

# SOLICITATION

## SECTION A - SOLICITATION/CONTRACT FORM

1. Purchase Authority: Public Law 92-218 as amended			
2. Request for Proposal (RFP) Number:  BAA-NIAID-DMID-NIHAI2008025	3. Issue Date:  May 12, 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 : Targeted Clinical Trials to Reduce the Risk of Antimicrobial Resistance			
7. ISSUED BY:  Office of Acquisitions, DEA National Institute of Allergy and Infectious Diseases National Institutes of Health, DHHS 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612		8. SUBMIT OFFERS TO:  <b>[NOTE: This solicitation has a required total page limitation of not-to-exceed 180 pages for the Technical Proposal]</b>  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, EDT on September 12, 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 THE OFFICIAL POINT OF RECEIPT FOR THE PURPOSE OF DETERMINING TIMELY DELIVERY AS STATED IN ATTACHMENT 1, "PACKAGING AND DELIVERY OF THE PROPOSAL." IF YOUR PROPOSAL IS NOT RECEIVED BY THE CONTRACTING OFFICER OR DESIGNEE AT THE PLACE AND TIME SPECIFIED, THEN IT WILL BE CONSIDERED LATE AND HANDLED IN ACCORDANCE WITH HHSAR 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. <a href="http://www.ccr.gov">http://www.ccr.gov</a>			
12. <b>PRIMARY POINT OF CONTACT:</b> Frank Videgar, Contract Specialist; Phone 301-402-1490; Email: <a href="mailto:vidergarf@niaid.nih.gov">vidergarf@niaid.nih.gov</a>  <b>SECONDARY POINT OF CONTACT:</b> Teresa A. Baughman, Contracting Officer; Phone: 301-451-3690; Email: <a href="mailto:tb14j@nih.gov">tb14j@nih.gov</a>  FAX: 301-402-0972 <b>COLLECT CALLS WILL NOT BE ACCEPTED.</b>			
		Teresa A. Baughman Contracting Officer and Team Lead, MIDRCB-B Office of Acquisitions, DEA National Institute of Allergy and Infectious Diseases National Institutes of Health, DHHS	

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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**

This contract will provide for the design and conduct of Phase III and/or Phase IV clinical trials to develop and test different therapeutic approaches/regimens that will reduce overexposure to antimicrobial drugs, thereby decreasing the likelihood of antimicrobial drug resistance and preserving the effectiveness of existing antimicrobials.

### **ARTICLE B.2. PRICES/COSTS**

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

### **ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS**

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

### **ARTICLE B.4. ADVANCE UNDERSTANDINGS**

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

#### **Review of Press Releases**

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 14 calendar days prior to the issuance of the press release.

## **SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT**

### **ARTICLE C.1. STATEMENT OF WORK**

- a. Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated (to be proposed by contractor).
- b. The applicable Privacy Act System of Records Number will be specified and shall be used in any design, development, or operation work to be performed under the resultant contract. Disposition of records shall be in accordance with SECTION C of the contract, and by direction of the Project Officer(s).

### **ARTICLE C.2. REPORTING REQUIREMENTS**

#### **a. Technical Progress Reports**

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1. In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this solicitation. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about planned activities for future reporting periods. The frequency and specific content of these reports will be determined prior to contract award.

For proposal preparation purposes only, it is estimated that in addition to the required electronic version(s) no hard copies of these reports will be required as follows:

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

#### **2. Summary of Salient Results**

The Contractor will be required to prepare and submit, with the final report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. This report will be required on or before the expiration date of the contract.

#### **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 this contract. The Contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the final report.

The Contractor shall submit the report in accordance with 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 III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website:

[http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](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.

#### b. Other Reports/Deliverables

Other Reports and Deliverables shall be required. This may include special reports required by regulation or policy and deliverables such as data, vaccine, etc. These will be developed after proposal receipt as a result of finalization of the Statement of Work during negotiations. Special instructions, if applicable, will be provided to offerors in the Attachment entitled "Additional Technical Proposal Instructions."

### ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor 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(b)(2)(ii)) shall be submitted to the Contracting Officer on the completion date of the contract.

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

Contracting Officer  
National Institutes of Health  
National Institute of Allergy and Infectious Diseases  
Office of Acquisitions  
MSC 7612  
6700-B 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.

If special instructions regarding packaging, marking and shipping are required, these will be developed after receipt of proposals as a result of finalization of the Statement of Work during negotiations. Special instructions, if applicable, will be provided to offerors in the Attachment entitled "Additional Technical Proposal Instructions."



## **SECTION E - INSPECTION AND ACCEPTANCE**

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the Project Officer identified in Article G.1. is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at the Division of Microbiology and Infectious Diseases, National Institute of Allergy and Infectious Diseases, National Institutes of Health, Bethesda, Maryland.

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

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

*FAR Clause 52.246-9, 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 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:

- a. 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

Item	Description	Quantity	Delivery Schedule
(1)			
(2)			
(3)			

- b. The above items shall be addressed and delivered to:

Addressee	Deliverable Item No	Quantity

Delivery of other reports and deliverables shall be proposed by the offerors in their technical proposal. They will be developed further after receipt of proposals as a result of finalization of the Statement of Work and other terms and conditions of any resultant contract during negotiations. Specific instructions, if applicable, will be provided to offerors in the Attachment entitled "Additional Technical Proposal Instructions."

### 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 prior to award]**

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

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

(End of Clause)

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

Name	Title
To be specified prior to award	To be specified prior to award

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

- a. Invoice/Financing Request Instructions and Contract Financial Reporting for NIH Cost-Reimbursement Type Contracts NIH(RC)-4 are attached and made part of this contract. The 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, DEA  
National Institute of Allergy and Infectious Diseases, NIH  
6700-B Rockledge Drive, Room 3214, MSC 7612  
Bethesda, MD 20892-7612

E-Mail: NIAIDOAInvoices@niaid.nih.gov

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 NIAID .
  - b. Central Point of Distribution. For the purpose of this contract, the Central Point of Distribution is NIAIDOAInvoices .
  - c. Vendor Identification Number. This is the 7 digit number that appears after the Contractor's name in Block 7 of Standard Form 26. *[Note: This only applies to new contracts awarded on/ after June 4, 2007, and any existing contract modified to include the number.]*
  - 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.

- b. 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. GOVERNMENT PROPERTY**

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

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

## **ARTICLE G.6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE**

### **a. Contractor Performance Evaluations**

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) shall be submitted \_\_\_\_\_ [Insert Dates].

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

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

### **b. Electronic Access to Contractor Performance Evaluations**

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

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

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

## **SECTION H - SPECIAL CONTRACT REQUIREMENTS**

### **ARTICLE H.1. HUMAN SUBJECTS**

Research involving human subjects shall not be conducted under this contract until the protocol developed in Phase I has been approved by the National Institute of Allergy and Infectious Diseases (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 and Plan shall be established and approved prior to beginning the conduct of the clinical trial.

#### **ARTICLE H.4. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)**

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

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

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

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

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds 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.

#### **ARTICLE H.6. NEEDLE EXCHANGE**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

#### **ARTICLE H.7. PRESS RELEASES**

Pursuant to the current HHS annual appropriations act, 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.

## **ARTICLE H.8. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to disseminate scientific information that is deliberately false or misleading.

## **ARTICLE H.9. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows:

"(3) Definition of unauthorized alien. - As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

## **ARTICLE H.10. RESTRICTION ON ABORTIONS**

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds for any abortion.

## **ARTICLE H.11. SALARY RATE LIMITATION LEGISLATION PROVISIONS**

- a. Pursuant to the current HHS annual appropriations act, the Contractor shall not use NIH Fiscal Year funds to pay the direct salary of an individual through this contract at a rate in excess of Executive Level I. 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. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred. See the following Web site for Executive Schedule rates of pay: <http://www.opm.gov/oca/>. *(For current year rates, click on Salaries and Wages / Executive Schedule / Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages / cursor to bottom of page and select year / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)*

## **ARTICLE H.12. 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.

(End of clause)

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](http://www.access.gpo.gov/nara/cfr/waisidx_06/45cfr5b_06.html).

The Privacy Act System of Records applicable to this project is Number **09-25-0200**. 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.13. OMB CLEARANCE or CLINICAL EXEMPTION**

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 has been obtained by the Project Officer and the Contracting Officer has issued written approval to proceed. In addition, in accordance with 5 CFR 1320.3(h)(5), this requirement may be eligible for a Clinical Exemption to OMB Clearance requirements subject to the approval of the NIH Clinical Exemption Review Committee (CERC). The clinical exemption must be obtained and written approval to proceed received from the Project Officer and Contracting Officer before data is collected under this contract or any subcontract.

## **ARTICLE H.14. SUBCONTRACTING PROVISIONS**

### **a. Small Business Subcontracting Plan**

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

### **b. Subcontracting Reports**

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

#### **1. Individual Subcontract Reports (ISR)**

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

April 30th  
October 30th

#### **2. Summary Subcontract Report (SSR)**

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

October 30th

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

[to be provided upon award]  
Contract Specialist

## ARTICLE H.15. INFORMATION SECURITY

The Statement of Work (SOW) requires the Contractor to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies, the Contractor and any subcontractor performing under this contract shall comply with the following requirements:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>

### a. Information Type

Administrative, Management and Support Information

Mission Based Information

### b. Security Categories and Levels

Confidentiality Level:  Low  Moderate  High

Integrity Level:  Low  Moderate  High

Availability Level:  Low  Moderate  High

**Overall Level:**  Low  Moderate  High

### c. Position Sensitivity Designations

- The following position sensitivity designations and associated clearance and investigation requirements apply under this contract.

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

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

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

- The Contractor shall submit a roster, by name, position, e-mail address, phone number and responsibility, of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a Federal information system(s). The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 calendar days of the effective date of the contract. Any revisions to the roster as a result of staffing changes shall be submitted within 15 calendar days of the change. The Contracting Officer shall notify the Contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at: <http://ais.nci.nih.gov/forms/Suitability-roster.xls>.

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov>.

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

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

Levels 5 and 1: Contractor/Subcontractor employees may begin work under the contract after the Contractor has submitted the name, position and responsibility of the employee to the Project Officer, as described in paragraph c. (2) above.

Level 6: In special circumstances the Project Officer may request a waiver of the pre-appointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the Contractor/Subcontractor employee to work under the contract.

d. Information Security Training

The Contractor shall ensure that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: <http://irtsectraining.nih.gov/> prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract.

The Contractor shall maintain a listing by name and title of each Contractor/Subcontractor employee working under this contract that has completed the NIH required training. Any additional security training completed by Contractor/Subcontractor staff shall be included on this listing. [The listing of completed training shall be included in the first technical progress report. (See Article C.2. Reporting Requirements.) Any revisions to this listing as a result of staffing changes shall be submitted with next required technical progress report.]

Contractor/Subcontractor staff shall complete the following additional training prior to performing any work under this contract: [To be determined at time of award.]

e. Rules of Behavior

The Contractor/Subcontractor employees shall comply with the NIH Information Technology General Rules of Behavior at: <http://irm.cit.nih.gov/security/nihitrob.html>.

f. Personnel Security Responsibilities

**Contractor Notification of New and Departing Employees Requiring Background Investigations**

1. The Contractor shall notify the Contracting Officer, the Project Officer, and the Security Investigation Reviewer **within five working days** before a new employee assumes a position that requires a suitability determination or when an employee with a security clearance stops working under the contract. The Government will initiate a background investigation on new employees requiring security clearances and will stop pending background investigations for employees that no longer work under the contract.
2. New employees: Provide the name, position title, e-mail address, and phone number of the new employee. Provide the name, position title and suitability level held by the former incumbent. If the employee is filling a new position, provide a description of the position and the Government will determine the appropriate security level.
3. Departing employees:
  - Provide the name, position title, and security clearance level held by or pending for the individual.

- Perform and document the actions identified in the "Employee Separation Checklist", attached in Section J, ATTACHMENTS of this contract, when a Contractor/Subcontractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request.

g. Commitment to Protect Non-Public Departmental Information Systems and Data

1. Contractor Agreement

The Contractor and its subcontractors performing under this SOW shall not release, publish, or disclose non-public Departmental information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of such information:

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

2. Contractor-Employee Non-Disclosure Agreements

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

h. NIST SP 800-53 Self-Assessment

The contractor shall annually update and re-submit its Self-Assessment required by NIST SP 800-53, *Recommended Security Controls for Federal Information Systems*. ( <http://csrc.nist.gov/publications> - under Special Publications).

Subcontracts: The Contractor's annual update to its Self-Assessment Questionnaire shall include similar information for any subcontractor that performs under the SOW to (1) develop a Federal information system(s) at the Contractor's/Subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the Contractor's/Subcontractor's facility.

The annual update shall be submitted to the Project Officer, with a copy to the Contracting Officer [For option contracts: no later than the completion date of the period of performance/ for all other contracts: indicate due date as determined by the Project Officer/Contracting Officer].

i. Information System Security Plan

The Contractor's draft ISSP submitted with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

Following approval of its draft ISSP, the Contractor shall update and resubmit its ISSP to the Project Officer every three years or when a major modification has been made to its internal system. The Contractor shall use the current ISSP template in Appendix A of NIST SP 800-18, *Guide to Developing Security Plans for Federal Information Systems*. ( <http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf> ). The details contained in the Contractor's ISSP shall be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels of this Article.

Subcontracts: The Contractor shall include similar information for any subcontractor performing under the SOW with the Contractor whenever the submission of an ISSP is required.

j. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

## **ARTICLE H.16. ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY (January 2008)**

Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, and/or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

The Section 508 standards applicable to this contract/order are identified in the Statement of Work. The contractor must provide a written Section 508 conformance certification due at the end of each order/contract exceeding \$100,000 when the order/contract duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its own expense.

In the event of a modification(s) to the contract/order, which adds new EIT products and services or revised the type of, or specifications for, products and services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the contractor submit a completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products and services support Section 508 accessibility requirements. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

[(End of HHSAR 352.270-19(b))]

Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding increment funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Contracting Officer's Technical Representative (also known as Project Officer or Contracting Officer's Representative). Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available at: <http://508.hhs.gov/> under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding incremental funding, as applicable.

### **Schedule for Contractor Submission of Section 508 Annual Report:**

[End of HHSAR 352.270-19(c)]

## **ARTICLE H.17. 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 Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN2722009xxxxxC"

## **ARTICLE H.18. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE**

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

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

## **ARTICLE H.19. YEAR 2000 COMPLIANCE**

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

### **1. Service Involving the Use of Information Technology YEAR 2000 COMPLIANCE--SERVICE INVOLVING THE USE OF INFORMATION TECHNOLOGY**

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

(End of Clause)

## **ARTICLE H.20. SHARING RESEARCH DATA**

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

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

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

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

## **ARTICLE H.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**

Beginning April 7, 2008, NIH-funded investigators shall 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-08-033.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/clausesDGS.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**



## **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** (November 2007) 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.]**

## 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 **52.203-13, Contractor Code of Business Ethics and Conduct** (December 2007).
2. FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).

".....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
HHS Contractor Code of Ethics and Business Conduct Poster	<a href="http://www.oig.hhs.gov/hotline/OIG_Hotline_Poster.pdf">http://www.oig.hhs.gov/hotline/OIG_Hotline_Poster.pdf</a>

3. FAR Clause **52.216-15, Predetermined Indirect Cost Rates** (April 1998).
4. 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."

5. FAR Clause **52.223-12, Refrigeration Equipment and Air Conditioners** (May 1995).
6. FAR Clause **52.224-1, Privacy Act Notification** (April 1984).
7. FAR Clause **52.224-2, Privacy Act** (April 1984).
8. **Alternate II** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).

Additional purposes for which the limited rights data may be used are:

- i) Use (except for manufacture) by support service contractors.
- (ii) Evaluation by nongovernment evaluators.
- (iii) Use (except for manufacture) by other contractors participating in the Government's program of which the specific contract is a part.

9. **Alternate IV** (December 2007), FAR Clause **52.227-14, Rights in Data - General** (December 2007).

10. **Alternate V** (December 2007), FAR Clause **52.227-14, Rights in Data--General** (December 2007).
11. FAR Clause **52.227-16, Additional Data Requirements** (June 1987).
12. FAR Clause **52.227-17, Rights in Data--Special Works** (December 2007).
13. FAR Clause **52.230-2, Cost Accounting Standards** (April 1998).
14. FAR Clause **52.230-3, Disclosure and Consistency of Cost Accounting Practices** (April 1998).
15. FAR Clause **52.230-5, Cost Accounting Standards - Educational Institution** (April 1998).
16. FAR Clause **52.230-6, Administration of Cost Accounting Standards** (March 2008).
17. FAR Clause **52.239-1, Privacy or Security Safeguards** (August 1996).
18. FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
19. FAR Clause **52.243-2, Changes--Cost Reimbursement** (August 1987), **Alternate V** (April 1984).
20. FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).
21. FAR Clause **52.251-1, Government Supply Sources** (April 1984).

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 **352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities** (January 2001).*
3. *HHSAR Clause **352.270-7, Paperwork Reduction Act** (January 2006).*
4. *HHSAR Clause **352.270-8(b), Protection of Human Subjects** (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).*
2. ***NIH(RC)-11, Research Patient Care Costs** (4/1/84).*

## 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 **52.219-28, Post-Award Small Business Program Representation** (June 2007).

(a) *Definitions.* As used in this clause--

*Long-term contract* means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-8, Option to Extend Services, or other appropriate authority.

*Small business concern* means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall rerepresent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the exercise date specified in the contract for any option thereafter.

(c) The Contractor shall rerepresent its size status in accordance with the size standard in effect at the time of this rerepresentation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at <http://www.sba.gov/services/contractingopportunities/sizestandardsttopics/>.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the rerepresentation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure they reflect current status. The Contractor shall notify the contracting office by e-mail, or otherwise in writing, that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following rerepresentation and submit it to the contracting office, along with the contract number and the date on which the rerepresentation was completed:

The Contractor represents that it [ ] is, [ ] is not a small business concern under NAICS Code assigned to contract number.

[Contractor to sign and date and insert authorized signer's name and title].

(End of clause)

b. **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.nlr.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)*

c. FAR Clause **52.247-67, Submission of Transportation Documents for Audit** (February 2006).

(a) The Contractor shall submit to the address identified below, for prepayment audit, transportation documents on which the United States will assume freight charges that were paid--

- (1) By Contractor under a cost-reimbursement contract; and
- (2) By a first-tier subcontractor under a cost-reimbursement subcontract thereunder.

(b) Cost-reimbursement Contractors shall only submit for audit those bills of lading with freight shipment charges exceeding \$100. Bills under \$100 shall be retained on-site by the Contractor and made available for on-site audits. This exception only applies to freight shipment bills and is not intended to apply to bills and invoices for any other transportation services.

(c) Contractors shall submit the above referenced transportation documents to--

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*[To be filled in by the Contracting Officer]*

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

### SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

#### SOLICITATION ATTACHMENTS

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of The Proposal	[Attached to BAA]
Attachment 2:	Proposal Intent Response Sheet	[Attached to BAA]
Attachment 3:	Broad Agency Announcement Description	[Attached to BAA]
Attachment 4:	Background and Introduction	[Attached to BAA]
Attachment 5:	Research and Technical Objectives	[Attached to BAA]
Attachment 6:	Additional Technical Proposal Instructions, Format for Technical Proposal, and Table of Contents	[Attached to BAA]
Attachment 7:	Uniform Cost Assumptions	[Attached to BAA]

#### TECHNICAL PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 8:	Targeted/Planned Enrollment Table	<a href="http://rcb.cancer.gov/rcb-internet/forms/enroll-table.pdf">http://rcb.cancer.gov/rcb-internet/forms/enroll-table.pdf</a>
Attachment 9:	Technical Proposal Cost Summary	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 10:	Summary of Related Activities	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 11:	Government Notice for Handling Proposals	<a href="http://www.niaid.nih.gov/contract/forms/form7.pdf">http://www.niaid.nih.gov/contract/forms/form7.pdf</a>
Attachment 12:	Protection of Human Subject Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (Formerly Optional Form 310)	<a href="http://rcb.cancer.gov/rcb-internet/forms/of310.pdf">http://rcb.cancer.gov/rcb-internet/forms/of310.pdf</a>
Attachment 13:	Project Objectives, NIH 1688-1	<a href="http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf">http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf</a>

#### BUSINESS PROPOSAL ATTACHMENTS

Attachment No.	Title	Location
Attachment 14:	Proposal Summary and Data Record, NIH-2043	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>
Attachment 15:	Small Business Subcontracting Plan	<a href="http://www.hhs.gov/osdbu/read/SampleSubcontractingPlan.doc">http://www.hhs.gov/osdbu/read/SampleSubcontractingPlan.doc</a>
Attachment 16:	Breakdown of Proposed Estimated Costs (plus fee) w/Excel Spreadsheet	<a href="http://oamp.od.nih.gov/contracts/BUSCOST.HTM">http://oamp.od.nih.gov/contracts/BUSCOST.HTM</a> <a href="http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls">http://oamp.od.nih.gov/Division/DFAS/spshexcl.xls</a>
Attachment 17:	Offeror's Points of Contact	<a href="http://www.niaid.nih.gov/contract/forms.htm">http://www.niaid.nih.gov/contract/forms.htm</a>



<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 18:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf">http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf</a>

## **INFORMATIONAL ATTACHMENTS**

<b>Attachment No.</b>	<b>Title</b>	<b>Location</b>
Attachment 19:	Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	<a href="http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf">http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf</a>
Attachment 20:	Privacy Act System of Records	<a href="http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm">http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm</a>
Attachment 21:	Safety and Health, HHSAR Clause 352.223-70	<a href="http://rcb.cancer.gov/rcb-internet.nci.nih.gov/forms/safety&amp;health-1-06.pdf">http://rcb.cancer.gov/rcb-internet.nci.nih.gov/forms/safety&amp;health-1-06.pdf</a>
Attachment 22:	Procurement of Certain Equipment, NIH(RC)-7	<a href="http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf">http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf</a>
Attachment 23:	Research Patient Care Costs, NIH(RC)-11	<a href="http://www.niaid.nih.gov/contract/forms/nih-rc-11.pdf">http://www.niaid.nih.gov/contract/forms/nih-rc-11.pdf</a>
Attachment 24:	Inclusion Enrollment Report	<a href="http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.pdf">http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.pdf</a>
Attachment 25:	Disclosure of Lobbying Activities, OMB Form SF-LLL	<a href="http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf">http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf</a>
Attachment 26:	Commitment to Protect Non-Public Information Contractor Agreement	<a href="http://irm.cit.nih.gov/security/Nondisclosure.pdf">http://irm.cit.nih.gov/security/Nondisclosure.pdf</a>
Attachment 27:	Roster of Employees Requiring Suitability Investigations	<a href="http://ais.nci.nih.gov/forms/Suitability-roster.xls">http://ais.nci.nih.gov/forms/Suitability-roster.xls</a>
Attachment 28:	Employee Separation Checklist	<a href="http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf">http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf</a>

## **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. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2006)]

*(a) Definitions. As used in this provision--*

*"Discussions" are negotiations that occur after establishment of the competitive range that may, at the Contracting Officer's discretion, result in the offeror being allowed to revise its proposal.*

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

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

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

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

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

*(c) Submission, modification, revision, and withdrawal of proposals.*

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

*(2) The first page of the proposal must show--*

*(i) The solicitation number;*

*(ii) The name, address, and telephone and facsimile numbers of the offeror (and electronic address if available);*

*(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the solicitation and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;*

*(iv) Names, titles, and telephone and facsimile numbers (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this solicitation; and*

*(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.*

*(3) Submission, modification, revision, and withdrawal of proposals.*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

*(e) Restriction on disclosure and use of data.*

*(1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following statements, specifying the particular portions of the proposal which are to be restricted:*

*Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.*

*The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.*

*If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.*

*The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages ( insert page numbers, paragraph designations, etc. or other identification).*

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

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

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

*(f) Contract award.*

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

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

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

*(4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.*

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

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

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

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

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

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

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

*(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.*

*(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.*

*(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;*

*(iv) A summary of the rationale for award.*

(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the solicitation, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

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

*(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.*

**b. NAICS CODE AND SIZE STANDARD**

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

1. The North American Industry Classification System (NAICS) code for this acquisition is 541712 .
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.**

**c. 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 June 1, 2009.

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

**d. ESTIMATE OF EFFORT**

In accordance with the Broad Agency Announcement (BAA) design, the Government has issued a general announcement of the agency's research interest. Submissions in response to this BAA will represent each offeror's creative and innovative approach to the specific research. Therefore, the Government is unable to provide an estimate of effort but reminds all offerors that they shall propose effort that is consistent with the nature and complexity of their proposed research.

**e. COMMITMENT OF PUBLIC FUNDS**

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

**f. COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

**g. RELEASE OF INFORMATION**

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

**h. PREPARATION COSTS**

This RFP 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, DEA  
National Institute of Allergy and Infectious Diseases, NIH, DHHS  
6700-B Rockledge Drive, Room 3214, MSC 7612  
Bethesda, MD 20892-7612

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

(End of Provision)

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

**k. AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."**

Copies of the "Federal ADP and Telecommunications Standards Index" can be purchased from the U.S. Government Printing Office, Superintendent of Documents, Washington, DC 20402.



## 2. INSTRUCTIONS TO OFFERORS

### a. GENERAL INSTRUCTIONS

#### INTRODUCTION

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

#### 1. Contract Type and General Clauses

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

#### 2. Authorized Official and Submission of Proposal

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

##### I. COVER PAGE

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

##### II. TECHNICAL PROPOSAL

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

##### III. BUSINESS PROPOSAL

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

#### 3. Proposal Summary and Data Record (NIH-2043)

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

#### 4. Separation of Technical and Business Proposals

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. Uniform Resource Locators (URLs) in Contract Proposals

All proposals must be self-contained within the specific page limitations cited elsewhere in this solicitation. Unless otherwise specified, URLs/Internet addresses shall not be used to provide information necessary to the review because reviewers are under no obligation to review the Internet sites.

#### 6. 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 Research and Technical Objectives (see Section J, Attachment 5). Such proposals may be considered if overall performance would be improved or not compromised and if they are in the best interests of the Government. Alternative proposals, or deviations from any requirements of this RFP, shall be clearly identified.

#### 7. Evaluation of Proposals

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

#### 8. 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.

#### 9. 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.

## 10. Standards for Privacy of Individually Identifiable Health Information

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

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

## 11. Privacy Act - Treatment of Proposal Information

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

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

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

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

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

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

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

- to the cognizant audit agency and the Government Accountability 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.

## 12. Selection of Offerors

- a. The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques.

The committee may suggest that the Contracting Officer request clarifying information from an offeror.

- b. The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c. If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d. If the Government intends to conduct discussions prior to awarding a contract -
  1. Based on the written recommendations of the technical review committee/peer review group/source evaluation panel, the Contract Officer will, in concert with Program Staff, establish an Order of Merit Ranking. This ranking will be based upon the scientific/technical merit, scientific priority, programmatic balance, and the availability of funds.
  2. Communications will be held with offerors whose proposals are the most highly rated. All aspects of the proposal are subject to discussion, including cost, technical approach, and contractual terms and conditions. At the conclusion of discussion, each offeror still being considered for award shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct limited negotiations to finalize details of the award with the selected source(s) in accordance with HHSAR 315.370.
- e. The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. The process will take into consideration the results of the technical evaluation, the past performance evaluation, and the cost analysis.
- f. The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding \$25,000 will be published in FedBizOpps.

### 13. 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.

#### 14. ROTC Access and Federal Military Recruiting on Campus

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

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

#### 15. Past Performance Information

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

A list of the last five contracts completed during the past three years and the last three contracts awarded that are similar in nature to the Research and Technical Objectives (Attachment 5). Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this solicitation, a "major subcontract" is defined as any subcontract greater than \$550,000.

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. North American Industry Classification System (NAICS) 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.

**16. Electronic and Information Technology Accessibility, HHSAR 352.270-19(a) (January 2008)**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794D), as amended by the Workforce Investment Act of 1998, and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Provisions (36 CFR part 1194), require that, unless an exception applies, all EIT products and services developed, acquired, maintained, or used by any Federal department or agency permit:

1. Federal employees with disabilities to have access to and use information and data that is comparable to the access and use of information and data by Federal employees who are not individuals with disabilities; and
2. Members of the public with disabilities seeking information or services from a Federal agency to have access to and use of information and data that is comparable to the access and use of information and data by members of the public who are not individuals with disabilities.

Accordingly, any vendor submitting a proposal/quotations/bid in response to this solicitation must demonstrate compliance with the established EIT accessibility provisions. Information about Section 508 provisions is available at <http://www.section508.gov/>. The complete text of Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm>.

The Section 508 standards applicable to this solicitation are identified in the Statement of Work/ Specification/Performance Work Statement. In order to facilitate the Government's evaluation to determine whether EIT products and services proposed meet applicable Section 508 accessibility standards, offerors must prepare an HHS Section 508 Product Assessment Template, in accordance with its completion instructions, and provide a binding statement of conformance. The purpose of the template is to assist HHS acquisition and program officials in determining that EIT products and services proposed support applicable Section 508 accessibility standards. The template allows vendors or developers to self-evaluate their products or services and document in detail how they do or do not conform to a specific Section 508 standard. Instructions for preparing the HHS Section 508 Product Assessment Template may be found at <http://508.hhs.gov>.

Respondents to this solicitation must also provide any additional detailed information necessary for determining applicable Section 508 standards conformance, as well as for documenting EIT products and/or services that are incidental to the project, which would constitute an exception to Section 508 requirements. If a vendor claims its products and/or services, including EIT deliverables such as electronic documents and reports, meet applicable Section 508 standards in its completed HHS Section 508 Product Assessment Template, and it is later determined by the Government - i.e., after award of a contract/order, that products and/or services delivered do not conform to the described accessibility in the Product Assessment Template, remediation of the products and/or services to the level of conformance specified in the vendor's Product Assessment Template will be the responsibility of the Contractor at its expenses.

(End of provision)

**17. 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.

**18. 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. Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).*
- c. Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).*
- d. Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).*
- e. 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. **[See also, ATTACHMENT 6 entitled "Additional Technical Proposal Instructions."]**

### 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. Research and Technical Objectives and Statement of Work

##### 1. Objectives

Offerors are required to provide a Statement of Work in accordance with the Attachment entitled "Research and Technical 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

The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. 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. 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.

## 3. Technical Evaluation

Proposals will be technically evaluated in accordance with SECTION M - Evaluation Factors for Award of this solicitation.

**IMPORTANT NOTE TO OFFERORS: The following 12 paragraphs [(5) through (16)] shall be addressed, as applicable, in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."**

#### 4. 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. 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)*

## **5. 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.

## **6. 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](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html) 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\\_prof\\_protect.html](http://www.centerwatch.com/order/pubs_prof_protect.html).

In addition, the NCI 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.

## **7. 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](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](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.**

## 8. 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 RFP.

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.

### **9. Research Involving Prisoners as Subjects**

- a. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: <http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.pdf>.
- b. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

1. The sole purposes are:
  - a. to describe the prevalence or incidence of a disease by identifying all cases, or
  - b. to study potential risk factor associations for a disease, and
2. The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2 7) and determined and documented that:
  - a. the research presents no more than minimal risk, and
  - b. no more than inconvenience to the prisoner subjects, and

c. prisoners are not a particular focus of the research.

For more information about this Waiver see [http://www.hhs.gov/ohrp/special/prisoners/Prisoner waiver 6-20-03.pdf](http://www.hhs.gov/ohrp/special/prisoners/Prisoner%20waiver%206-20-03.pdf)

#### 10. **Research Involving Human Fetal Tissue**

Human Fetal Tissue means tissue or cells obtained from a dead human fetus, including human embryonic stem cells, human pluripotent stem cells and human embryonic germ cells.

The governing federal statute is the Public Health Service Act, 42 U.S.C. 289g 1 and 289g 2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and <http://grants1.nih.gov/grants/guide/notice-files/not93-235.html> and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

By signing the face page of the proposal, the offeror (authorized institutional official) certifies that researchers using human fetal tissue are in compliance with 42 USC 289g 2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to profit, and does not include reasonable payment for costs associated with the collection processing, preservation, storage, quality control or transportation of these tissues.

Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local law.

#### 11. **Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)**

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

The NIH Guidelines for Research Involving Recombinant DNA Molecules at:

( <http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html> and the May 28, 2002 Notice, Compliance with the NIH Guidelines for Research Involving Recombinant DNA Molecules at:

( <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html> ) and any subsequent revisions to the Guide Notice) stipulates biosafety and containment measures for recombinant DNA research and delineates critical, ethical principles and key safety reporting requirements for human gene transfer research (See Appendix M of the NIH Guidelines). These guidelines apply to both basic and clinical research studies.

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

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

As specified in Appendix M 1 C 4 of the NIH Guidelines, any serious adverse event must be reported immediately to the IRB, the IBC, the Office for Human Research Protections (if applicable), and the

NIH Office for Biotechnology Activities (OBA), followed by the filing of a written report with each office/group and copies to the Project Officer and Contracting Officer, at:

( [http://www4.od.nih.gov/oba/rac/guidelines\\_02/Appendix\\_M.htm#\\_Toc7255836](http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836)).

## 12. 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 Review by Human Pluripotent Stem Cell Review Group (HPSCRG)

If, in response to the solicitation, the offeror proposes to use human embryonic germ cells, it must submit, as a separate attachment to its proposal, an original and two copies of the documentation and assurances that address the areas covered in the "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells" at: ( <http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html>).

Prior to any award made under this solicitation, the documentation and assurances will be subject to review by the HPSCRG, which meets in a public meeting. No research involving the use of human embryonic germ cells may begin prior to HPSCRG approval.

Offerors are encouraged to review issues pertaining to informed consent processes described in Section II.B.2.b of the NIH Guidelines. Offerors should also review the March 19, 2002, DHHS Office of Human Research Protection's document titled "Guidance for Investigators and Institutional Review Boards Regarding Research Involving Human Embryonic Stem Cells, Germ Cells, and Stem Cell Derived Test Articles," at ( <http://stemcells.nih.gov/StaticResources/news/newsArchives/stemcell.pdf>).

## 13. 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.

#### 14. 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.

## 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**

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

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

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

If the resultant contract is part of a collaborative program involving multiple sites, the data sharing will be governed by a dissemination plan to be developed jointly following award. Offerors must include in their proposals a statement of willingness to work collaboratively after award with the other funded sites to prepare a joint dissemination plan. Coordinating Center proposals should describe methods to coordinate the dissemination planning and implementation. The Coordinating Center must include a budget and justification for any additional costs of this collaborative effort.

16. **Information Security** is applicable to this solicitation and the following information is provided to assist in proposal preparation.

**IMPORTANT NOTE TO OFFERORS: The following information shall be addressed in a separate section of the Technical Proposal entitled, "INFORMATION SECURITY."**

The Federal Information Security Management Act of 2002 (P.L. 107-347) (FISMA) requires each agency to develop, document, and implement an agency-wide information security program to safeguard information and information systems that support the operations and assets of the agency, including those provided or managed by another agency, contractor (including subcontractor), or other source. The National Institute of Standards and Technology (NIST) has issued a number of publications that provide guidance in the establishment of minimum security controls for management, operational and technical safeguards needed to protect the confidentiality, integrity and availability of a Federal information system and its information.

The Statement of Work (SOW) requires the successful offeror to (1) develop, (2) have the ability to access, or (3) host and/or maintain a Federal information system(s). Pursuant to Federal and HHS Information Security Program Policies the following requirements apply to this solicitation:

Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>

a. Information Type

Administrative, Management and Support Information:

Scientific and Technical Research and Innovation

Mission Based Information:

b. Security Categories and Levels

Confidentiality Level:  Low  Moderate  High  
 Integrity Level:  Low  Moderate  High  
 Availability Level:  Low  Moderate  High  
**Overall Level:  Low  Moderate  High**

c. Position Sensitivity Designations

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

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

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

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

Upon award, the Contractor will be required to submit a roster of all staff (including subcontractor staff) working under the contract who will develop, have the ability to access, or host and/or maintain a federal information system(s). The Government will determine and notify the Contractor of the appropriate level of suitability investigation required for each staff member. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for Contractor use at:

<http://ais.nci.nih.gov/forms/Suitability-roster.xls>

Upon receipt of the Government's notification of applicable Suitability Investigations required, the Contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: <http://ais.nci.nih.gov>.

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

d. Information Security Training

HHS policy requires Contractors/Subcontractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each Contractor/Subcontractor employee has completed the NIH Computer Security Awareness Training course at: <http://irtsectraining.nih.gov/> prior to performing any contract work, and thereafter completing the NIH-specified fiscal year refresher course during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

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

e. Offeror's Official Responsible for Information Security

The offeror shall include in the "Information Security" part of its Technical Proposal the name and title of its official who will be responsible for all information security requirements should the offeror be selected for an award.



f. NIST SP 800 53 Self Assessment

The offeror must include in the "Information Security" part of its Technical Proposal, a completed Self-Assessment required by NIST Draft SP 800-53, Recommended Security Controls for Federal Information Systems. ( <http://csrc.nist.gov/publications> - under Special Publications).

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW to (1) develop a Federal information system(s) at the offeror's/subcontractor's facility, or (2) host and/or maintain a Federal information system(s) at the offeror's/subcontractor's facility.

## g. Draft Information System Security Plan

**[NOTE: Offerors are requested to submit the ISSP with their Business Proposal.]**

The offeror must include a draft Information System Security Plan (ISSP) using the current template in Appendix A of NIST SP 800 18, Guide to Developing Security Plans for Federal Information Systems ( <http://csrc.nist.gov/publications/nistpubs/800-18-Rev1/sp800-18-Rev1-final.pdf>). The details contained in the offeror's draft ISSP must be commensurate with the size and complexity of the requirements of the SOW based on the System Categorization determined above in subparagraph (b) Security Categories and Levels.

Subcontracts: The offeror must include similar information for any proposed subcontractor that will perform under the SOW with the offeror whenever the submission of an ISSP is required.

Note to Offeror: The resultant contract will require the draft ISSP to be finalized in coordination with the Project Officer no later than 90 calendar days after contract award. Also, a contractor is required to update and resubmit its ISSP to NIH every three years following award or when a major modification has been made to its internal system.

## h. Common Security Configurations

The contractor shall ensure that any information technology acquired under this contract incorporates the applicable common security configuration established by the National Institute of Standards and Technology (NIST) at <http://checklists.nist.gov>.

## i. References

1. Federal Information Security Management Act of 2002 (FISMA), Title III, E-Government Act of 2002, Pub. L. No. 107-347 (Dec. 17, 2002); <http://csrc.nist.gov/drivers/documents/FISMA-final.pdf>
2. DHHS Personnel Security/Suitability Handbook: <http://www.hhs.gov/ohr/manual/pssh.pdf>
3. NIH Computer Security Awareness Training Course: <http://irtsectraining.nih.gov/>

The following NIST publications may be found at the following site: <http://csrc.nist.gov/publications/>

[Note: The search tool on the left side of this page provides easy access to the documents.]

4. NIST Special Publication 800-16, Information Technology Security Training Requirements; and Appendix A-D

5. NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems
6. NIST SP 800-26, Revision 1, Computer Security
7. NIST SP 800-53, Revision 1, Recommended Security Controls for Federal Information Systems
8. NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I; and  
Volume II, Appendices to Guide For Mapping Types of Information and Information Systems To Security Categories, Appendix C, and Appendix D
9. NIST SP 800-64, Security Considerations in the Information System Development Life Cycle
10. FIPS PUB 199, Standards for Security Categorization of Federal Information and Information Systems
11. FIPS PUB 200, Minimum Security Requirements for Federal Information and Information Systems

## c. BUSINESS PROPOSAL INSTRUCTIONS

### 1. Basic Cost/Price Information

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

### 2. Proposal Cover Sheet

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

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

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

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

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

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

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

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

**1. Direct Labor**

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

**2. Materials**

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

**3. Subcontracted Items**

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

**4. Raw Materials**

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

**5. Purchased Parts**

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

**6. Fringe Benefits**

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

**7. Indirect Costs**

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

**8. Special Equipment**

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

**9. Travel**

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing.

**10. Other Costs**

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

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

*(a) Exceptions from cost or pricing data.*

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

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

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

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

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

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

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

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

*(1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15.2 of FAR 15.408.*

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

*(End of provision)*

## 5. Salary Rate Limitation in Fiscal Year 2008

Offerors are advised that pursuant to P.L.110-161, no NIH Fiscal Year 2008 (October 1, 2007 - September 30, 2008) 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/08tables/pdf/ex.pdf>

**\*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 Executive Level I Salary rates.

## 6. 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 RFP 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 (Individual Subcontract Reports (ISRs) and Summary Subcontract Reports (SSRs) 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 in the subcontracting plan, see FAR Clause 52.219-9, Small Business Subcontracting Plan, and the Sample Subcontracting Plan which is provided as an attachment to this RFP in SECTION J.

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

30% for Small Business; 11% for Small Disadvantaged Business; 5% for Women-Owned Small Business; 3% for HUBZone Small Business; and 3% for Veteran-Owned Small Business and Service-Disabled Veteran-Owned Small Business.

## 7. HUBZone Small Business Concerns

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

## 8. Extent of Small Disadvantaged Business Participation

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS 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 RFP. A total target for SDB participation by the Prime Contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors.



In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

#### EXAMPLE

##### Targets for SDB Participation - NAICS Industry Subsector 223

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

\*Note: FAR Subpart 9.6 defines "Contractor team arrangements" to include two or more companies forming a partnership or joint venture to act as a potential Prime Contractor, or a potential Prime Contractor who agrees with one or more companies to have them act as its subcontractors on a specific contract or acquisition program. For purposes of evaluation of the SDB participation factor, FAR 19.1202-4 requires that SDB joint ventures and teaming arrangements at the prime level be presented separately from SDB participation by subcontractors.

## 9. 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.**

## 3. Government-Furnished Property

No Government Furnished Property is offered for this acquisition

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, Contractors Guide for Control of Government Property, which can be found at: <http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm>

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

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

- (1) The solicitation number (or other procurement identification number).*
- (2) The offeror's name and remittance address, as stated in the offer.*
- (3) The signature (manual or electronic, as appropriate), title, and telephone number of the offeror's official authorized to provide this information.*
- (4) The name, address, and 9 digit Routing Transit Number of the offeror's financial agent.*
- (5) The offeror's account number and the type of account (checking, savings, or lockbox).*
- (6) If applicable, the Fedwire Transfer System telegraphic abbreviation of the offeror's financial agent.*

*(7) If applicable, the offeror shall also provide the name, address, telegraphic abbreviation, and 9 digit Routing Transit Number of the correspondent financial institution receiving the wire transfer payment if the offeror's financial agent is not directly on line to the Fedwire and, therefore, not the receiver of the wire transfer payment.*

*(End of Provision)*

**c. Financial Capacity**

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

**d. Incremental Funding**

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

**10. Qualifications of the Offeror**

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

**a. General Experience**

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

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

Organizational experience is defined as the accomplishment of work, either past or on-going, which is comparable or related to the effort required by this RFP. This includes overall offeror or

corporate experience, **but not** the experience and/or past performance of individuals who are proposed as personnel involved with the Statement of Work in this RFP.

**c. Performance History**

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

**d. Pertinent Contracts**

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

**e. Pertinent Grants**

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

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

**11. Subcontractors**

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

- a. Willingness to perform as a subcontractor for specific duties (list duties).
- b. What priority the work will be given and how it will relate to other work.
- c. The amount of time and facilities available to this project.
- d. Information on their cognizant field audit offices.
- e. How rights to publications and patents are to be handled.
- f. A complete cost proposal in the same format as the offeror's cost proposal.

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this RFP should refer to the following Web Site for a listing of clauses that are required to be incorporated in Research & Development (R&D) subcontracts with educational institutions:

<http://ocm.od.nih.gov/contracts/rfps/FDP/FDPclausecover.htm>

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

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

**13. Representations and Certifications - SECTION K**

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

**14. Travel Costs/Travel Policy**

**a. Travel Policy**

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

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

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be 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

Proposals will be evaluated against the following four evaluation factors in the order of importance: 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, 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. The estimated cost of an offer must be reasonable for the tasks to be performed and will be subject to a cost realism analysis by the Government.

The merit of each technical proposal will be evaluated by a peer review group. The Government reserves the right to convene multiple peer review groups to evaluate proposals. Offerors must demonstrate in their proposals that they have the necessary expertise and capabilities for conducting the proposed research. The evaluation will be based on the demonstrated capabilities of the offerors in relation to the needs of the project as set forth in the BAA. Each proposal must document the feasibility of successful implementation of its approach to the Research and Technical Objectives of the BAA. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria.

Following the peer review, the Government will establish an Order of Merit Ranking of all proposals. Negotiations are conducted with offerors selected from the Order of Merit Ranking to address identified weaknesses, questions, and areas for clarification, as well as to refine the proposed Statement of Work. The final selection for award(s) is based upon the evaluation factors, in addition to importance to the agency programs (programmatic balance) and fund availability.

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

### 2. 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 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 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](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 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 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 with 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 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 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 trials 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 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 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. TECHNICAL EVALUATION CRITERIA

The technical evaluation criteria are used by the peer review group when reviewing the technical proposals. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes, however, the subfactors within each criterion are of equal importance and will be given equal consideration.

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO THE ATTACHMENT ENTITLED "ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS" OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF TECHNICAL PROPOSALS.

<b>CRITERIA</b>	<b>WEIGHT</b>
<b>CRITERION 1: SCIENTIFIC AND TECHNICAL MERIT</b>	<b>70</b>
A. Adequacy, feasibility, and scientific and technical merit of the offeror's proposed methods and approaches to successfully complete each of the requirements specified in the offeror's Statement of Work, including proposed solutions for resolving potential methodological and inferential problems.	
B. Applicability of the offeror's Statement of Work to the overall research and technical objectives of the BAA.	
C. Potential of the study design proposed by the offeror to challenge the current paradigms of clinical practice and impact the public health problem of antimicrobial resistance.	
<b>CRITERION 2: SCIENTIFIC AND TECHNICAL PERSONNEL</b>	<b>10</b>
A. Principal Investigator (PI): Appropriateness and adequacy of the education, training, experience, expertise, qualifications and effort of the proposed PI with respect to the conduct of clinical trials in compliance with all current Federal regulations (21 CFR 11 and/or similar regulations)	
B. Scientific and Technical Personnel: Appropriateness and adequacy of the education, training, experience, expertise, qualifications and effort of all proposed scientific and technical personnel, including proposed subcontractors, and consultants with respect to the conduct of clinical trials in compliance with all current Federal regulations (21 CFR 11 and/or similar regulations).	
<b>CRITERION 3: PROJECT MANAGEMENT</b>	<b>10</b>
Adequacy of the management approach in terms of staffing, coordinating, organization, communications, leadership, and lines of authority, as well as management of subcontracts and consultants.	
<b>CRITERION 4: ORGANIZATIONAL EXPERIENCE, CAPABILITY, AND FACILITIES</b>	<b>10</b>
A. Availability and adequacy of the necessary facilities, equipment, and other resources to successfully implement the proposed research.	
B. Experience and capability of the organization, as well as proposed subcontractors and consultants, if any, with similar projects of comparable size and scope.	
<b>TOTAL POSSIBLE POINTS:</b>	<b>100</b>

## 5. PAST PERFORMANCE FACTOR

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

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

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

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

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

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

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

## 6. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

The extent of the offeror's Small Disadvantaged Business Participation Targets will be evaluated before 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 to which SDB concerns are specifically identified
- b. Extent of commitment to use SDB concerns
- c. Complexity and variety of the work SDB concerns are to perform
- d. Extent of participation of SDB concerns in terms of the value of the total acquisition.

# ATTACHMENT 1: PACKAGING AND DELIVERY OF THE PROPOSAL

**PAPER SUBMISSION:** The paper copy is the official copy for recording timely receipt of proposals.

SUBMISSION OF PROPOSALS BY FACSIMILE OR E-MAIL IS **NOT** ACCEPTABLE.

**A. EXTERNAL PACKAGE MARKING:**

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

**"BAA-NIAID-DMID-NIHAI2008025"  
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"**

**B. PAPER COPIES and CD-Rom to:**

<b>If Hand Delivery or Express Service</b>	<b>If using U.S. Postal Service</b>
Frank Vidergar Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Frank Vidergar Contract Specialist Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

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

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

**C. NUMBER OF COPIES:**

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

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

**FORMATTING AND LAYOUT:**

Use your usual word processing and spreadsheet programs to prepare and format the technical and business proposals.

**Documents submitted using Adobe .pdf shall be submitted using a .pdf searchable format.**

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

- Offerors shall NOT use 8.5 x 14 legal size paper.
- Proposals shall NOT include links to Internet Web site addresses (URLs) or otherwise direct readers to alternate sources of information.

**CREATING AND NAMING ELECTRONIC FILES:**

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

2. It is preferred that the Technical Proposal be submitted as one electronic file document.

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

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

3. CDs should be named using the following format:

**Technical Proposal: Company name-RFP number-technical-date**

**Business Proposal: Company name-RFP number-business-date**

**THE NUMBER OF COPIES AND APPLICABLE PAGE LIMITATIONS REQUIRED OF EACH PART OF YOUR PROPOSAL ARE AS SPECIFIED BELOW. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.**

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

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	<p><b><u>PAPER</u></b> One (1) unbound SIGNED ORIGINAL. Ten (10) unbound COPIES</p> <p><b><u>ELECTRONIC FILES ON CD</u></b> Three (3) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)</p>	<b>Not to Exceed 180 pages (inclusive of all Attachments and Appendices)</b>
Business Proposal	<p><b><u>PAPER</u></b> One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES</p> <p><b><u>ELECTRONIC FILES ON CD</u></b> Three (3) Compact Disks containing an electronic copy of the Business Proposal</p>	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	<p>This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk.</p> <p>See Section J, Attachment entitled <a href="#">Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet</a> to access the Excel Workbook.</p>	N/A

**ATTACHMENT 2: PROPOSAL INTENT RESPONSE SHEET**

**BAA-NIAID-DMID-NIHAI2008025**

**BAA Title: Targeted Clinical Trials to Reduce the Risk of Antimicrobial Resistance**

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **July 25, 2008**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

DO INTEND TO SUBMIT A PROPOSAL

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

**Company/Institution Name (print):** \_\_\_\_\_

**Address (print):** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Project Director's Name (print):** \_\_\_\_\_

**Title (print):** \_\_\_\_\_

**Signature/Date:** \_\_\_\_\_

**Telephone Number and E-mail Address (print clearly):**

\_\_\_\_\_

\_\_\_\_\_

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

**Name:** \_\_\_\_\_

**Title:** \_\_\_\_\_

**E-Mail Address:** \_\_\_\_\_

**Telephone Number:** \_\_\_\_\_

**Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

*(Continue list on a separate page if necessary)*

RETURN VIA FAX OR E-MAIL TO:

OA, DEA, NIAID, NIH

6700-B Rockledge Drive, Room 3214, MSC 7612

Bethesda, MD 20892-7612

Attn: Frank Vidergar

BAA-NIAID-DMID-NIHAI2008025

FAX# (301) 402-0972

Email: [vidergarf@niaid.nih.gov](mailto:vidergarf@niaid.nih.gov)

## **ATTACHMENT 3: BROAD AGENCY ANNOUNCEMENT DESCRIPTION**

### **TARGETED CLINICAL TRIALS TO REDUCE THE RISK OF ANTIMICROBIAL RESISTANCE BAA NIAID-DMID-NIHAI2008025**

#### **BROAD AGENCY ANNOUNCEMENT INFORMATION**

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA). 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 solicitation. The proposed 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 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 in response to the BAA are evaluated in accordance with the Evaluation Criteria specified in SECTION M, EVALUATION FACTORS FOR AWARD.

The NIAID will assess whether the work proposed should be redirected, removed, and/or whether schedule or budget adjustments should be made. As a result, during discussions with offerors, the NIAID reserves the right to modify or delete proposed milestones, decision points, research plans, process, schedule, budget or product.

The NIAID estimates that the total cost (direct and indirect costs combined) available for **all** contract awards is \$9.1 million per year. However, it is anticipated that the total cost for the award(s) may vary depending upon the scope of the project and the technical objectives of the award(s). The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. In no event shall the period of performance exceed seven (7) years.

## ATTACHMENT 4: BACKGROUND and INTRODUCTION

### TARGETED CLINICAL TRIALS TO REDUCE THE RISK OF ANTIMICROBIAL RESISTANCE BAA NIAID-DMID-NIHAI2008025

Research supported and conducted by the National Institute of Allergy and Infectious Diseases (NIAID), the National Institutes of Health (NIH), the 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 success of antimicrobials against disease-causing microbes is among modern medicine's greatest achievements. However, after more than 50 years of widespread use, many disease-causing microbes have developed resistance to available antimicrobials, as documented by *in vitro* susceptibility testing. For example, more than 70 percent of the bacteria that cause hospital-acquired infections are resistant to at least one commonly used antimicrobial agent. In addition, resistant bacteria such as community-associated methicillin resistant *Staphylococcus aureus* (CA-MRSA) have developed resistance to existing antimicrobials and cause widespread and often severe infections in otherwise healthy people.

Every use of antimicrobials creates a selective pressure for the development of resistant organisms. The inappropriate use of antimicrobials accelerates this process. For example, a physician will sometimes prescribe unnecessary antimicrobials to placate an insistent patient who has a viral infection or an as-yet undiagnosed condition. Other times physicians opt to treat a non-existing bacterial infection rather than risk missing a potentially treatable disease.

Compounding the situation is the fact that the rate of drug "loss" due to antimicrobial resistance is greater than the rate of new drug licensure. In the past, it was widely assumed that as the overall effectiveness of an antimicrobial decreased due to increased resistance within a population, a new antimicrobial would soon be developed to replace it. But today, the pipeline for new antimicrobials is sparse. The pharmaceutical industry continues to move away from antimicrobial development to focus on more profitable areas, such as medicines for chronic illnesses.

Finding ways to effectively treat bacterial infections with antimicrobials that minimize the development of drug resistance is a key goal of antimicrobial resistance research supported by DMID. The NIAID works with academic, industry, medical, and Federal partners to:

- Find ways to quickly diagnose drug-resistant microbes;
- Determine how microbes develop drug resistance;
- Test new strategies of antimicrobial usage in the clinic setting that may limit emergence of drug-resistant microbes; and
- Develop new drugs and vaccines targeted to drug-resistant microbes.

Of particular interest to the NIAID is to further investigate whether more prudent use of antimicrobials will help slow the development of resistance; and whether the efficacy of an antimicrobial that is "lost" due to the existence of resistance warrants further study in a variety of disease entities, host conditions and pharmacokinetic/pharmacodynamic parameters (PK/PD).



## ATTACHMENT 5: RESEARCH AND TECHNICAL OBJECTIVES

### TARGETED CLINICAL TRIALS TO REDUCE THE RISK OF ANTIMICROBIAL RESISTANCE BAA NIAID-DMID-NIHAI2008025

#### RESEARCH AND TECHNICAL OBJECTIVES:

This BAA targets infectious diseases where improved treatment strategies could reduce the risk of antimicrobial resistance and preserve the effectiveness of existing antimicrobials. A central goal of this solicitation is to target disease areas experiencing the greatest antimicrobial selective pressure, and within these areas, develop strategies that test the safety and effectiveness of different therapeutic approaches/regimens that reduce the probability of the emergence of drug resistance by minimizing unnecessary drug exposure.

Contracts to be awarded under this BAA will support the design and conduct of Phase III and/or Phase IV clinical trials of new strategies for the use of licensed, off-patent antimicrobial therapies to reduce the risk of antimicrobial resistance in selected infectious diseases.

For the purposes of this BAA, the disease areas of interest are the following:

- Acute otitis media
- Pneumonia
- Urinary tract infections
- Bacteremia

Both community- and hospital-associated infections in these disease areas are eligible.

For the purposes of this BAA, the experimental variables of interest are the following:

- Need for antimicrobial therapy (single or combination therapy)
- Length of antimicrobial therapy
- Frequency/dosage of antimicrobial therapy

Eligible strategies may include, but are not limited to:

- Shorter treatment duration for pneumonia and other infections, e.g., otitis media, urinary tract infections and bacteremia;
- Different dosage or frequency, supported by PK/PD data, where optimal treatment has not been well defined, e.g., the use of penicillin in penicillin-resistant pneumonia; or
- Withholding of antimicrobials (altogether) for certain diseases, e.g., otitis media and identifying eligible populations for this type of strategy.

Proposals may be submitted by the same organization for more than one clinical trial but a separate Technical and Business Proposal will be required for each proposed clinical trial.

**This solicitation will not support research to evaluate the safety and efficacy of investigational therapeutics.**

For contract(s) awarded under this BAA, the contractor shall:

1. be responsible for the design and development of the clinical protocol, protocol-related documents, e.g., Case Report Forms, Manual of Operations, informed consent form, and protocol amendments;
2. be responsible for the implementation and conduct of the clinical trial in accordance with all Federal regulatory requirements, Good Clinical Practice (GCP), International Conference on Harmonization (ICH), and Good Laboratory Practice (GLP) guidelines;
3. manage and oversee the conduct of the clinical trial at no more than a total of six participating clinical sites, including the prime contractor;
4. provide clinical research support services, which should include statistical support and data management;
5. provide monitoring and safety oversight (must be provided by other than the prime contractor); and
6. provide all necessary equipment, facilities, training and other resources, including study products.

Responsibility for the sponsorship of Investigational New Drug (IND) applications shall be determined post-award and may rest with the prime contractor or with the NIAID.

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

**TARGETED CLINICAL TRIALS TO REDUCE THE RISK OF  
ANTIMICROBIAL RESISTANCE  
BAA NIAID-DMID-NIHAI2008025**

**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 Additional Technical Proposal Instructions are tailored to the specific requirements of the BAA. The information requested in these instructions should be used along with Section L of the BAA 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 BAA, 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 and/or consultants to perform portions of the Statement of Work should clearly identify the specific tasks for which they plan to utilize subcontractors and/or consultants, as well as the method and level of integration/coordination between the prime Contractor and all proposed subcontractors and/or consultants, and the expected advantages of such an approach.

**Offerors must refer to the BAA Attachment entitled "Packaging and Delivery of the Proposal," which details strict guidelines, including page limitations, formatting and layout of proposals, and prohibits the offerors use of links to internet web site addresses (URLs) to direct readers to alternate sources of information.**

**TECHNICAL PROPOSAL – TABLE OF CONTENTS**

1. **PROPOSAL TITLE PAGE.** Include BAA title and number, name of organization, DUNS number, and identify if the proposal is an original or a copy.
2. **GOVERNMENT NOTICE FOR HANDLING PROPOSALS** (See SECTIONS J and L of the BAA.)
3. **TECHNICAL PROPOSAL - TABLE OF CONTENTS** (Each offeror's Technical Proposal shall include a Table of Contents.)

4. **TECHNICAL PROPOSAL OVERVIEW** (suggested 3-page maximum – included in total page limits)

Provide a brief description of the proposed project, including:

- A. A 1-2 paragraph summary of the proposed clinical trial, including: the infectious disease to be studied, rationale, patient population(s) and sample size (including number of participating sites), study arms, and outcome measurements.
- B. Identify the prime Contractor **key** personnel with degrees, titles and role(s) in the project.
- C. Identify the subcontractors proposed as clinical sites and list subcontractor **key** personnel with degrees, titles and role in the project.
- D. Identify any other proposed subcontractors and list **key** personnel with degrees, titles and role in the project.
- E. A brief description of the facilities and other resources to be made available by the offeror and all proposed subcontractors.

5. **TECHNICAL DISCUSSIONS**

IN ADDITION TO THE GUIDANCE IN SECTION L OF THE BAA, THIS SECTION OF YOUR TECHNICAL PROPOSAL SHOULD INCLUDE DOCUMENTATION TO DEMONSTRATE HOW YOU WILL ACCOMPLISH THE WORK DETAILED IN YOUR STATEMENT OF WORK. IT IS RECOMMENDED THAT YOUR PROPOSAL BE ORGANIZED IN ACCORDANCE WITH THE ORDER OF YOUR STATEMENT OF WORK AND THE TECHNICAL EVALUATION CRITERIA PROVIDED IN SECTION M.

ADDITIONALLY, PLEASE ENSURE THAT YOUR TECHNICAL PROPOSAL ADDRESSES THE FOLLOWING:

**NOTE:** All Technical Requirements that **MUST** be satisfied after award are indicated in Attachment 6, Section 6, Post-Award Requirements. Offerors must address responsibility for complying with these post-award requirements in their proposed Statement of Work.

A. **SCIENTIFIC AND TECHNICAL MERIT**

1. **Protocol Development**

- a. **Protocol Synopsis:** Provide a detailed synopsis for the proposed Phase III or Phase IV clinical trial. The protocol synopsis should be limited to a maximum of 20 pages (included in total page limits) and should include the following:
  - 1) Rationale and Background (explain innovative aspects of the approach);
  - 2) Study Objectives;
  - 3) Primary hypothesis;
  - 4) Study population(s) (describe inclusion/exclusion criteria and rationale for study population choices, addressing age, gender and demographic preferences);
  - 5) Study arms and duration;
  - 6) Primary and secondary endpoints;
  - 7) Duration of follow-up of study subjects and contingency plans for any safety-related issues; and
  - 8) Sample size calculation and statistical method employed, rationale for the sample size calculation, and relevance to the power of outcome measurement.
- b. **Protocol Timelines:** Provide proposed timelines for protocol development, protocol implementation, clinical trial completion and analysis of final study data.

## 2. Protocol Implementation

- a. **Recruitment and Retention of Study Participants:** Provide a plan for the screening, recruitment, enrollment and retention of the number and types of subjects required to serve as subjects for the proposed clinical trial. Identify anticipated problems and difficulties that may arise in recruiting and retaining these subjects and discuss proposed approaches to overcome or minimize such problems and difficulties.
- b. **Access to Study Populations:** Provide evidence of the incidence of resistance associated with the disease to be studied at each proposed clinical site with documentation regarding numbers of patients visiting or admitted at each clinical site.
- c. **Selection of Proposed Clinical Sites:** Provide a rationale for the selection of clinical sites proposed and describe approaches to be used and remedial actions to be taken when clinical sites fail to meet projected target accrual within the protocol timelines proposed.

## 3. Clinical Trial Support Services

### a. Statistical Support and Data Management

- 1) Discuss proposed plans and procedures to be developed and implemented to ensure appropriate objectivity and independence in carrying out statistical support and data management services.
- 2) Describe plans and procedures to establish, maintain and update the data collection system and to provide for the quality control of all clinical and laboratory data in compliance with all current Federal regulations (21 CFR 11 and/or similar regulations).
- 3) Describe how the data shall be presented to DMID/NIAID and what provisions shall be made available for DMID to query the data.
- 4) Describe plans and procedures to provide security against anticipated risks, including loss of confidentiality of subject electronic records and data summaries.

### b. Monitoring and Safety Oversight

- 1) Provide a general description of the Data and Safety Monitoring Plan for the proposed Phase III or Phase IV clinical trial. Technical Requirements for the final Data and Safety Monitoring Plan are indicated in Section L.
- 2) Provide plans and discuss procedures appropriate to the proposed clinical trial to monitor all participating clinical sites to verify that the rights and well-being of the subjects are protected, trial data are accurate, complete and verifiable, and the conduct of the trial is in compliance with GCP and GLP (Good Laboratory Practice, ICH Harmonization), the approved protocol and applicable regulatory requirements.

## **B. SCIENTIFIC AND TECHNICAL PERSONNEL**

The Technical Proposal should include all information relevant to document individual education, training, experience, qualifications and expertise, including that of the Principal Investigator (PI) and scientific and technical personnel of the prime contractor and any proposed subcontractors and consultants, necessary for the successful completion of all scientific and technical requirements of the contract in compliance with all current Federal regulations (21 CFR Part 11, 21 CFR Part 312 and/or similar regulations). Clearly identify who is to be assigned as Key Personnel. Limit CVs to 2-3 pages (to be included in total page limits), provide selected references for publications relevant to the scope of the BAA, and include experience with projects of similar scope, size and complexity.

## **C. PROJECT MANAGEMENT**

### **1. Overall Project Management**

- a. Describe how the project, including the clinical trial, will be organized and managed. Provide a Staffing Plan indicating role descriptions, level of effort of key scientific and technical personnel, and clear lines of authority and responsibility for the personnel, including all proposed subcontractors. Include a diagram of the proposed organizational/management structure for the project.
- b. Describe project management systems that will be used to track activities and to keep multiple activities on time and within budget. The plan should include a description of quality control methods that will be used to ensure the effective initiation, implementation, management and oversight of contract activities.
- c. Discuss and outline communication, monitoring, and management of the project both internally and externally (at subcontractor facilities).
- d. Discuss plans to organize a post-award contract initiation meeting. Discuss plans to organize Annual Review Meetings to provide for a thorough assessment of contract status, progress, problems and approaches to their resolution, and future plans.

### **2. Acquisition and Management of Subcontractors**

Describe plans to secure, execute, and manage any subcontractor services in accordance with the requirements established by Federal contracting regulations (FAR Clause 52.244.2). Discuss proposed plans to assess subcontractor performance, identify problems and deficiencies, and develop and implement correction actions when necessary.

## **D. ORGANIZATIONAL EXPERIENCE, CAPABILITIES, AND FACILITIES**

### **1. Organizational Experience and Capabilities**

In addition to the information requested under Section L, Part c. Business Proposal Instructions, paragraph 12, Qualifications of the Offeror, all offerors are requested to include in their technical proposals a description of at least two examples of similar projects performed by your organization, and any proposed subcontractors, that are of comparable size and scope and/or related to the effort proposed in response to this BAA. The projects may be either completed or ongoing.

## 2. Facilities

As appropriate to the proposed Statement of Work, the Technical Proposal must document the following:

- a. ownership/lease of facilities, including availability of proposed facilities for the duration of the contract;
- b. plan for obtaining, adding or deleting facilities as necessary due to progress or performance issues that arise during the course of the project;
- c. clinical facilities for patient screening, enrollment, administration of study product(s), monitoring and follow-up, including inpatient facilities, where necessary, for the conduct of the proposed clinical trial;
- d. laboratory facilities and equipment for performing protocol-specific tests to determine patient eligibility and monitor safety;
- e. pharmacy facilities for receipt, labeling, packaging, storage and inventory of study product(s);
- f. facilities for the storage, under appropriate conditions, of clinical specimens, as required for the proposed clinical trial;
- g. areas for the secure storage of patient records, including procedures for secure access for designated personnel only;
- h. provision of computers at all clinical sites for the secure entry and maintenance of clinical and laboratory data; and
- i. data management facility for receipt, verification, storage and retrieval of clinical and laboratory data.

## 6. POST-AWARD REQUIREMENTS

The following POST-AWARD requirements will apply. Offerors are instructed to address responsibility for complying with these requirements in the proposed Statement of Work for the Technical Proposal. Offerors are NOT required to submit documentation to address these post-award requirements in their technical proposals. Instructions for submitting documentation associated with post-award requirements will be provided by the Project Officer following award.

### A. Protocol Implementation Requirements

1. Contractors must develop their clinical protocols and associated documents such as the Data and Safety Monitoring Plan, in accordance with DMID standardized protocol development processes and templates (<http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/>) and must ensure that the clinical trial is conducted in accordance with all Federal regulations, NIAID Clinical Terms of Award (<http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf>) and, the International Conference on Harmonization ICH-E6-GCP guidelines.
2. The clinical protocol and all protocol-related documents, including the Manual of Operations, Investigators Brochure, Case Report Forms, and informed consent documents, must be submitted to the Project Officer for review by the appropriate NIAID staff and modified, as necessary, to accommodate recommendations resulting from such review. The final clinical protocol and protocol-related documents require approval by the Project Officer in order to proceed to the protocol implementation stage.

3. The contractor shall be required to submit, for Project Officer and appropriate DMID Staff to review and provide written approval of, all clinical protocols, as well as amendments and modifications to the final protocol, and protocol-related documents prior to implementation.
4. Following DMID approval of the clinical protocol, the contractor shall secure Institutional Review Board (IRB) approval and submit to the Project Officer copies of all Essential Documentation, as defined by the ICH-E6-GCP (<http://www.fda.gov/cder/guidance/959fnl.pdf>), to conduct the final, Project Officer-approved, clinical trial for all participating clinical sites.
5. The contractor shall be required to submit a list of research-related Standard Operating Procedures (SOPs) that shall be used to carry out the clinical research activities.
6. Responsibility for Investigational New Drug (IND) sponsorship will be determined post-award and may rest with either the contractor or with the NIAID; the NIAID will make this determination. If an IND is necessary, the contractor shall be responsible for preparing and submitting required documentation as instructed by the Project Officer to the U.S. Food and Drug Administration (FDA) to implement the IND, e.g., providing a list of references for the study and the general investigational plan.
7. The contractor shall retain all study-related documents in compliance with regulatory requirements 2 CFR312.62(c) and 45 CFR46.115(b).

#### **B. Clinical Trial Support Services Requirements**

1. The Contractor shall be required to submit a final Data and Safety Monitoring Plan to the NIAID Medical Officer, his/her designees, and the DMID Medical Affairs/Pharmacovigilance support contractor for approval.
2. DMID will establish an independent Safety Oversight Structure, e.g., Data and Safety Monitoring Board (DSMB), to review study data and monitor the safety of study participants. The final protocol, study data, and interim and final data analyses must be presented to the Safety Oversight Structure in accordance with the approved Data and Safety Monitoring Plan.
3. It is required that Serious Adverse Events (SAEs) must be reported on the DMID SAE Report Form located at <http://www3.niaid.nih.gov/research/resources/DMIDClinRsrch/SAE.htm>. All SAE Reports must be submitted to the NIAID Medical Officer, his/her designees, and the DMID Medical Affairs/Pharmacovigilance support contractor.
4. Written reports resulting from initial clinical site assessments, if required, and ongoing clinical site monitoring, including problems and deficiencies identified along with recommended corrective actions, must be submitted to the Project Officer for review. In addition, corrective actions will require Project Officer approval prior to implementation.
5. The contractor shall respond to FDA inquiries on statistical design and statistical analysis plans pre- and post-IND submission, if required, as directed by the Project Officer.
6. The contractor shall be required to prepare interim analyses and reports, as requested by the DSMB or Project Officer, for use in monitoring and safety oversight.



7. The contractor shall be required to prepare an ICH/FDA compliant Clinical Study Report upon completion of the clinical trial.

7. **TECHNICAL PROPOSAL -- STATEMENT OF WORK FORMAT** (suggested maximum of 15 pages – included in total page limits)

Offeror(s) are required to provide a Statement of Work in their proposal(s). The Statement of Work shall be developed by each offeror based on the information in the Attachment entitled "Research and Technical Objectives," and shall consist of two parts: (1) Scope, and (2) Technical Requirements. Provided below is an outline of the Statement of Work format that should be used by all offeror(s) in the preparation of their Technical Proposals. The headers and subheaders may be adjusted to match the requirements as proposed in each offeror's individual technical proposal.

Contracts awarded as a result of this BAA will include the Statement of Work proposed by the offeror, as negotiated and accepted by the Government. Offeror(s) will be required to perform the activities and provide the resources appropriate to the scope of their specific negotiated Statement of Work.

The opening paragraph under the Technical Requirements section of the Statement of Work shall be followed by a description of all activities that the Contractor shall perform after the award of the contract. The Technical Requirements shall include all activities required to effectively implement the project and shall 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, along with a timetable for their delivery.

***[NOTE TO OFFEROR: Each offeror shall provide detailed specifications of the requirement utilizing the following sample outline of tasks and subtasks. Any tasks or subtasks that are not applicable to your proposed effort should be deleted. Any tasks or subtasks specific to your proposed effort not addressed below shall be added.]***

***[See Statement of Work outline on next page]***

## STATEMENT OF WORK

### 1. **SCOPE**

**Instruction to offerors:** Provide a brief description (one to two paragraphs) of the overall project and objectives in broad terms that indicates the size and magnitude of the proposed effort.

### 2. **TECHNICAL REQUIREMENTS**

***[NOTE TO OFFEROR: The Technical Requirements shall begin with the following introductory paragraph.]***

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

#### **A. PROTOCOL DEVELOPMENT**

#### **B. PROTOCOL IMPLEMENTATION**

#### **C. CLINICAL TRIAL SUPPORT SERVICES**

1. Statistical Support and Data Management
2. Monitoring and Safety Oversight

#### **D. SCIENTIFIC AND TECHNICAL PERSONNEL**

#### **E. PROJECT MANAGEMENT**

#### **F. CLINICAL RESEARCH FACILITIES, EQUIPMENT, AND OTHER RESOURCES**

1. Outpatient Clinical Research Facilities
2. Inpatient Clinical Research Facilities
3. Clinical Laboratory Facilities
4. Research Pharmacy Facilities
5. General Clinical Research Facilities and Resources
6. Standard Operating Procedures (SOPs)

## **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 clearly marked sections of the Technical Proposal. Refer to Section L of the BAA for specific requirements. 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**
- B. **Biological Agents or Toxins**
- C. **Obtaining and Disseminating Biomedical Research Resources**
- D. **Sharing Research Data (Plan)**
- E. **Information Technology (IT) Systems Security**

**ATTACHMENT 7: UNIFORM COST ASSUMPTIONS**  
**TARGETED CLINICAL TRIALS TO REDUCE THE RISK OF**  
**ANTIMICROBIAL RESISTANCE**

**BAA NIAID-DMID-NIHAI2008025**

**In addition to the instructions and format requirements for the proposal that are contained in Section L of the BAA, the information presented in this attachment is intended to provide uniform cost assumptions that apply to the subject BAA.**

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 here should be used as further guidance for the development of your proposal. Offerors should consider and include the information provided below in the development of their Technical and Business Proposal.

**UNIFORM COST ASSUMPTIONS**

**General Instruction:** Offerors may submit proposals for more than one clinical trial; however, a separate Business Proposal is required for each proposed clinical trial.

The following uniform cost assumptions shall be used by all offerors in preparation of their cost proposal.

- A. **Study Drugs** – Any study drug proposed must be an off-patent antibiotic.
- B. **Statistical support and data management** – Appropriate support in this area for the proposed clinical trial must be included in the proposal.
- C. **Clinical monitoring costs** - Appropriate support in this area for the proposed clinical trial must be included in the proposal.
- D. **Meetings and Teleconferences**

The Contractor shall be required to make all logistical arrangements for all contract meetings and teleconferences (except 3. below). For cost purposes, assume that the conference room required for each meeting will need to accommodate 40 people. Assume that the Contractor will prepare a 30-page hand-out for all 40 attendees at each meeting.

- 1. **Contract Initiation Meeting:** Assume one meeting in Bethesda, Maryland within three months after contract award to discuss contract initiation. Assume that this meeting will require a two-night stay and shall be attended by the Contractor's Principal Investigator and key personnel. (Assume that Subcontractor personnel will not attend this meeting.)

2. Annual Contract/Protocol Meetings: Assume one meeting per year in Bethesda, Maryland to discuss clinical trial status, progress and issues. Assume that this will require a two-night stay and shall be attended by the Contractor's Principal Investigator and key personnel, as well as any proposed subcontractors' Principal Investigator and key personnel.
3. Data and Safety Monitoring Board (DSMB) Meetings: Assume one meeting per year in Bethesda, Maryland. Assume that this will require a two-night stay and shall be attended by the Contractor's Principal Investigator and two other key personnel.

**NOTE: The Contractor will not be required to make logistical arrangements for the DSMB meetings.**

4. General Scientific Meetings: Offerors shall propose a total of \$3,500 annually for the Principal Investigator (PI) and three key personnel for travel to general scientific meetings for presentations of work conducted under this contract.
  5. Protocol Specific Teleconferences: Assume two protocol specific teleconferences per month with participation of the Contractor's Principal Investigator and key personnel, as well as any proposed subcontractors' Principal Investigator and key personnel. Assume that these teleconferences will have 20 participants per teleconference.
  6. FDA Teleconference: Assume three teleconferences over the life of the contract with the Food and Drug Administration (FDA) with participation of the Contractor's Principal Investigator and two other key personnel. Assume that these teleconferences will have 30 participants per teleconference.
- E. **Purchase of Equipment** - Support will NOT be provided for the purchase of equipment under this contract.
- F. **Alterations and Renovations** - Support will NOT be provided for facility alterations and renovations under this contract.