gov/cber/rules/humeffic.htm).

Plans for advancing therapeutic candidates/products or lead series through the product development path shall be proposed, implemented and funded in stages with specific decision points/gates and well defined criteria for determining the merit and feasibility of advancing to the next stage. NIAID and BARDA recognize the inherent risk and the potential to increase both time and budget in utilizing broad spectrum technologies or platforms for the development of new products. Offerors shall clearly identify those risks and specific bench-marks by which broad spectrum technologies and platforms will be evaluated. Offerors shall also provide sufficient information to demonstrate that the broad spectrum technologies and/or platforms proposed are innovative.

Offerors may submit proposals for more than one therapeutic candidate/product or lead series; however, a separate Technical and Business Proposal is required for each therapeutic candidate/product or lead series. If a single therapeutic candidate/product or lead series is being proposed for activity against more than one of the selected pathogens within the scope of this BAA, only a single Technical and Business Proposal is required.

The NIAID and BARDA recognize that product development is an iterative process and that the progress of a candidate/product or lead series through the development pathway requires ongoing evaluation to assess and reassess the likelihood of the candidate/product to meet the desired therapeutic objectives. Therefore, the NIAID and BARDA reserve the right to determine, at any time during the contract period, that a particular candidate therapeutic or lead series has not demonstrated sufficient potential to merit further investment in the development and evaluation of that candidate/product.

The NIAID and BARDA, therefore, reserve the right to modify or delete milestones, staged decision points/gates, research plans, process, schedule, budget, or product as need may arise. Because of the nature of this contract and complexities inherent in this and prior programs, at designated milestones or staged decision points/gates,

the NIAID and BARDA will evaluate whether work should be redirected, removed, or whether schedule or budget adjustments should be made.

The NIAID and BARDA are aware that no single organization or institution may have the expertise and facilities required to perform all parts of their Statement of Work. Therefore, it may be necessary for the Contractor to subcontract a portion of the work. The Contractor is not limited to a domestic institution or organization, and subcontracting to foreign organizations/institutions is permitted. The Contractor shall be responsible for ALL work performed under this contract including that performed by any subcontractor(s).

ATTACHMENT 4: RESEARCH AND TECHNICAL OBJECTIVES

Application of Platform Technologies for the Development of Therapeutics for Biodefense

DMID-NIAID-NIHAI20080022BARDA

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 overall objectives. Contracts awarded as a result of this BAA will include the Statement of Work 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.

SCOPE:

The purpose of this solicitation is to fund organizations with expertise in product development, including regulatory submissions, to advance the development and evaluation of innovative broad spectrum technologies and/or platforms to progress candidate therapeutics against select biothreat pathogens and toxins (listed in the Background and Introduction section) toward licensure. Offerors should have:

1) Identified innovative broad spectrum technology(ies) and/or platform(s)

a) For the purposes of this BAA an innovative broad spectrum technology or platform is defined as any technology or method that has the potential to improve either product performance or the product development process with the potential to advance "state-of-the-art".

b) Sufficient data should be available to demonstrate the potential of the technology and/or platform to advance the specific product proposed for development under the BAA, as well as the potential to impact future products.

c) A plan for development and evaluation of innovative technologies and/or platforms to be used for advanced development of proposed therapeutic candidate/product or lead series.

2) Identified a "promising candidate therapeutic agent or lead series"

For the purposes of this BAA, a "promising candidate therapeutic agent or lead series" is defined as a single agent or one or more agents in a lead series that meet the following three criteria/definitions.

i) A drug (synthetic or natural product) or a biological product (e.g. monoclonal antibody or a derivative of a monoclonal antibody) intended for use in the cure, mitigation, treatment, or as post-exposure prophylactic; AND

ii) A single agent or a lead series with demonstrated activity in appropriate *in vitro* assays and/or *in vivo* models against one or more of the selected pathogens (see Background and Introduction section); AND
iii) An agent that either has completed or will have completed evaluation in a Phase 1 clinical trial within the 5-year contract period of performance. Phase 1 clinical trial completion is defined as completion of a Final Clinical Study Report following International Conference on Harmonization (ICH) Guidelines on Structure and Content of Clinical Study Reports E3 (http://www.pharmacontract.ch/support/su_ich_liste.htm).

3) Devised a Comprehensive Product Development Plan

A Comprehensive Product Development Plan is expected to summarize:

a) The intended use/indication of the proposed therapeutic candidate/product or lead series and the biodefense/public health gap the product is intended to fill (e.g. potential for licensure for a treatment indication, for formulation with long-term stability, oral bioavailability, simple dosing regimen, safety in diverse populations, broad spectrum activity).
b) The intended product profile.
c) The performance specifications and features the therapeutic candidate/product should have in order to provide therapeutic benefit.
d) A description of the therapeutic candidate/product or lead series as it is currently configured.
e) A description and developmental status of the assays for product release and characterization, including activity/potency and efficacy.
f) Data to support the characterization and selection of the therapeutic candidate/product or lead series for further development. Specifically, a summary of data that demonstrates activity in *in vitro* assays and/or in appropriate animal models against one or more of the selected pathogens (see Background and Introduction section). This includes: a detailed description of the assays and animal models, the choice of pathogen challenge, strain and route, and a rationale for the choice of animal model, pathogen challenge, strain and route, as well as for the outcome/endpoints selected; documentation that the animal infection experiments were performed under well-controlled experimental conditions and data that support whether and how the candidate therapeutic specifically addresses antimicrobial resistance, engineered threats, or broad spectrum activity, as appropriate to the proposed therapeutic indication.
g) Summaries/records of discussions with FDA, if available, that are relevant to development activities for the proposed therapeutic candidate/product.

The NIAID and BARDA recognize that the regulatory path to licensure for therapeutics for the pathogens within the scope of this BAA may not be well defined. The regulatory requirements are likely to be defined in an iterative decision-making process with the FDA based on therapeutic candidate/product-specific data as they emerge. Despite this uncertainty, based on current data and/or discussions with the FDA, a critical path to licensure for product must be devised, recognizing risks and areas of significant uncertainty. Risk mitigation strategies are desired.

4) Devised a Strategic Staged Product Development Plan

A Strategic Staged Product Development Plan is expected to detail:

a) Activities and stages of product development that the Offeror is proposing to perform under contract funding.
b) Distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Strategic Staged Product Development Plan.
c) The qualitative and quantitative criteria and accompanying data elements to be used to assess the scientific merit and feasibility of proceeding to the next stage of product development.
d) Milestones/timelines for the initiation, conduct and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
e) A description of product development technology(ies) and/or platform(s) that are proposed to be employed within the Strategic Staged Product Development Plan. These technologies and/or platforms may address development timeframes and productivity, drug efficacy, specificity, safety and stability, delivery, etc. This description should clearly identify how the technology and/or platform will contribute to and improve the drug development process for the specific therapeutic candidate/product proposed for development under this contract.

Although it is the responsibility of the Offeror to propose a Statement of Work, the types of product development activities that are within the scope of this BAA include:

Non-Clinical Research and Development

Product development activities in this area include:

a) Evaluate the safety, pharmacokinetics/pharmacodynamics, bioavailability, solubility, formulation, dose, route and schedule of the therapeutic candidate/product or lead series *in vitro* and in animal models following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations – 21CFR §58).
b) Optimize the therapeutic candidate/product or lead series through medicinal chemistry.
c) Develop, characterize, and qualify and/or validate reagents, reference standards and assays required for the clinical and non-clinical evaluation of the therapeutic candidate/product or lead series.
d) Develop animal models to support the evaluation of therapeutic products where efficacy cannot be evaluated in humans. Animal models should be developed in the context of the anticipated indication for which the therapeutic candidate /product is being developed. As needed develop and characterize challenge strain banks.

Manufacturing of Therapeutics

Product development activities in this area include:

a) Develop master and working cell banks under current Good Manufacturing Practice guidelines (cGMP: as defined in the U.S. Code of Federal Regulations – 21 CFR §211).
b) Conduct of process development for the manufacture of cGMP therapeutic product.
c) Manufacture of non-cGMP and of cGMP pilot lots of therapeutic product in amounts sufficient to carry out required/proposed non-clinical and Phase 1 and/or Phase 2 clinical trials.
d) Formulate final drug product.

e) Prepare final drug product.
f) Conduct of long-term stability studies of cGMP bulk and final drug product.

Phase 1 Clinical Evaluation
Product development activities in this area include:

a) Design a Phase 1 clinical trial to evaluate the safety and pharmacokinetics of the therapeutic candidate/product in humans.
b) Prepare and submit an IND application to the FDA.
c) Conduct Phase 1 clinical trial in accordance with all Federal guidelines, Good Clinical Practice guidelines (GCP: as defined by 21 CFR §312 and ICH Guidelines document E6 (http://www.pharmacontract.ch/support/su_ich_liste.htm) and DMID, NIAID, NIH policies and guidelines.

Post-Phase 1 BLA- or NDA-Enabling Activities
Product development activities in this area include:

a) Conduct manufacturing scale-up leading to consistency lot manufacturing of the therapeutic candidate /product.
b) Design and conduct a Phase 2 clinical trial in accordance with all Federal regulations and guidelines, Good Clinical Practice guidelines (GCP: as defined by 21 CFR §312 and ICH Guidelines document E6 (http://www.pharmacontract.ch/support/su_ich_liste.htm) and DMID, NIAID, NIH policies and guidelines.

NOTE: **Contracts awarded under this solicitation will not support:**

a) **The design and conduct of Phase 3 clinical trials.**
b) **The development of vaccines (vaccine is defined as an intervention that elicits a pathogen specific immune response).**

TECHNICAL REQUIREMENTS:

The Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to provide the services delineated in the negotiated Statement of Work. The specific components of the Statement of Work and the scope of the product development activities to be undertaken will depend on the status of the individual therapeutic candidate/product or lead series as part of an overall Strategic Staged Product Development Plan, as well as regulatory requirements. The Contractor shall carry out activities within the contract Statement of Work only as requested and approved by the Project Officer, and may not conduct work on the contract without prior approval from the Project Officer. Approval to carry out specific activities will be linked to approval by the Project Officer of the Strategic Staged Product Development Plan following contract award, approval of Monthly and Annual Progress Reports, review and approval of a Clinical Trial Protocol and supporting materials, and approval of Decision Gate Reports or Decision Gate Change and Work Plan Change Request (see reporting requirements for a description of these reports).

Each Contractor shall be required to perform the following activities and provide the following resources as appropriate to the scope of the specific negotiated Statement of Work:

1. STRATEGIC STAGED PRODUCT DEVELOPMENT

The Contractor shall update, as needed, and implement the Strategic Staged Product Development Plan to advance the therapeutic candidate/product or lead series along a well-defined development path leading to a therapeutic product suitable for testing in humans in a Phase 1 clinical trial and/or for post-Phase 1 BLA- or NDA-enabling activities within the maximum 5-year period of the contract award. The Contractor shall perform all technical, regulatory, management, and administrative activities that are required to implement the Strategic Staged Product Development Plan. The Strategic Staged Product Development Plan shall include:

a) Clearly defined goals, stages of product development and product development activities.
b) Go/No-Go decision gates.
c) Quantitative and qualitative criteria and accompanying data elements for assessing the scientific merit and feasibility of moving to the next stage of product development.
d) A detailed timeline for each stage covering the initiation, conduct and completion of product development activities and a budget (in direct costs) linked to each stage.
e) A description of product development technology (ies) and/or platform (s) that is proposed to be employed within the Strategic Staged Product Development Plan. These technologies and/or platforms may address development timeframes and productivity, drug efficacy, specificity, safety and stability, delivery, etc. This description should clearly identify how the technologies and/or platforms will contribute to and improve the drug development process for the specific therapeutic candidate/product or lead series proposed for development under this contract, as well as generally for other products.

Within fourteen (14) calendar days of the effective date of the contract, the Contractor shall submit an updated Strategic Staged Product Development Plan and Work Plan. The Strategic Staged Product Development Plan and Work Plan shall be approved by the Project Officer and the Contracting Officer prior to initiation of any activities related to their implementation. Upon completion of a stage of product development, as defined in the approved Strategic Staged Product Development Plan, the Contractor shall prepare and submit to the Project Officer and the Contracting Officer a Decision Gate Report that contains:

a) Sufficient detail, documentation and analysis to support successful completion of the stage according to the predetermined qualitative and quantitative criteria that have been established for Go/No Go decision-making.
b) Costs incurred to complete the stage.
c) A description of the next stage of product development to be initiated, a revised Work Plan, if necessary, an updated budget and a request for approval to proceed to the next stage of product development.

In response to a need to change the Strategic Staged Product Development Plan or the Work Plan, the Contractor shall submit a Decision Gate Change and Work Plan Change Request Report. This report shall request a change in the agreed Work Plan, timelines and/or decision gates. This report shall include:

a) Discussion of the justification/rationale for the proposed change.
b) Options for addressing the needed change/deviation from the approved timelines and and/or decision gates, including a cost-benefit analysis of each option.
c) Recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program, timelines, and budget.

2. CLINICAL TRIAL PROTOCOL DEVELOPMENT AND IMPLEMENTATION

The Contractor shall develop all clinical trial protocols and shall have ultimate responsibility for the conduct of all clinical trials and adherence to Federal regulations and the DMID, NIAID, NIH policies and guidelines for the conduct of research involving human subjects. Copies of Department of Health and Human Services (DHHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), Office of the Secretary (OS), DHHS – http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm. DMID policies, guidelines, templates and other important information regarding performing human subjects research are available at: http://www.niaid.nih.gov/dmid/clinresearch/. It is required that the information contained in the DMID Serious Adverse Event (SAE) Report Form be included in the Contractor's SAE Report Form, and it is recommended that the Contractor use the DMID SAE Report Form located at http://www.niaid.nih.gov/dmid/clinresearch/. SAE Reports must be submitted to the DMID Office of Clinical Research Affairs, according to the Clinical Terms of Award (see below). In addition, the Contractor shall develop and implement a Clinical Trials Monitoring Plan as part of the DMID Clinical Protocol.

The Contractor shall be required to:

a) Comply with all Federal and NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf).
b) Submit clinical trial protocols and supporting documentation (e.g. sample informed consent forms and clinical investigators brochures at the time of protocol submission, and case report forms, manuals of procedures, site quality management plan, data management plan, safety oversight plan and local Institutional Review Board committee approvals prior to study initiation) and amendments to the Project Officer for review and approval by the appropriate NIAID review committee (The Clinical Trials Monitoring Plan is part of the DMID protocol template and is also subject to approval by the Project Officer).
c) Obtain from the Project Officer final approval of protocols to be undertaken prior to FDA IND submission and participant enrollment.
d) Serve as the product sponsor with responsibility for:
    i) Preparing materials for and requesting, scheduling and participating in all meetings with the CDER, FDA, including meetings to review IND, NDA and BLA packages.
    ii) Submitting all documentation to the FDA in a timely manner, consistent with timelines set out in the contract and by the FDA.
    iii) Including NIAID staff, as designated by the Project Officer, in meetings and teleconferences with the FDA.

iv) Providing copies of all FDA correspondence and meeting minutes that are relevant to the therapeutic candidate/product to the Project Officer.

3. REGULATORY COMPLIANCE AND DATA MANAGEMENT

As required for the implementation of the Strategic Staged Product Development Plan, the Contractor shall:

a) 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.
b) Provide for the statistical design and analysis of data resulting from the research undertaken.
c) Provide raw data or specific analyses of data generated with contract funding to the Project Officer.
d) Ensure strict adherence to FDA regulations and guidance, including requirements for the conduct of animal studies and assays under GLP, the manufacturing of the therapeutic candidate/product under cGMP, and the conduct of clinical trials under GCP standards. The Contractor shall maintain quality assurance documentation to support adherence in these areas.
e) Arrange for independent audits, as needed or as requested by the Project Officer. Audits may be requested to assure that Contractor and/or subcontractor facilities and all planned procedures comply with the FDA regulations and guidance that are required to meet GLP, cGMP and GCP standards. In addition, the Contractor shall ensure that all Contractor and/or subcontractor records and staff are available for site visits or audits. The Contractor shall provide interim and final audit reports to the Project Officer and the Contracting Officer within thirty (30) calendar days of the completion of the audit. The NIAID reserves the right to conduct independent audits of the Contractor and its subcontractors as needed to evaluate compliance with the FDA regulations and guidance, including those required to meet GLP, cGMP or GCP standards. Such audits may also be conducted prior to contract award as a part of the technical evaluation of the Offeror's Technical Proposal.

4. SCIENTIFIC, TECHNICAL, MANAGEMENT, AND ADMINISTRATIVE TEAM

The Contractor shall provide all expertise needed for the implementation of the Strategic Staged Product Development Plan to be performed under this contract, including: research, manufacturing, regulatory, clinical, statistical, management and administrative activities. The Contractor's team must include strong scientific leadership, as well as experience and expertise in the management, design and execution of a research and development program focused on product development, manufacturing, and testing in humans and in vertebrate animals. The Principal Investigator (PI) shall be responsible for all aspects of project performance and communication with the Project Officer and the Contracting Officer. In addition, the Contractor shall provide a Project Manager who is responsible for the day-to-day monitoring and tracking of progress and timelines, the coordination of project activities and costs incurred.

5. FACILITIES, EQUIPMENT AND OTHER RESOURCES

The Contractor shall provide the equipment, facilities, training and other resources required to implement the Statement of Work and the Strategic Staged Product Development Plan in compliance with all Federal and NIH regulations. Depending on the stage of development of the therapeutic candidate/product or lead series, this may include:

a) The performance of IND-enabling assays and animal studies under GLP.

b) Production, characterization and release testing of therapeutic agent under cGMP conditions.

c) Performance of clinical trial(s) in humans under GCP.

d) The humane care and use of vertebrate animals.

e) The handling, storing and shipping of potentially dangerous biological and chemical agents, including Select Agents, under biosafety levels required for working with the biological agents under study. The Biosafety in Microbiology and Biomedical Laboratories, 5th edition is available at: http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm. The Centers for Disease Control and Prevention (CDC) Select Agent program can be found at: http://www.cdc.gov/od/sap.

The Contractor is required to undertake all studies with approval from their Institutional Biosafety Committee. At the request of the Project Officer, the Contractor shall provide copies of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments.

6. PROJECT MANAGEMENT

The Contractor shall provide for:

a) Overall Project Management

i) The overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, direction and completion of all contract activities.
ii) Regular and effective communication with the Project Officer and the Contracting Officer.
iii) A PI with responsibility for overall project management and communication, tracking performance and cost, monitoring and reporting on project status and progress, and recommending modifications to project requirements and timelines, including projects undertaken by subcontractors.
iv) A Project Manager with responsibility for monitoring and tracking day-to-day progress and timelines, coordinating communication, project activities and costs incurred.
v) Administrative staff with responsibility for financial management and reporting on all administrative activities conducted by the Contractor and any subcontractors.

b) Intellectual Property: The Contractor shall be 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 the 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 FAR 52.227-11 (Bayh-Dole Act).

c) Reports and Deliverables: The Contractor shall prepare and provide all reports and other deliverables listed in the "Reporting Requirements and Other Deliverables" section of this BAA as they relate to the Contractor's specific Statement of Work. The Contractor, the Project Officer and the Contracting Officer shall agree in the final contract negotiations on which reports and deliverables are relevant to the awarded contract Statement of Work and shall, therefore, be required as deliverables.

7. EXTERNAL ADVISORY GROUP

After contract award and in consultation with the Project Officer and the Contracting Officer, the Contractor shall establish an External Advisory Group with the relevant expertise to critically evaluate technical progress in meeting product development objectives and established timelines. It is anticipated that the External Advisory Group will consist of approximately 4-6 members. The membership of the External Advisory Group will be proposed by the Contractor and approved by the Project Officer and Contracting Officer post-award. External Advisory Group members should NOT be proposed in the Offeror's technical or business proposal.

The specific roles and duties of the External Advisory Group members shall be defined by the Contractor and approved by the Project Officer. Compensation for this role shall be provided by the Contractor with contract funds as approved by the Contracting Officer and shall be commensurate with the specific roles and duties assigned to the members.

Contractors shall submit the following to the Project Officer and the Contracting Officer to request approval of External Advisory Group membership within 6 months of the effective date of the contract:

a) A short biosketch for each member being proposed.
b) A description of the roles and duties of each member.
c) The proposed compensation for each member.

All meetings and communications with the External Advisory Group or its individual members shall be documented and submitted to the Project Officer and Contracting Officer. Documentation of such meetings/communications shall be provided within twenty-one (21) calendar days and shall include a summary of the discussions and copies of slide presentations.

8. CONTRACT REVIEW MEETINGS

Post-Award Contract Initiation Meeting: Within thirty (30) calendar days of the effective date of the contract, the Contractor shall plan, conduct and be responsible

for the logistical arrangements for a post-award kick-off meeting to be held at a site proposed by the PI and approved by the Project Officer. The PI, Project Manager, all key investigators, key subcontractor personnel, the Project Officer and the Contracting Officer shall attend this meeting. Other NIAID and BARDA staff, as designated by the Project Officer, may also attend this meeting. The purpose of this meeting shall be to review the Strategic Staged Product Development Plan and the Work Plan and to coordinate activities and communication. The PI shall provide slide presentations and a detailed summary of meeting discussions to the Project Officer and the Contracting Officer within twenty-one (21) calendar days following the date of the meeting. External Advisory Group members may attend if they have been named and approved prior to the Contract Initiation meeting.

Annual Review Meetings: At the 12 month mark of each contract year, the Contractor shall plan, conduct and be responsible for logistical arrangements for an annual review meeting, to be held at a site proposed by the PI and approved by the Project Officer, for NIAID and BARDA contract and program staff and the External Advisory Group. The PI, Project Manger, all key investigators, and key subcontractor personnel shall attend these meetings. The agenda will be prepared by the Project Officer in consultation with the PI. Meetings will be closed to the public and shall involve oral and electronic presentations, including:

a) Updates on results of activities undertaken or completed since the last review meeting.
b) Updates on progress toward or reaching a decision gate.
c) Interim reports on active preclinical or clinical protocols.
d) A description of any problems encountered or anticipated.
e) A discussion of approaches to overcoming problems.
f) A description of activities to be undertaken in the coming year.

The PI shall provide slide presentations and a detailed summary of meeting discussions to the Project Officer and the Contracting Officer within twenty-one (21) calendar days following the date of the Annual Review meeting.

For Contractors with domestic or foreign subcontracts, this annual review meeting shall also report on approvals for manufacturing, preclinical or clinical testing that have been obtained from both the U.S. and/or foreign governments.

The PI, Project Manager, key investigators, and key subcontractor personnel shall attend additional meetings in Bethesda, Maryland at the request of the Project Officer. Such meetings will be requested, as necessary, to discuss contract specific issues.

9. PUBLICATIONS

Any manuscript or scientific meeting abstract containing data generated under this contract shall be submitted for Project Officer review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. NIAID contract support shall be acknowledged in all such publications. A “publication” is defined as an issue of printed material offered for distribution or any communication or oral presentation of information. The Project Officer will review all manuscripts and abstracts in a period of time not to exceed thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstract from receipt, and will either agree to the publication/disclosure or recommend changes. If Project Officer comments are not

provided within these timelines, the Contractor may proceed with public presentation or publication.

10. IT AND NETWORK SYSTEMS

Provide and maintain a secure, internal IT systems and network architecture, software development environment and computational infrastructure to support the modeling activities, algorithms and software application development, data analysis and integration, data dissemination and other computational needs of the Application of Platform Technologies for the Development of Therapeutics for Biodefense. The Contractor's institution's security policies and guidelines must be followed. Provide a System Security Plan (SSP) of the program infrastructure to the Project Officer within 3 months. A template for the SSP can be found in NIST Special Publications SP-800-37 Guide for Security Certification and Accreditation of Federal Information Systems (http://csrc.nist.gov/publications/nistpubs/800-37/SP800-37-final.pdf) and in NIST Special Publication SP-800-18 Revision 1 Guide for Developing Security Plans for Federal Information Systems (http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/SP800-18-Rev!-final.pdf).
An updated SSP is to be delivered after any major change to the cyber infrastructure to which the IT system is connected.

ATTACHMENT 5: REPORTING REQUIREMENTS AND OTHER DELIVERABLES

Application of Platform Technologies for the Development of Therapeutics for Biodefense

DMID-NIAID-NIHAI20080022BARDA

REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one (1) hardcopy of each report shall be submitted to the Contracting Officer and two (2) hardcopies to the Project Officer, unless otherwise specified.

a. Technical Reports

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

The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to technical inspection and requests for clarification by the Project Officer. These reports shall be brief and factual and prepared in accordance with the format described below.

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

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

(1) Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

(4) Annual Progress Report

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

(5) 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 the 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 the DELIVERIES Article in SECTION F of this 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 3 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.

(6) Final Report

This report is to include a summation of the work performed and the results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. An Annual Progress Report will not be required for the period when the Final Report is due.

The Contractor shall provide the Contracting Officer with 2 copies of the Final Report in **draft** form sixty (60) calendar days prior to the completion date of this contract. The Project Officer will review the draft Final Report and provide the Contracting Officer with comments within thirty (30) calendar days after receipt. The Final Report shall be corrected by the Contractor, if necessary and the final version delivered as specified in the above paragraph.

(7) Summary of Salient Results

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

b. Other Reports and Deliverables

In addition to the above reports, the following are considered other reports and deliverables under this contract and are identified in the Statement of Work. A listing is included in the DELIVERIES Article in SECTION F.

Human Subjects IRB Annual Report (Form OMB No. 0990-0263-formerly Optional Form 310)

Invention Report Requirement - *Use when Patent Rights (FAR 52.227-11 or 52.227-13) may be included in the contract.*

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

OTHER TECHNICAL REPORTS

1) Decision Gate Report

A Decision Gate Report shall be submitted when the Contractor has completed a stage of product development and has reached a Go/No Go decision point, as defined in the approved Strategic Staged Product Development Plan. These reports shall be in sufficient detail to explain comprehensively the results achieved. The description shall also include pertinent data and/or conclusions resulting from the analysis and scientific evaluation of data accumulated to date under the project.

Decision Gate Reports shall include the following specific information:

a) Cover page that lists the contract number and title, the period of performance being reported, the Contractor's name and address, telephone number, fax number, email address, and the date of submission.
b) An introduction covering the purpose and scope of the contract effort, and the specific Decision Gate that has been reached.
c) Document and summarize the results of work undertaken that supports the completion of the stage of product development, including an analysis of the data as it relates to the qualitative and quantitative criteria established for Go/No Go decision-making.
d) Actual costs incurred in relation to costs estimated in the original approved budget.
e) A description of the next stage of product development to be initiated and a request for Project Officer approval to proceed to the next stage of product development.

2) Decision Gate and Work Plan Change Request

The Contractor shall submit a written request for a change in the approved Strategic Staged Product Development Plan and WorkPlan. This request shall include the following:

a. A discussion of the justification/rationale for the request based on current data and a description of those data.
b. Options for addressing the needed change/deviation from the approved timelines and/or decision gates, including a cost-benefit analysis of each option.

c. A recommendation for the preferred option that includes a full analysis and discussion of the effects of the change on the entire product development program, timelines, and budget.

3) Audit Reports

Within thirty (30) calendar days of completion of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP or GCP guidelines, the Contractor shall provide copies of the audit report and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

4) Clinical Trial Protocols

The NIAID has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in NIAID-funded clinical trials. Therefore, as described in the NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf), the Contractor shall develop a protocol for each clinical trial and submit all protocols and protocol amendments for approval by the Project Officer. Protocols must be submitted using the approved DMID template and include a sample Informed Consent and Clinical Trials Monitoring Plan. The DMID templates and other important information regarding performing human subjects research are available at http://www.niaid.nih.gov/dmid/clinresearch/.

5) Final Clinical Study Report

For each clinical study performed with contract support, a Final Clinical Study Report shall be provided within thirty (30) calendar days of the completion of the analysis of all data generated in the clinical trial. Final Clinical Study Reports shall follow the ICH guidelines on Structure and Content of Clinical Study Reports E3 (http://www.pharmacontract.ch/support/su_ich_liste.htm).

6) Draft and Final Animal Efficacy Report

For each animal efficacy study performed with contract support, a Draft Animal Efficacy Study Report and a Final Animal Efficacy Study Report shall be submitted within thirty (30) and sixty (60) calendar days (unless otherwise approved by the Project Officer), respectively, of the completion of the analysis of all data generated in the animal study. The Animal Efficacy Study Reports shall include a complete description of the experimental design, protocol, methods, reagents, data analysis, and conclusions of studies performed to demonstrate efficacy of therapeutic product for the indication (i.e., post-exposure prophylaxis or treatment) being sought. For GLP studies the Draft and Final Animal Efficacy Study Report shall have been audited for quality assurance by the Contractor or subcontractor.

Other Reports

1) Strategic Staged Product Development Plan and Work Plan

The Contractor shall be required to update the Strategic Staged Product Development Plan and the Work Plan to incorporate progress since the effective date

of the contract. Within fourteen (14) calendar days of the effective date of the contract and prior to initiation of product development activities, unless otherwise negotiated with the Project Officer and the Contracting Officer, the Contractor shall submit an updated Strategic Staged Product Development Plan and Work Plan for approval. This updated Strategic Staged Product Development Plan shall include:

a) Clearly defined goals, product development stages and product development activities.
b) Go/No Go decision gates.
c) Quantitative and qualitative criteria and associated data elements for assessing the scientific merit and feasibility of moving to the next stage of product development.
d) A detailed timeline for each stage covering the initiation, conduct and completion of product development activities and a budget linked to each stage.

The Work Plan shall include a description of the studies to be performed within each stage of the project.

The Contractor shall also be required to submit a revised Strategic Staged Product Development Plan and associated Work Plan when a change to the approved plans is requested. At any time during the contract period the Project Officer may request additional detail from the Contractor regarding the Strategic Staged Product Development Plan and the Work Plan.

2) External Advisory Board Approval Request

The Contractor shall submit the following to the Project Officer and the Contracting Officer to request approval of External Advisory Group membership within six (6) months of the effective date of the contract:

a) A brief biosketch for each member being proposed.
b) A description of the roles and duties of each member.
c) The proposed compensation for each member.

3) Contract Meeting Reports

A report of the Post-Award Contract Initiation Meeting, Annual Review Meetings and External Advisory Group meetings shall be prepared by the Contractor and submitted within twenty-one (21) calendar days following the date of the meetings. These reports shall include the slide presentations and all other meeting materials as well as summaries of all discussions.

Minutes of regular, as well as, ad hoc teleconferences and meetings shall be provided by the Contractor within seven (7) calendar days following the date of the teleconference or meeting.

4) Copies of FDA Correspondence and Meeting Summaries

Within thirty (30) calendar days of receiving correspondence from or meeting with the FDA, submit copies of the correspondence or meeting minutes/summaries to the Project Officer.

DELIVERIES

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

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

a. Technical Progress Reports

Type of Report	Addresses / Distribution	Due Date
PROGRESS		
Monthly Progress Report	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	The 15th of each month. First report is due following the first full month of contract performance, including any portion of the prior month since award. The Monthly Progress Report shall not be required on months when an Annual Progress Report is due.
Annual Technical Progress Report	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	15th of the month following the end of each 12 months of the performance period. The Annual Progress Report shall not be required when the Final Progress Report is due.
DRAFT Final Progress Report	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	60 calendar days prior to completion date of the contract
Final Progress Report	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	15 calendar days before completion of the contract period
Summary of Salient Results	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	This report will be required on or before the expiration date of the contract
TECHNICAL		
Decision Gate Report	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	Following completion of a pre-defined stage of product development and prior to initiation of a new stage.
Decision Gate Change and Work Plan Change Request	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	As soon as the Contractor has sufficient data to support the need for a change from the approved Strategic Staged Product Development Plan.

Audit Reports	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	Within 30 calendar days of the audit.
Clinical Trials Protocols	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	To be negotiated with the NIAID Project Officer and prior to IND submission or enrollment of human subjects.
Final Clinical Study Report	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	30 calendar days after completion of analysis of clinical trial data.
Draft Animal Efficacy Study Reports	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	30 calendar days after completion of all analysis of animal efficacy study data, unless otherwise approved by the PO.
Final Animal Efficacy Study Reports	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	60 calendar days after completion of all analysis of animal efficacy study data, unless otherwise approved by the CO.
OTHER REPORTS		
Strategic Staged Product Development Plan and Work Plan	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	Within 14 calendar days after contract award and prior to initiation of product development activities, when a Decision Gate/Workplan Change Request is submitted or as requested by the PO.
External Advisory Group Approval Request	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	Within 6 months after contract award.
Annual Review Meeting Report	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	Within 21 calendar days following the date of the Annual Review Meeting.
External Advisory Group Meeting	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	Within 21 calendar days following the date of the Annual Review Meeting.
FDA Correspondence and Meeting Summaries	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	Within 30 calendar days of receiving correspondence or meeting with the FDA.
Teleconference and Meeting Minutes	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	Within 7 calendar days of the teleconference or meeting.
Human Subject IRB Annual Review Report	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	Annually submitted 30 days after the anniversary date

Invention Report	1 Original hardcopy to CO 2 Hardcopies to PO and (1) electronic copy to CO and PO	As required

D. Other Deliverables

1) Samples of Therapeutics: The Contractor shall submit samples of non-GMP candidate therapeutics and GMP material manufactured with contract funding. The type of material and the amount will be specified in the contract. The Contractor will be advised by the Project Officer how samples are to be packaged and where samples are to be shipped. It is acceptable to label material "Not for Clinical Use".

2) Animal Model: Technology Transfer packages that include complete protocols and critical reagents for animal models developed and/or improved with contract funding must be submitted at the request of the Project Officer.

3) Copies of other reports generated during the contract period related to performance of the contract, including: Process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis at the request of the Project Officer.

4) Institutional Biosafety Approval: The Contractor shall provide documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments at the request of the Project Officer.

5) Data: Provide raw data or specific analysis of data generated with contract funding at the request of the Project Officer and in sufficient detail as specified by the Project Officer.

ATTACHMENT 6: ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS, FORMAT FOR TECHNICAL PROPOSAL, and TABLE OF CONTENTS

Application of Platform Technologies for the Development of Therapeutics for Biodefense

DMID-NIAID-NIHAI20080022BARDA

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

These additional Technical Proposal instructions reflect the requirements of the BAA and provide specific instructions and formatting for the Technical Proposal. While Section L.2.b. of the BAA provides a generic set of Technical Proposal instructions applicable to all NIH R&D solicitations, these instructions are tailored to the specific requirements of the BAA. The information requested in these instructions should be used to format and prepare the Technical Proposal, and should be used as a Table of Contents for your Technical Proposal. Offerors should follow the instructions in Section L of the solicitation, and include the information requested here.

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Background and Introduction, Research and Technical Objectives, all reference materials, and attachments, the Technical Evaluation Criteria in Section M, and the BAA as a whole in the development of their Technical Proposals.

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

Offerors are reminded that the total page limitation for the entire Technical Proposal is 150 pages including all appendices and attachments. Any pages in excess of this limit will be expunged from the proposal and will not be considered in the technical review.

USE OF WEB LINKS AND URLs: Offerors should NOT place web links or URLS in the proposal, or otherwise direct readers to alternate sources of information, as reviewers will be instructed not to access any links.

TECHNICAL PROPOSAL – TABLE OF CONTENTS

GENERAL NOTES

The NIAID recognizes that the regulatory path to licensure for therapeutics for the pathogens within the scope of this BAA may not be well defined. The regulatory requirements are likely to be defined in an iterative decision-making process with the FDA based on candidate/product-specific data as they emerge. Despite this uncertainty, Offerors must propose, to the best of their ability and based on current data and/or discussions with the FDA, a critical path to licensure for their product. The Technical Proposal should discuss areas of significant uncertainty and propose likely alternatives.

SECTION 1:

This Section will precede the Technical Proposal requirements identified in Section L.2. of the BAA.

1) PROPOSAL TITLE PAGE. Include BAA title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.
2) PROJECT OBJECTIVES, NIH FORM 1688
3) GOVERNMENT NOTICE FOR HANDLING PROPOSALS
4) PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)
5) TABLE OF CONTENTS

SECTION 2: TECHNICAL PROPOSAL OVERVIEW (suggested 3-page maximum)

Provide a brief description of the proposed project, including:

1) A 1-2 sentence summary describing the therapeutic candidate/product or lead series the offeror is proposing to advance and the innovative broad spectrum technology and/or platform the offeror is proposing to develop and evaluate.
2) A summary describing the scope of product development activities proposed.
3) A description of the activities to be performed by the offeror and those that shall be provided by any proposed subcontractor, including the identification of the proposed subcontractors and a list of key personnel of the offeror and the proposed subcontractors with degrees and titles.
4) A brief description of the facilities and other resources to be made available by the offeror and any proposed subcontractors.
5) The period of contract funding requested and the total budget (direct plus indirect) for each year.

SECTION 3: INNOVATION and PRODUCT POTENTIAL

1: INNOVATIVE BROAD SPECTRUM TECHNOLOGIES AND/OR PLATFORMS

Technical Proposals shall include:

a) A detailed description of each broad spectrum technology and/or platform being proposed

b) Data to demonstrate the potential of the technology and/or platform to advance the development of the product being proposed, as well as the potential to advance the "state-of-the-art"
c) An assessment of the potential risks and benefits of applying and evaluating the technology and/or platform within the context of the proposed product
d) A plan to evaluate the performance of the technology and/or platform within the context of this product development proposal

2: COMPREHENSIVE PRODUCT DEVELOPMENT PLAN

Technical Proposal shall include a Comprehensive Product Development Plan that describes the critical path for the proposed therapeutic candidate/product to eventual licensure and identifies the decision points/gates for progressing the therapeutic candidate/product or lead series. The Comprehensive Product Development Plan shall include a summary of the following:

a) The intended use/indication of the proposed therapeutic candidate/product and the biodefense/public health gap the product is intended to fill (e.g. post-exposure treatment; post-exposure prophylaxis; broad spectrum; narrow spectrum).
b) The intended product profile including potential stability, bioavailability, dosing and safety.
c) The performance specifications and features the product should have in order to provide therapeutic benefit.
d) A description of the therapeutic candidate/product or lead series as it is currently configured.
e) Data to support the characterization and selection of the therapeutic candidate/product or lead series for further development. If available, a summary of the data that demonstrates therapeutic activity in an appropriate animal model against one or more of the selected pathogens. Include a detailed description of the animal model and pathogen challenge, as well as for the outcome/endpoints selected. Document that the animal infection experiments were performed under well-controlled experimental conditions.
f) Discussions with FDA, if available, that are relevant to development activities for the proposed therapeutic candidate/product.
g) A description of activities that are part of the critical product development path through submission of a BLA or NDA.

SECTION 4: TECHNICAL PLAN/APPROACH

1: STRATEGIC STAGED PRODUCT DEVELOPMENT PLAN

Technical Proposals shall include a Strategic Staged Product Development Plan detailing the specific tasks and stages of the Comprehensive Product Development Plan that the Offeror is proposing to perform with contract funding and that can reasonably be completed within the 5-year maximum period of performance. The Strategic Staged Product Development Plan must detail:

a) Activities and stages of product development that the Offeror is proposing to perform under contract funding.

b) Distinct stages of the product development pathway that are decision gates for Go/No Go decisions for advancing to the next stage of the Strategic Staged Product Development Plan.
c) The qualitative and quantitative criteria and accompanying data elements to be used to assess the merit and feasibility of proceeding to the next stage of product development.
d) Timelines for the initiation, conduct and completion of product development activities for each stage and a budget (direct costs) linked to each stage. If a Phase 1 clinical trial has not been completed, the Offeror should clearly note the timeline for completing the Phase 1 clinical trial and Final Clinical Study Report with the five (5) year contract period.
e) A description of how the proposed broad spectrum technologies and/or platforms will be integrated into the Strategic Staged Product Development Plan.

2: WORKPLAN FOR IMPLEMENTATION OF THE STRATEGIC STAGED PRODUCT DEVELOPMENT PLAN

Technical Proposals shall include a Work Plan describing each step that the Offeror proposes to perform after contract award that is required to implement the Strategic Staged Product Development Plan and complete all proposed work within the 5-year period of performance:

The Work Plan shall include:

a) Key development objectives and defined decision points for the development of the therapeutic candidate/product or lead series.
b) A detailed discussion of the proposed technical approach for each activity to be performed to achieve the project objectives. The Work Plan shall contain sufficient detail to fully explain and justify the scientific/technical rationale for the proposed approach and/or methodologies and should reflect a clear understanding of the scope and nature of the work being undertaken.
c) A detailed Gantt Chart organized by each specific decision gate/stage of product development proposed, as well as the overall product development program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, the date of a stated event, as for example receipt of a required approval from the Project Officer or the Contracting Officer.
d) For each decision gate proposed, a description of the process for making decisions to proceed or not proceed (Go/No-Go), including specific qualitative and quantitative criteria and associated data elements for advancement of therapeutic candidates/products or lead series through each stage of the product development process. For example, decision to proceed or not to proceed vis a vis human safety, pharmacokinetic (PK) and pharmacodynamic (PD) testing.
e) Plans for quality control over the implementation, coordination and conduct of the activities set forth in the Strategic Staged Product Development Plan, including plans to conduct regulatory audits.
f) Approaches to integrate adverse experimental or production results or new scientific findings into the proposed goals and timelines.

g) A plan for sharing data, reagents, and animal model resources developed with contract funding with the scientific community.
h) A list and description of all items to be delivered to the Government at each stage in the product development process during the performance of the contract and a timeline for delivery.
i) A Technical Proposal Cost Summary to include: a list of all subcontracts by activity (e.g., GMP manufacture, IND-enabling toxicologic studies, formulation and fill, etc.): a budget for each stage of product development proposed for funding (direct plus indirect) – linked to a timeline for completion of each stage.

3: CLINICAL TRIAL PROTOCOL DEVELOPMENT AND IMPLEMENTATION

Work Plans that propose clinical trials must include:

a) A description of previous experience in the conduct of human subjects research that demonstrates the Offeror's and all proposed subcontractors' expertise and thorough knowledge of Federal regulations for the conduct of human subjects research. A description of experience in the conduct of human subjects research in accordance with DMID, NIAID, NIH policies and guidelines or a statement acknowledging willingness to conduct clinical research according to DMID, NIAID, NIH policies and guidelines.
b) A Protocol Synopsis for each proposed clinical trial. The Synopsis should include: the name(s) of the individual(s), organization(s) and site(s) that will perform the clinical trial, and documentation of their capability and willingness to perform the trial; primary and secondary objectives of the trial, trial design, and assays to be performed. The Offeror shall also address issues of human subjects protection, provisions for data and safety monitoring, recruitment and retention of study participants, informed consent, the quality management plan, clinical monitoring plan and the statistical analysis plan.
c) A plan that specifies at which points in the Strategic Staged Product Development Plan it will be critical to engage in written communications and meetings with the FDA.
d) A plan that specifies the frequency and methods by which NIAID will be kept apprised of progress and provided with documentation of communications with the FDA, including correspondence from the FDA and minutes/summaries of meetings with the FDA.

4: REGULATORY COMPLIANCE, QUALITY ASSURANCE AND DATA MANAGEMENT

a) Data Management and Quality Assurance: The Technical Proposal must include the following:

    i) The data management and quality control systems/procedures that will be used for all studies and procedures for data entry and validation, documentation of data corrections, routine maintenance and backup, transmission of data, data reporting and exporting system, access control and confidentiality, and data retrieval and disaster recovery.

ii) A description of the statistical design and analysis resources that will be used to support contract activities.

The NIAID is connected to the INTERNET and uses IBM-compatible computers that currently run on the Microsoft XP operating system and Microsoft Office 2003 software. MAC users must guarantee that data can be transferred to the Project Officer without corruption of data or figures.

b) Regulatory Compliance: The Technical Proposal must include the following:

i) A plan to develop and maintain quality assurance documentation to support adherence to FDA regulatory standards and guidance that bear on the conduct of assays under GLP, manufacturing under GMP, and performance of clinical trials under GCP standards, as relevant to the Work Plan. Include information on data management for GLP, cGMP, and GCP activities.
ii) Documentation of experience of the Offeror and any proposed subcontractors with performing studies in accordance with FDA regulations and guidance, including GLP, cGMP, and/or GCP guidelines as appropriate to their proposed Statement of Work.
iii) A plan to determine when audits need to be performed, timely scheduling of audits, performance of audits, and responding to audit reports.
iv) An audit history of the facilities proposed for use in carrying out contract activities that will be performed under GLP, GMP and/or GCP.
v) Letters signed by the appropriate authority allowing for pre-award site visits to the Offeror's facility and proposed subcontractors' facilities. Site visits may include GLP, cGMP, or GCP audits (as appropriate) performed by independent auditors contracted by NIAID.

5: EXTERNAL ADVISORY GROUP

The Technical Proposal should describe the types of expertise the Offeror proposes to include on their External Advisory Group. It must also include a plan that describes the agreements to be put in place with members of the External Advisory Group in order to safeguard confidentiality of data and information that may be shared with these external advisors at the Annual Review Meetings.

DO NOT CONTACT POTENTIAL MEMBERS PRIOR TO AWARD OR NAME PROPOSED MEMBERS OF THE EXTERNAL ADVISORY GROUP IN THE TECHNICAL PROPOSAL.

6: ANNUAL REVIEW MEETINGS

The Technical Proposal must include a plan for how the Contractor will plan, organize and conduct Annual Review Meetings that will include the Project Officer and the Contracting Officer, the External Advisory Group, the PI, the Project Manager, key subcontractor staff, and principal scientists involved on the contract.

7: OFFEROR'S PROPOSED STATEMENT OF WORK (maximum 10 pages)

In contracts awarded under this BAA, the Statement of Work shall be the Statement of Work proposed by the Offeror and negotiated and accepted by the NIAID. The Statement of Work is used to define the overall scope of activities that are allowed under the contract. The specific components of the Statement of Work and the scope of the product development activities to be undertaken will depend on the status of the individual therapeutic candidate/product or lead series as part of an overall Strategic Staged Product Development Plan, as well as regulatory requirements. Due to the inherently unpredictable path for many product development activities, it is advisable that the Statement of Work be written in broad enough terms to encompass activities that are not anticipated at the time of award.

The Statement of Work is distinguished from the Work Plan in that it describes what the Contractor shall provide, while the Work Plan describes the specific detailed plan for the implementation of the Staged Strategic Product Development Plan.

The opening paragraph should be followed by a full Statement of Work written in outline format describing each activity (e.g. Manufacturing, Non-Clinical, Clinical) that the Contractor shall perform after the award of the contract. The Statement of Work shall include all activities required to effectively implement the Staged Strategic Product Development Plan and should address all the Specific Technical Requirements described in the Research and Technical Objectives section of the BAA that are applicable to the scope of research for which funding is requested. 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 other deliverables and a timetable for their delivery. Each activity described in the Statement of Work will begin with the words "The Contractor shall…" Where appropriate, divide the Statement of Work into separate Activities and Sub-activities.

The Offeror's proposed Statement of Work should begin as follows:

"Independently, and not as an agent of the U.S. Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to provide the services delineated in the negotiated Statement of Work. The Contractor shall carry out activities within the contract's Statement of Work only as requested and approved by the Project Officer, and may not conduct work on the contract without prior approval from the Project Officer. Approval to carry out specific activities will be linked to approval by the Project Officer of the Strategic Staged Product Development Plan and Work Plan following contract award, approval of Monthly and Annual Progress Reports, review and approval of a Clinical Trial Protocol and supporting materials, and approval of Decision Gate Reports or Decision Gate Change or Deviation Requests (see reporting requirements for a description of these reports).

The Contractor acknowledges the Government's right to modify or delete milestones, process, schedule, budget, or product as need may arise. Because of the nature of this contract and complexities inherent in this and prior programs, at designated

milestones the government will evaluate whether work should be redirected, removed, or whether schedule or budget adjustments should be made. Further, the Government reserves the right to change product, process, schedule, or event to add or delete part or all of these elements as need arise."

Offerors are strongly advised to use the format provided below in preparing the proposed Statement of Work. Examples of Statement of Work language and instructions on functions to be included under each major section of the Statement of Work are provided in italics.

1. Overall Objectives and Scope

   For Example:

   The overall objective of this contract is to advance the development of (name of the candidate/product or lead series) as a therapeutic for the treatment of (name the pathogen). The scope of work for this contract includes preclinical and clinical development activities that fall into the following areas: IND-enabling activities; manufacturing activities; clinical activities; pivotal animal study activities; and NDA-enabling activities."

2. Broad Spectrum Technology (ies) and/or Platform(s) Development Plan

   Specify here the components of the plan to be carried out by the Contractor to develop and evaluate the innovative broad spectrum technology (ies) and/or platform (s) and include information to demonstrate the potential for use to advance the specific product proposed and detailed in the Strategic Staged Product Development and Work Plan.

3. Strategic Staged Product Development Plan and Work Plan

   Within 14 calendar days of the effective date of the contract, the Contractor shall submit an updated Strategic Staged Product Development Plan and Work Plan to the Project Officer and the Contracting Officer for approval prior to the initiation of any activities related to the implementation of these plans. The updated Strategic Staged Product Development Plan and Work Plan shall include the following:

   (Specify here the specific components of the Strategic Staged Product Development Plan and the Work Plan to be carried out by the Contractor and include all technical, regulatory, management, and administrative activities required for implementation If applicable, include the specific components of the Strategic Staged Product Development Plan with respect to product development platform technologies.)

The Contractor shall implement the Strategic Staged Product Development Plan and Work Plan in accordance with activities and timelines approved by the Project Officer and the Contracting Officer.

4. Non-clinical Research and Development

Delineate the specific non-clinical research activities to be carried out under the contract in order to implement the Strategic Staged Product Development Plan, e.g., evaluation of the safety, pharmacokinetics/pharmacodynamics, bioavailability, solubility, formulation, dose, route and schedule of the therapeutic candidate/product or lead series in vitro and in animal models; optimization of the therapeutic candidate/product or lead series through medicinal chemistry; and development, characterization, and quantification and/or validation of reagents and assays required for the clinical and non-clinical evaluation of the therapeutic candidate/product or lead series. If applicable, include functions/activities to be undertaken with respect to the development of animal models to support the evaluation of therapeutic candidates/ products or lead series where efficacy cannot be evaluated in humans.

5. Manufacturing of Therapeutics

Delineate the specific product manufacturing functions and activities to be performed under the contract in order to implement the Strategic Staged Product Development Plan, e.g., development of master and working cell banks; conduct of process development for the manufacture of cGMP therapeutic product; manufacture of non-cGMP and of cGMP pilot lots of therapeutic product in amounts sufficient to carry out required non-clinical and Phase 1 and/or Phase 2 clinical trials; formulation of final drug product; preparation of final drug product; and conduct of long-term stability studies of cGMP bulk and final drug product.

6. Phase 1 Clinical Evaluation

Insert appropriate language as determined by the candidate therapeutic/product or lead series, the scope of clinical research to be carried out, and the study population(s) as specified in the Strategic Staged Product Development Plan. For example, the Contractor shall design, develop, and conduct a (insert Phase 1 and/or Phase 2 clinical trial as appropriate) to evaluate the (insert safety, pharmacokinetics, etc of the candidate therapeutic/product or lead series in the following study populations).

Delineate all additional functions to be performed by the Contractor with respect to the design and implementation of the clinical trial(s), including IND preparation and submission and interactions with the FDA, compliance with NIAID clinical terms of award, the preparation of interim and final analyses of study data, etc.

7. Post-Phase 1 BLA- or NDA-enabling Activities

Delineate the specific post-Phase 1 BLA- or NDA-enabling functions and activities to be undertaken as required to implement the Strategic Staged Product Development Plan, e.g., conduct of manufacturing scale-up leading to consistency lot manufacturing of the therapeutic candidate/product or lead series; design and conduct of a Phase 2 clinical trial; and conduct of animal studies to support licensing under the "Animal Rule".

8. Regulatory Compliance and Data Management

Delineate all regulatory compliance and data management functions and activities to be carried out by the Contractor in order to implement the Strategic Staged Product Development Plan, including: development and implementation of data management and quality control systems and procedures, including the transmission, storage, confidentiality and retrieval of all study data; statistical design and analysis of data resulting from the research undertaken; the provision of raw data or specific analyses of data generated with contract funding; strict adherence to FDA regulations and guidance, including requirements for the conduct of animal studies and assays under GLP, the manufacturing of the therapeutic candidate/product under cGMP, and the conduct of clinical trials under GCP standards; and arranging for independent audits and the provision of interim and final audit reports.

9. Scientific, Technical, Management and Administrative Team

Specify the scientific, technical, management and administrative personnel to be provided by the Contractor in order to implement the Strategic Staged Product Development Plan, including research, manufacturing, regulatory, clinical, statistical, management and administrative activities.

10. Facilities, Equipment and Other Resources

Delineate all facilities, equipment and other resources to be provided by the Contractor in order to implement the Strategic Staged Product Development Plan, including facilities, equipment and other resources required for: conducting IND-enabling assays and animal studies; the production, characterization and release testing of the therapeutic candidate/product or lead series; the design and conduct of clinical trials in humans; the humane care and use of vertebrate animals; and the handling, storing and shipping of potentially dangerous biological and chemical agents.

11. Project Management

Delineate the specific functions and activities to be undertaken by the Contractor to ensure the efficient and effective planning, initiation, implementation, coordination, direction and completion of all contract activities, including the scientific, technical and administrative infrastructure to be provided. Include the functions and activities to be

implemented and associated documentation required, to ensure the timely acquisition of all proprietary rights, including intellectual property rights and all materials needed to perform the project, as well as reporting to the Government all inventions made in the performance of the project.

12. External Advisory Group

Delineate the specific functions to be carried out by the Contractor to establish an External Advisory Group post-award, define the roles and responsibilities of this group, and provide compensation for the services of its members.

13. Contract Review Meetings

Delineate the functions to be carried out by the Contractor to plan and conduct contract review meetings, including the Post-Award Contract Initiation Meeting, the Annual Review Meetings and other meetings with the Project Officer and other Federal staff as may be necessary to monitor progress and review future plans. Include requirements for the preparation and submission of slide presentations and meeting summaries.

14. Publications

Delineate the functions and procedures to be used by the Contractor to comply with project requirements regarding the submission of abstracts and publications for Project Officer review prior to presentation and publication.

SECTION 5: SCIENTIFIC AND TECHNICAL PERSONNEL

The Technical Proposal should include all information relevant to document individual training, education, experience, qualifications and expertise necessary for the successful completion of all contract requirements. Proposals should include a Staffing Plan for the conduct of the Statement of Work with role descriptions and level of effort of scientific and technical personnel, including scientific and technical personnel of all proposal subcontractors. Clearly identify who is to be assigned as Key Personnel. Limit CVs to 2-3 pages and provide selected references for publications relevant to the scope of the BAA, and include experience with projects of similar scope, size and complexity carried out by the offer and any proposed subcontractors over the past 5 years.

1) **Principal Investigator (PI),** including experience and qualifications of the PI to plan, manage, and direct the activities to be carried out under this contract.

2) **Project Manager,** including experience and qualifications to monitor and track day-to-day progress and timelines, coordinate communication, project activities and costs incurred.

3) **Scientific and Technical Personnel:** including experience, expertise, qualifications with respect to non-clinical research and development, manufacture and process development of therapeutics, design and conduct of clinical trials, regulatory compliance, and data management.

SECTION 6: FACILITIES, EQUIPMENT AND OTHER RESOURCES

As appropriate to the Offeror's proposed Statement of Work, the Technical Proposal must:

a) Document the availability and adequacy of facilities, equipment and other resources available for performance of the contract, including:
   i) Detailed laboratory layouts.
   ii) Information regarding ownership/lease of the facility(ies), including documentation of the availability of proposed facilities for the duration of the contract.
   iii) Plans for and procedures to be utilized to insure compliance with all safety guidelines and regulations, including training and monitoring of personnel.
   iv) Plans for obtaining, adding or deleting facilities as necessary due to progress or performance issues that arise during the course of product development.
   v) Availability or plans for obtaining equipment required to perform the proposed Work Plan.

b) Document the availability of appropriate facilities for performing assays and animal studies under GLP standards, production of therapeutic material under GMP guidelines, and performance of clinical studies following GCP guidance as required to implement the Strategic Staged Product Development Plan.

c) Describe provisions for complying with NIH guidelines for the housing and humane care and use of laboratory animals as delineated by the Office of Laboratory Animal welfare (OLAW; http://grants.nih.gov/grants/olaw/olaw.htm).

d) Describe provisions for ensuring safe facilities and resources and for conducting work in accordance with the Biosafety in Microbiological and Biomedical Laboratories guidelines, Centers for Disease Control and Prevention and the National Institutes of Health, 4th edition, May 1999 (http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm) and interim guidelines for influenza, 5th edition (http://www.cdc.gov/flu/h2n2bsl3.htm), as well as Department of Health and Human Services (DHHS) regulations regarding the transfer of select agents (42 CFR Part 72; http://www.cdc.gov/od/ohs/biosfty/shipregs.htm. Safety and Health HHSAR 352.223-70 clauses shall apply.

e) Describe provisions for ensuring safe facilities for the conduct of work in accordance with Recommendations for the Safe Handling of Cytotoxic Drugs, NIH Publication No. 92-2621 and the NIH Guidelines for the Laboratory use of Chemical Carcinogens, NIH Publication No. 81-2385 (http://grants2.nih.gov/grants/guide/notice-files/not92-070.html).

SECTION 7: PROJECT MANAGEMENT

The Technical Proposal must include a Project Management Plan addressing the following:

a) Describe how the project will be staffed, organized and managed, including a detailed description of the responsibilities and the level of effort for all proposed personnel who will be assigned to the contract, and an administrative framework indicating clear lines of authority and responsibility for all personnel including proposed subcontractors and consultants.
b) Describe project management systems that will be used to track activities and to keep multiple activities on time and budget.
c) Outline how the PI will communicate and interact with the Project Officer and the Contracting Officer and how the PI will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).
d) Provide a plan for soliciting, evaluating, negotiating, awarding, and managing subcontracts in accordance with FAR Clause 52.244-2.
e) Describe experience and education of contract management staff in the acquisition and management of subcontracts under Federal contracts.
f) Describe experience with identification and remediation of subcontractor performance problems or noncompliance with subcontract terms and conditions.
g) Provide a Letter of Understanding (LOU) signed by persons with authority to bind each collaborating party involved in the proposed work. The LOU must describe how the collaborating parties will coordinate their efforts to:
    i) Protect intellectual property arising in the performance of the contract.
    ii) Facilitate the development for commercialization of the resulting therapeutic product.
    iii) Resolve disputes among the collaborating parties should such disputes arise in performance of the contract.

SECTION 8: OTHER CONSIDERATIONS

Section L of the BAA provides minimum documentation requirements for the following items. The required information described in Section L should be assembled together, in the following clearly marked sections of the Technical Proposal. Refer to Section L of the BAA for specific requirements. Read each section below carefully. In some cases, offerors may be asked to provide documentation which is in addition to the minimum requirements identified in Section L.

a) Human Subjects

Section L of the BAA specifies the minimum documentation requirements for Human Subjects use. All related documentation should be included in the proposal in a clearly marked section. The Technical Proposal should document all information necessary to evaluate Human Subject use.

b) Care of Live Vertebrate Animals

Section L of the BAA specifies the minimum documentation requirements for Animal Welfare compliance. All related documentation should be included in the proposal in a

clearly marked section. The Technical Proposal should document all information necessary to evaluate Animal Welfare issues.

c) Biological Agents or Toxins
The Technical Proposal should include a plan for biohazard safety and security requirements.

d) Obtaining and Disseminating Biomedical Research Resources
Section L of the BAA specifies the minimum documentation requirements for this element. The Technical Proposal should document all information necessary to evaluate this issue.

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

f) Sharing of Model Organisms for Biomedical Research (Plan)
Section L of the BAA specifies the minimum documentation requirements for Model Organism sharing. All related documentation should be included in the proposal in this clearly marked section. The Technical Proposal should include a plan for sharing Model Organisms as required by this BAA.

ATTACHMENT 14: ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

Application of Platform Technologies for the Development of Therapeutics for Biodefense

DMID-NIAID-NIHAI20080022BARDA

In addition to the format requirements for the Business Proposal that are contained in Section L of the solicitation, the information presented in this section of the BAA is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Background and Introduction, Research and Technical Objectives, all reference material provided as 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 here, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL – TABLE OF CONTENTS

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

SECTION 2 – COST OR PRICE SUPPORT

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

SECTION 3 – UNIFORM COST ASSUMPTIONS

1) **External Advisory Group**
   - **a)** Budget payments to members of the External Advisory Group as Consulting costs. Budget should be commensurate with the proposed number of members and the roles and responsibilities of each member.
2) **Travel**
   - **a)** Budget travel costs for the External Advisory members that are commensurate with their proposed roles and responsibilities.
   - **b)** Budget travel to the Contract Initiation Meeting. Assume the meeting will be held at the Contractor's site.

c) Budget travel for Annual Meetings. Assume Annual Meetings will be held at the Contractor's site. Budget for the Principal Investigator, Project Manager, Business Administrator, Key Personnel and Key Subcontractors to attend a one day meeting.

d) Budget travel for one additional one day meeting per year to be held in Bethesda. Budget for the Principal Investigator, Project Manager, Business Administrator, Key Personnel and Key Subcontractors to attend this meeting.

3) Meetings

a) The Contractor is responsible for organizing and hosting the following meetings and should budget accordingly.

1) Contract Initiation Meeting to be held at the Contractor's site within 30 days of contract initiation

2) Annual Meeting to held at the Contractor's site annually.

3) One additional meeting to held in Bethesda annually.

SECTION 5 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

1) Small Business Subcontracting Plan

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

2) Extent of Small Disadvantaged Business Participation

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

3) Past Performance Data, including references

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