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

RFP-NIH-NIAID-DMID-07-12
"Clinical Trial for Community-Acquired Methicillin-Resistant Staphylococcus aureus (CA-MRSA) Infections"

OMB Control Number 0990-0115

1. **OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY SOLICITATION AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.** http://www.fedbizopps.gov/

2. **SECTION A – SOLICITATION/CONTRACT FORM -- PURCHASE AUTHORITY: FAR 1.602-1**
NOTE: The issuance of this solicitation does not commit the government to an award.

3. **Issue Date:**	4. **Due Date:**	5. **Small Bus. Set-Aside:**
April 15, 2006	August 15, 2006 **Time:** 4:00 PM, Local Time	[ ]Yes [x] No **8(a) Set-Aside:** [ ]Yes [x] No **NAICS: 541710** (See Part IV, Section L.)

6. **Just In Time:**	7. **Number of Awards:**	8. **Technical Proposal Page Limits:**
[x] No [ ] Yes (See Part IV, Section L.)	[x] Only 1 Award [ ] Multiple Awards	[ ] No [x] Yes **160 Pages** **See Attachment 1, Packaging and Delivery of Proposal**

9. **Issued By:**	10. [x] **NIAID reserves the right to make awards without discussion.**	
Ross Kelley Contracting Officer Office of Acquisitions, DEA, NIH, NIAID 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	11. **Options:** **[x] No** **[ ] Yes** (See Part IV, Section L.)	12. **Period of Performance:** **June 15, 2007 through June 14, 2012**

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : Ross Kelley **Phone:** 301- 402-2234 **Fax:** 301-480-4675 **E-Mail:** RKelley@niaid.nih.gov	**Name:** Barbara A. Shadrick **Phone:** 301-496-7288 **Fax:** 301-402-0972 **E-Mail:** bs92y@nih.gov	Director, OA Address (see Block 9.)

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

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

18. **DELIVERY ADDRESS INFORMATION**

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

21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with FAR 15.208 entitled " Submission, Modification, Revision, and Withdrawal of Proposals." FACSIMILE OR E-MAIL SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

DETAILED TABLE OF RFP CONTENTS

PART I - THE SCHEDULE

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

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The contract will conduct a multi-site Phase II/III clinical trial to evaluate off-patent antimicrobials and/or wound care for the management of uncomplicated skin and soft tissue infection among outpatients in areas in the United States where the prevalence of Community Acquired Methicillin-Resistant Staphylococcus aureus (CA-MRSA) is high.

ARTICLE B.2. PRICES/COSTS

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

ARTICLE B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

ARTICLE B.4. ADVANCE UNDERSTANDINGS

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

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work, dated April 15, 2006, attached hereto and made a part of this Solicitation. (See Section J - List of Attachments, Attachment 4)

ARTICLE C.2. REPORTING REQUIREMENTS

Reporting Requirements and Deliverables

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

SECTION D - PACKAGING, MARKING AND SHIPPING

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

SECTION E - INSPECTION AND ACCEPTANCE

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

b. For the purpose of this SECTION, the Project Officer identified in Article G.1., is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at, 6610 Rockledge Drive, Bethesda, MD 20892.

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 Article C.1. and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the items in SECTION C, ARTICLE C.2. in accordance with the stated delivery schedule.

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

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

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

SECTION G - CONTRACT ADMINISTRATION DATA

Any contract awarded from this RFP will contain the following:

ARTICLE G.1. PROJECT OFFICER

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

[To be specified prior to award]

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

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

The Government may unilaterally change its Project Officer designation.

ARTICLE G.2. KEY PERSONNEL

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

The following individuals are considered to be essential to the work being performed hereunder:

NAME TITLE

[To be specified prior to award]

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

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

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

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

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

Contract No. (This is the 17 digit number that appears in Block 2 of the SF-26, i.e. HHSN266200711000C.)

ADB Contract No. (This is the 10 digit number that appears in the upper left hand corner of the SF-26, i.e. N01-AI-71234.)

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

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

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

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

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

ARTICLE G.4. GOVERNMENT PROPERTY

If this RFP will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the DHHS Publication (OS) 686, entitled, **Contractor's Guide for Control of Government Property**, which can be found at:

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

ARTICLE G.5. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

a. Contractor Performance Evaluations

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

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

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the

contract file, and may be used to support future award decisions.

b. Electronic Access to Contractor Performance Evaluations

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

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

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

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. HUMAN SUBJECTS

Research involving human subjects shall not be conducted under this contract until the final protocol has been approved by the Project Officer. Written notice of such approval shall be provided by the Contracting Officer, after 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 coompleted 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

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

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

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

[Applicable information to be included at award]

ARTICLE H.6. NEEDLE EXCHANGE

a. Pursuant to Public Law(s) cited in paragraph b., below, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

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

[Applicable information to be included at award]

ARTICLE H.7. PRIVACY ACT

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

The Privacy Act System of Records applicable to this project is Number 09-25-0200 (see http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm).

ARTICLE H.8. 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 or for conducting interviews 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.9. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

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

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

b. Subcontracting Reports

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

(1) Individual Subcontract Reports (ISR)

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

April 30th
October 30th

(2) Summary Subcontract Report (SSR)

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

October 30th

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

Contracting Officer/Contract Specialist
[e-mail address will be provided at time of award]

ARTICLE H.10. SALARY RATE LIMITATION LEGISLATION PROVISIONS

[NOTE: This requirement will be revised in the resultant contract subject to the implementation of a FY07 Public Law covering the period of 10/01/2006 through 09/30/2007.]

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

b.

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

[Applicable information to be included at award]

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

For the period 10/1/05 - 12/31/05, the Executive Level I rate is $180,100. Effective January 1, 2006, the Executive Level I rate increased to $183,500 and will remain at that rate until it is revised. See the web site listed below for the Executive Schedule rates of pay:

FOR FY-06 EXECUTIVE LEVEL SALARIES EFFECTIVE JANUARY 1, 2006:
http://www.opm.gov/oca/06tables/html/ex.asp
(Note: This site shows the FY-06 rates. For previous years, click on "salaries and wages" and then scroll down to the bottom of the page and click on the year to locate the desired Executive Level salary rates.)

ARTICLE H.11. INFORMATION SECURITY

The Statement of Work (SOW) requires the contractor to develop or access Federal automated information systems; therefore, the contractor shall comply with the "DHHS Information Security Program Policy" (http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc) as set forth below. The

contractor shall include this provision in any subcontract awarded under this contract.

a. Information Type

******** ***(NOTE: The resultant contract will include the Information Type, however for the purposes of this RFP, the Information Type is specified in SECTION L.2.b. Technical Proposal Instructions of this RFP.) *******

[ ] Administrative, Management and Support Information:

[ ] Mission Based Information:

b. Security Categories and Levels

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

c. Position Sensitivity Designations

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

[ ] **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).

(2) The contractor shall submit a roster, by name, position and responsibility, of all IT staff working under the contract. The roster shall be submitted to the Project Officer, with a copy to the Contracting Officer, within 14 days of the effective date of the contract. Any revisions to the Roster as a result of staffing changes shall be submitted within fifteen (15) calendar days of the change. The Contracting Officer shall notify the contractor of the appropriate level of suitability investigations to be performed. An electronic template, "Roster of Employees Requiring Suitability Investigations," is available for contractor use at:
http://ais.nci.nih.gov/forms/Suitability-roster.xls

Upon receipt of the Government's notification of applicable Suitability Investigation required, the contractor shall complete and submit the required forms within 30 days of the notification. Additional submission instructions can be found at the "NCI Information Technology Security Policies, Background Investigation Process" website: http://ais.nci.nih.gov. **Please note that NCI points of contract do not apply to this acquisition. Contact your NIAID Contract Specialist for applicable contact information.**

Contractor employees who have had a background investigation conducted by the U.S. Office of Personnel Management (OPM) within the last five years may only require an updated or upgraded investigation.

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

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

Level 6: In special circumstances the Project Officer may request a waiver of the preappointment investigation. If the waiver is granted, the Project Officer will provide written authorization for the contractor employee to work under the contract.

d. Systems Security Plan

The contractor shall protect Federal automated information systems that are developed or accessed by the contractor. System security shall be accomplished in accordance with the contractor's System Security Plan dated _____. The plan must:

(1) Include a detailed plan of present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. The contractor shall use the **NIH Systems Security Plan Template** (detailed) at http://irm.cit.nih.gov/security/secplantemp.doc or **NIH Systems Security Plan Outline** (outline only) at http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc.

[OR** (To be determined during negotiations)**]

(1) Include a plan of present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed include, but are not limited to administrative, technical, and physical security as follows:

(i) Security Awareness Training
(ii) Logical Access Control
- -Network (ex: firewall)
- -System (ex: network OS, tcp wrappers, SSH)
- -Application (ex: S-LDAP, SSL)
- -Remote Access (ex: VPN)
- -Monitoring and support (ex: IDS, pager, NOC)

(iii) Protection against data loss
- -OS security (ex: patch management, configuration)
- -Application security (ex: patch management)
- -Database security
- -Back-up and recovery
- -Fault tolerance, high availability

(iv) Malicious Code Protection (ex: Antivirus, filtering of e-mail attachments, etc)
(v) Physical Security
- -Access control (ex: locks, guards)
- -Power conditioning and/or UPS
- -Air conditioning
- -Fire protection

Include an acknowledgment of its understanding of the security requirements.

Provide similar information for any proposed subcontractor developing or accessing an AIS.

e. Rules of Behavior

The contractor shall comply with the the **NIH Information Technology General Rules of Behavior** at: http://irm.cit.nih.gov/security/nihitrob.html.

f. Information Security Training

Each contractor employee shall complete the NIH Computer Security Awareness Training (http://irtsectraining.nih.gov/) prior to performing any contract work, and on an annual basis thereafter, during the period of performance of this contract.

The contractor shall maintain a listing by name and title of each individual working under this contract that has completed the NIH required training. Any additional security training completed by contractor staff shall be included on this listing.

Contractor staff shall complete the following additional training prior to performing any work under this contract:

***** [Additional courses will be listed here in the resultant contract, if applicable.] *****

g. Personnel Security Responsibilities

The contractor shall perform and document the actions identified in the "Employee Separation Checklist", attached and made a part of this contract, when a contractor employee terminates work under this contract. All documentation shall be made available to the Project Officer and/or Contracting Officer upon request

h. Commitment to Protect Departmental Information Systems and Data

(1) Contractor Agreement

The Contractor shall not release, publish, or disclose sensitive Department information to unauthorized personnel, and shall protect such information in accordance with provisions of the following laws and any other pertinent laws and regulations governing the confidentiality of sensitive information:

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

(2) Contractor-Employee Non-Disclosure Agreements

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

i. References

(1) DHHS Information Security Program Policy: http://www.hhs.gov/ohr/manual/pssh.pdf
(2) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(3) NIST Special Publication 800-16, Information Technology Security Training Requirements: http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
Appendix A-D: http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf
(4) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems: http://csrc.nist.gov/publications/nistpubs/index.html
(5) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf
(6) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf
(7) NIST SP 800-64, Security Considerations in the Information System Development Life Cycle: http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf
(8) NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/
(9) Roster of Employees Requiring Suitability Investigations: http://ais.nci.nih.gov/forms/Suitability-roster.xls
(10) NCI Information Technology Security Policies, Background Investigation Process:

http://ais.nci.nih.gov/
(11) NIH Systems Security Plan Template (detailed): http://irm.cit.nih.gov/security/secplantemp.doc
(12) NIH Systems Security Plan Outline (outline only): http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc
(13) NIH Information Technology General Rules of Behavior: http://irm.cit.nih.gov/security/nihitrob.html
(14) Commitment To Protect Non-Public Information - Contractor Agreement: http://irm.cit.nih.gov/security/Nondisclosure.pdf

ARTICLE H.12. ELECTRONIC AND INFORMATION TECHNOLOGY STANDARDS

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

ARTICLE H.13. PUBLICATION AND PUBLICITY

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

"This project has been funded in whole or in part with Federal funds from the National Institute of Allergy and Infectious Diseases, National Institutes of Health, Department of Health and Human Services, under Contract No. HHSN2662007xxxxxxC.

ARTICLE H.14. PRESS RELEASES

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

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

[Applicable information to be included at award]

ARTICLE H.15. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in NIH funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS** (**1-800-447-8477).**

All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489

Washington, D.C. 20026

ARTICLE H.16. ANTI-LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used, for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

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

[Applicable information to be included at award]

ARTICLE H.17. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

ARTICLE H.18. SHARING RESEARCH DATA

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

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

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

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

ARTICLE H.19 . 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.20. NIH POLICY ON ENHANCING PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM NIH-FUNDED RESEARCH

The Policy requests that beginning May 2, 2005, NIH-funded investigators submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, resulting from research supported in whole or in part with direct costs from NIH. NIH defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and NIH. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

Additional information is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-05-022.html.

ARTICLE H.21. 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:

General Clauses for a Cost-Reimbursement Contract with Educational Institutions

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

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

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

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

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

FAR Clause **52.216-7, Allowable Cost And Payment** (December 2002), is modified in paragraph (a). The reference to Subpart 31.2 is changed to Subpart 31.3. [For Educational Institutions]

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

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

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

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

USE WHEN A NON-PROFIT (OTHER THAN EDUCATIONAL) WILL BE RECEIVING A FEE

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

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

Alternate I (July 1985) of FAR Clause **52.245-5, Government Property (Cost-Reimbursement, Time-And-**

Material, Or Labor-Hour Contracts) (January 1986) is deleted.

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

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

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

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

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

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

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

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

(7) FAR Clause **52.227-14, Rights in Data - General** (June 1987) with Alternates III and V.

(8) FAR Clause **52-227-15, Representation of Limited Rights Data and Restricted Software** (May 1999).

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

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

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

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

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

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

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

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

(14) HHSAR Clause **352.223-70**, **Safety and Health** (January 2001).

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

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

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

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

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

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

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

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

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

Notice to Employees

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office

of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

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

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

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

b. **Alternate V, Advance Payment Without Special Account** (May 2001), **Alternate II** (May 2001), and **Alternate IV** (April 1984), of FAR Clause **52.232-12, Advance Payments** (May 2001).

(a) *Requirements for payment.* Advance payments will be made under this contract (1) upon submission of properly certified invoices or vouchers by the contractor, and approval by the administering office, [*insert the name of the office designated under agency procedures*] , or (2) under a letter of credit. The amount of the invoice or voucher submitted plus all advance payments previously approved shall not exceed $ _____. If a letter of credit is used, the Contractor shall withdraw cash only when needed for disbursements acceptable under this contract and report cash disbursements and balances as required by the administering office. The Contractor shall apply terms similar to this clause to any advance payments to subcontractors.

(b) *Use of funds*. The Contractor may use advance payment funds only to pay for properly allocable, allowable, and reasonable costs for direct materials, direct labor, and indirect costs. Determinations of whether costs are properly allocable, allowable, and reasonable shall be in accordance with generally accepted accounting principles, subject to any applicable subparts of Part 31 of the Federal Acquisition Regulation.

(c) *Repayment to the Government*. At any time, the Contractor may repay all or any part of the funds advanced by the Government. Whenever requested in writing to do so by the administering office, the Contractor shall repay to the Government any part of unliquidated advance payments considered by the administering office to exceed the Contractor's current requirements or the amount specified in paragraph (a) of this clause.

(d) *Maximum payment*. When the sum of all unliquidated advance payments, unpaid interest charges, and other payments equal the total estimated cost of $ _____ (not including fixed-fee, if any) for the work under this contract, the Government shall withhold further payments to the Contractor. Upon completion or termination of the contract, the Government shall deduct from the amount due to the Contractor all unliquidated advance payments and interest charges payable. The Contractor shall pay any deficiency to the Government upon demand. For purposes of this paragraph, the estimated cost shall be considered to be the stated estimated cost, less any subsequent reductions of the estimated cost, plus any increases in the estimated costs that do not, in the aggregate, exceed $ _____ [*Insert an amount not higher than 10 percent of the stated estimated cost inserted in this paragraph*]. The estimated cost shall include, without limitation, any reimbursable cost (as estimated by the Contracting Officer) incident to a termination for the convenience of the Government. Any payments withheld under this paragraph shall be applied to reduce

the unliquidated advance payments. If full liquidation has been made, payments under the contract shall resume.

(e) *Interest*. No interest shall be charged to the prime Contractor for advance payments except for interest charged during a period of default. The terms of this paragraph concerning interest charges for advance payments shall not apply to the prime Contractor.

(1) The Contractor shall pay interest to the Government on the daily unliquidated advance payments at the daily rate specified in subparagraph (e)(3) below. Interest shall be computed at the end of each calendar month for the actual number of days involved. For the purpose of computing the interest charge, the following shall be observed:

(i) Advance payments shall be considered as increasing the unliquidated balance as of the date of the advance payment check.

(ii) Repayments by Contractor check shall be considered as decreasing the unliquidated balance as of the date on which the check is received by the Government authority designated by the Contracting Officer.

(iii) Liquidations by deductions from payments to the Contractor shall be considered as decreasing the unliquidated balance as of the dates on which the Contractor presents to the Contracting Officer full and accurate data for the preparation of each voucher. Credits resulting from these deductions shall be made upon the approval of the reimbursement vouchers by the Disbursing Officer, based upon the Contracting Officer's certification of the applicable dates.

(2) Interest charges resulting from the monthly computation shall be deducted from any payments on account of the fixed-fee due to the Contractor. If the accrued interest exceeds the payment due, any excess interest shall be carried forward and deducted from subsequent payments of the contract price or fixed-fee. Interest carried forward shall not be compounded. Interest on advance payments shall cease to accrue upon (i) satisfactory completion or (ii) termination of the contract for the convenience of the Government. The Contractor shall charge interest on advance payments to subcontractors in the manner described above and credit the interest to the Government. Interest need not be charged on advance payments to nonprofit educational or research subcontractors for experimental, developmental, or research work.

(3) If interest is required under the contract, the Contracting Officer shall determine a daily interest rate based on the rate established by the Secretary of the Treasury under Pub. L. 92-41 (50 U.S.C. App., 1215(b)(2)). The Contracting Officer shall revise the daily interest rate during the contract period in keeping with any changes in the cited interest rate.

(4) If the full amount of interest charged under this paragraph has not been paid by deduction or otherwise upon completion or termination of this contract, the Contractor shall pay the remaining interest to the Government on demand.

(f) *Lien on property under contract*. (1) All advance payments under this contract, together with interest charges, shall be secured, when made, by a lien in favor of the Government, paramount to all other liens, on the supplies or other things covered by this contract and on all material and other property acquired for or allocated to the performance of this contract, except to the extent that the Government by virtue of any other terms of this contract, or otherwise, shall have valid title to the supplies, materials, or other property as against other creditors of the Contractor.

(2) The Contractor shall identify, by marking or segregation, all property that is subject to a lien in favor of the Government by virtue of any terms of this contract in such a way as to indicate that it is subject to a lien and that it has been acquired for or allocated to performing this contract. If, for any reason, the supplies, materials, or other property are not identified by marking or segregation, the Government shall be considered to have a lien to the extent of the Government's interest under this contract on any mass of property with which the supplies, materials, or other property are

commingled. The Contractor shall maintain adequate accounting control over the property on its books and records.

(3) If, at any time during the progress of the work on the contract, it becomes necessary to deliver to a third person any items or materials on which the Government has a lien, the Contractor shall notify the third person of the lien and shall obtain from the third person a receipt in duplicate acknowledging the existence of the lien. The Contractor shall provide a copy of each receipt to the Contracting Officer.

(4) If, under the termination clause, the Contracting Officer authorizes the contractor to sell or retain termination inventory, the approval shall constitute a release of the Government's lien to the extent that--

(i) The termination inventory is sold or retained; and
(ii) The sale proceeds or retention credits are applied to reduce any outstanding advance payments.

(g) *Insurance*.

(1) The Contractor shall maintain with responsible insurance carriers--

(i) Insurance on plant and equipment against fire and other hazards, to the extent that similar properties are usually insured by others operating plants and properties of similar character in the same general locality;
(ii) Adequate insurance against liability on account of damage to persons or property; and
(iii) Adequate insurance under all applicable workers' compensation laws.

(2) Until work under this contract has been completed and all advance payments made under the contract have been liquidated, the Contractor shall--

(i) Maintain this insurance;
(ii) Maintain adequate insurance on any materials, parts, assemblies, subassemblies, supplies, equipment, and other property acquired for or allocable to this contract and subject to the Government lien under paragraph (f) of this clause; and
(iii) Furnish any evidence with respect to its insurance that the administering office may require.

(h) *Default*. (1) If any of the following events occur, the Government may, by written notice to the Contractor, withhold further payments on this contract:

(i) Termination of this contract for a fault of the Contractor.
(ii) A finding by the administering office that the Contractor has failed to--
(A) Observe any of the conditions of the advance payment terms;
(B) Comply with any material term of this contract;
(C) Make progress or maintain a financial condition adequate for performance of this contract;
(D) Limit inventory allocated to this contract to reasonable requirements; or
(E) Avoid delinquency in payment of taxes or of the costs of performing this contract in the ordinary course of business.
(iii) The appointment of a trustee, receiver, or liquidator for all or a substantial part of the Contractor's property, or the institution of proceedings by or against the Contractor for bankruptcy, reorganization, arrangement, or liquidation.
(iv) The commission of an act of bankruptcy.

(2) If any of the events described in subparagraph (h)(1) of this clause continue for 30 days after the written notice to the Contractor, the Government may take any of the following additional actions:

(i) Charge interest, in the manner prescribed in paragraph (e) of this clause, on outstanding advance payments during the period of any event described in subparagraph (h)(1) of this clause.

(ii) Demand immediate repayment by the Contractor of the unliquidated balance of advance payments.

(iii) Take possession of and, with or without advertisement, sell at public or private sale all or any part of the property on which the Government has a lien under this contract and, after deducting any expenses incident to the sale, apply the net proceeds of the sale to reduce the unliquidated balance of advance payments or other Government claims against the Contractor.

(3) The Government may take any of the actions described in subparagraphs (h)(1) and (h)(2) of this clause it considers appropriate at its discretion and without limiting any other rights of the Government.

(i) *Prohibition against assignment*. Notwithstanding any other terms of this contract, the Contractor shall not assign this contract, any interest therein, or any claim under the contract to any party.

(j) *Information and access to records*. The Contractor shall furnish to the administering office (1) monthly or at other intervals as required, signed or certified balance sheets and profit and loss statements, and, (2) if requested, other information concerning the operation of the contractor's business. The Contractor shall provide the authorized Government representatives proper facilities for inspection of the Contractor's books, records, and accounts.

(k) *Other security*. The terms of this contract are considered to provide adequate security to the Government for advance payments; however, if the administering office considers the security inadequate, the Contractor shall furnish additional security satisfactory to the administering office, to the extent that the security is available.

(l) *Representations*. The Contractor represents the following:

(1) The balance sheet, the profit and loss statement, and any other supporting financial statements furnished to the administering office fairly reflect the financial condition of the Contractor at the date shown or the period covered, and there has been no subsequent materially adverse change in the financial condition of the Contractor.

(2) No litigation or proceedings are presently pending or threatened against the Contractor, except as shown in the financial statements.

(3) The Contractor has disclosed all contingent liabilities, except for liability resulting from the renegotiation of defense production contracts, in the financial statements furnished to the administering office.

(4) None of the terms in this clause conflict with the authority under which the Contractor is doing business or with the provision of any existing indenture or agreement of the Contractor.

(5) The Contractor has the power to enter into this contract and accept advance payments, and has taken all necessary action to authorize the acceptance under the terms of this contract.

(6) The assets of the Contractor are not subject to any lien or encumbrance of any character except for current taxes not delinquent, and except as shown in the financial statements furnished by the Contractor. There is no current assignment of claims under any contract affected by these advance payment provisions.

(7) All information furnished by the Contractor to the administering office in connection with each request for advance payments is true and correct.

(8) These representations shall be continuing and shall be considered to have been repeated by the submission of each invoice for advance payments.

(m) *Covenants*. To the extent the Government considers it necessary while any advance payments made under this contract remain outstanding, the Contractor, without the prior written consent of the

administering office, shall not--

(1) Mortgage, pledge, or otherwise encumber or allow to be encumbered, any of the assets of the Contractor now owned or subsequently acquired, or permit any preexisting mortgages, liens, or other encumbrances to remain on or attach to any assets of the Contractor which are allocated to performing this contract and with respect to which the Government has a lien under this contract;

(2) Sell, assign, transfer, or otherwise dispose of accounts receivable, notes, or claims for money due or to become due;

(3) Declare or pay any dividends, except dividends payable in stock of the corporation, or make any other distribution on account of any shares of its capital stock, or purchase, redeem, or otherwise acquire for value any of its stock, except as required by sinking fund or redemption arrangements reported to the administering office incident to the establishment of these advance payment provisions;

(4) Sell, convey, or lease all or a substantial part of its assets;

(5) Acquire for value the stock or other securities of any corporation, municipality, or Governmental authority, except direct obligations of the United States;

(6) Make any advance or loan or incur any liability as guarantor, surety, or accommodation endorser for any party;

(7) Permit a writ of attachment or any similar process to be issued against its property without getting a release or bonding the property within 30 days after the entry of the writ of attachment or other process;

(8) Pay any remuneration in any form to its directors, officers, or key employees higher than rates provided in existing agreements of which notice has been given to the administering office, accrue excess remuneration without first obtaining an agreement subordinating it to all claims of the Government, or employ any person at a rate of compensation over $_____ a year;

(9) Change substantially the management, ownership, or control of the corporation;

(10) Merge or consolidate with any other firm or corporation, change the type of business, or engage in any transaction outside the ordinary course of the Contractor's business as presently conducted;

(11) Deposit any of its funds except in a bank or trust company insured by the Federal Deposit Insurance Corporation or a credit union insured by the National Credit Union Administration;

(12) Create or incur indebtedness for advances, other than advances to be made under the terms of this contract, or for borrowings;

(13) Make or covenant for capital expenditures exceeding $_____ in total;

(14) Permit its net current assets, computed in accordance with generally accepted accounting principles, to become less than $_____; or

(15) Make any payments on account of the obligations listed below, except in the manner and to the extent provided in this contract:

[*List the pertinent obligations*]

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are incorporated into this RFP:

SOLICITATION ATTACHMENTS:

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	Linked to the Attachment Title
Attachment 2:	Proposal Intent Response Sheet	Linked to the Attachment Title
Attachment 3:	Background	Linked to the Attachment Title
Attachment 4:	Statement of Work	Linked to the Attachment Title
Attachment 5:	Reporting Requirements and Deliverables	Linked to the Attachment Title
Attachment 6:	Appendix A - Additional Technical Proposal Instructions and Format for Technical Proposal - Table of Contents	Linked to Attachment Title
Attachment 7:	Appendix B - Additional Business Proposal Instructions and Uniform Cost Assumptions	Linked to the Attachment Title
Attachment 8:	Appendix C - Current NIAID-funded Clinical Research Support Services Contracts	Linked to the Attachment Title
Attachment 9:	Appendix D - Data Submission Requirements	Linked to the Attachment Title

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

Title	Location
Targeted/Planned Enrollment Table	http://rcb.cancer.gov/rcb-internet/forms/enroll-table.pdf
Annual Technical Progress Report Format for Each Study	http://rcb.cancer.gov/rcb-internet/forms/atpr.pdf
Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms.htm
Summary of Related Activities	http://www.niaid.nih.gov/contract/forms.htm
Government Notice for Handling Proposals	http://www.niaid.nih.gov/contract/forms/form7.pdf
Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (formerly Optional Form 310	http://rcb.cancer.gov/rcb-internet/forms/of310.pdf
Project Objectives, NIH 1688-1	http://rcb.cancer.gov/rcb-internet/forms/nih1688-1.pdf

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

Title	Location
Proposal Summary and Data Record, NIH-2043	http://www.niaid.nih.gov/contract/forms.htm
Small Business Subcontracting Plan	http://rcb.cancer.gov/rcb-internet/forms/sb-subplan-nci.pdf
Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	http://www.niaid.nih.gov/contract/forms.htm http://ocm.od.nih.gov/contracts/spsh/spshexcl.xls
Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms.htm
Disclosure of Lobbying Activities, OMB Form SF-LLL	http://rcb.cancer.gov/rcb-internet/forms/sflllin.pdf

INFORMATIONAL ATTACHMENTS: (The following Attachments and Reports will become part of any contract resulting from this RFP and will be required during contract performance.) They may be accessed at: http://www.niaid.nih.gov/contract/forms.htm.)

Title	Location
Invoice/Financing Request and Contract Financial Reporting Instructions--Cost Reimbursement, NIH(RC)-4	http://rcb.cancer.gov/rcb-internet/forms/rc4.pdf
Privacy Act System of Records *System of Records No. 09-25-0200 is applicable to this RFP.*	http://oma.od.nih.gov/ms/privacy/pa-files/read02systems.htm
Safety and Health, HHSAR 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf
Procurement of Certain Equipment, NIH(RC)-7	http://www.niaid.nih.gov/contract/forms/NIH-RC-7.pdf
Research Patient Care Costs, NIH(RC)-11	http://www.niaid.nih.gov/contract/forms/nih-rc-11.pdf
Inclusion Enrollment Report	http://rcb.cancer.gov/rcb-internet/forms/inclusion-enrollment.pdf
Commitment To Protect Non-Public Information Contractor Agreement	http://irm.cit.nih.gov/security/Nondisclosure.pdf
Roster of Employees Requiring Suitability Investigations	http://ais.nci.nih.gov/forms/Suitability-roster.xls
Employee Separation Checklist	http://rcb.cancer.gov/rcb-internet/forms/Emp-sep-checklist.pdf

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

SECTION K can be accessed electronically from the INTERNET at the following address:

http://rcb.cancer.gov/rcb-internet/wkf/sectionk.pdf

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

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE SECTION K AND SUBMIT IT AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L - INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

n. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Provision 52.215-1 (January 2004)]

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(e) *Restriction on disclosure and use of data.* (1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads:

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

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

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

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

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

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

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

(4) The Government intends to evaluate proposals and award a contract without discussions with

offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

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

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

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

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

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

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

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

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

(End of Provision)

o. **NAICS CODE AND SIZE STANDARD**

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

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

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

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

It is anticipated that one award will be made from this solicitation and that the award will be made on/about June 15, 2007.

It is anticipated that the award from this solicitation will be a multiple-year, cost reimbursement, completion type contract with a period of performance of five (5) years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

q. **ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 9.65 FTEs for each year of performance. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes. Offerors should state the standard number of hours that are equivalent to one full-time person year of effort as used in their business proposal.

r. **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.

s. **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.

t. **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.

u. **COMPARATIVE IMPORTANCE OF PROPOSALS**

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

v. **PREPARATION COSTS**

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

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

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

Contracting Officer
Office of Acquisitions, DEA
NIAID, NIH, DHHS
6700-B Rockledge Drive, 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)

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

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

(End of provision)

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

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

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

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

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

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions and as specified in SECTION J, List of Attachments (See Appendix A - Attachment 7).

III. BUSINESS PROPOSAL

It is recommended that the business proposal consist of a cover page, a table of contents, and the information requested in the Business Proposal Instructions and as specified in SECTION J, List of Attachments (See Appendix B - Attachment 8).

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

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

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

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

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

(5) **Alternate Proposals**

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

(6) **Evaluation of Proposals**

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

(7) **Potential Award Without Discussions**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.
- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(11) **Selection of Offerors**

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

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

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

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

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

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

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

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

e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.

f) The NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

(12) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

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

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

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

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

(e) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the

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

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

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

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

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

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

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

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

(13) **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.

(14) **Past Performance Information**

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

A list of the last 5 contracts completed during the past 3 years and the last 3 contracts awarded currently in process that are similar in nature to the solicitation workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors that are newly formed entities without prior contracts should list contracts and subcontracts as required above for all key personnel.

Include the following information for each contract or subcontract:

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

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as any subcontract over $550,000.

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

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

(15) **Electronic and Information Technology Accessibility**

Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by P.L.105-220 under Title IV (Rehabilitation Act Amendments of 1998) and the Architectural and Transportation Barriers Compliance Board Electronic and Information Technology (EIT) Accessibility Standards (36 CFR part 1194) require that all EIT acquired must ensure that:

a. Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities; and

b. Members of the public with disabilities seeking information or services from an agency have access to and use of information and data that is comparable to the access to and use of information and

data by members of the public who are not individuals with disabilities.

This requirement includes the development, maintenance, and/or use of EIT products/services, therefore, any proposal submitted in response to this solicitation must demonstrate compliance with the established EIT Accessibility Standards.

Further information about Section 508 is available via the Internet at http://www.section508.gov .

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

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

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

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

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

(1) **Technical Discussions**

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

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

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

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

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

b) **Statement of Work**

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

c) **Personnel**

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

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

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

-The specific items or expertise they will provide.

-Their availability to the project and the amount of time anticipated.

-Willingness to act as a consultant.

-How rights to publications and patents will be handled.

(4) Resumes

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

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria, Section M., below).

(3) **Additional Technical Proposal Information**

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

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

(4) **Other Considerations**

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

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

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

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

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

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

IMPORTANT NOTE TO OFFERORS: The following 12 paragraphs [(5) through (15)] shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

(5) **Human Subjects**

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (MARCH 2005)

(a) Copies of the Department of Health and Human Services (Department) 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 Department.

(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: 301-496-7005), is recommended.

(e) In accordance with 45 CFR Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. The contracting officer will direct the offeror/contractor to the OHRP IRB Registration and Assurance Filing website, found at http://www.hhs.gov/ohrp/ or to the physical address if the offeror/contractor cannot access the Internet. HHS regulations for the protection of human subjects may be found at:
http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html

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

(End of provision)

(6) **Instructions to Offerors Regarding Protection of Human Subjects**

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

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

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

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.

- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.

- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.

- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.

- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.

- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.

- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

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

Collaborating Site(s)

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

(7) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

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

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

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

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

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), ***and applies to research subjects of all ages***.

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:
http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research," at: (http://www.nih.gov/news/crp/97report/execsum.htm).

Information Required for ALL Clinical Research Proposals

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

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

The proposal must include the following information:

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

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

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

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

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials**[1] require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, Definitions - Significant Difference), by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

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

Also, the proposal must include one of the following plans:

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

- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR

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

Use the form entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities. (See Section J-List of Documents, Exhibits and Other Attachments of the RFP)

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

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

(9) **Inclusion of Children in Research Involving Human Subjects**

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

---

1 See NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm, for the Definition of an "NIH-Defined Phase III clinical trial.

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.

(10) **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.

(11) **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.

(12) **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://ohrp.osophs.dhhs.gov/humansubjects/guidance/prisoner.htm

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

(13) **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 (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.
(http://www4.od.nih.gov/oba/rac/guidelines_02/Appendix_M.htm#_Toc7255836)

(14) **Human Embryonic Germ Cell (HEGC) Research**

1. Guidelines.

   Research use of human embryonic germ cells derived from fetal tissue with Federal funds requires review of compliance with the NIH Guidelines for Research Using Human Pluripotent Stem Cells (http://stemcells.nih.gov/policy/guidelines.asp) (only the information regarding human embryonic germ cells is relevant). Embryonic germ cells are pluripotent stem cells derived from human

embryos. See NIH Guide for Grants and Contracts Notice NOT-OD-02-049, requiring that offerors/contractors submit certain documents to the Human Pluripotent Stem Cell Review Group (HPSCRG), which will be reviewed in a public meeting. Research using human embryonic germ cells may not be performed prior to approval by the HPSCRG.

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

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

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

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

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

The resultant contract will be divided into discrete phases or option period(s). During Option Period(s)/Phase(s) N/A of the contract, the contractor shall submit the original and two copies of the required documentation and assurances that address the areas covered in "Procedures for Submission of Compliance Documents to the Human Pluripotent Stem Cell Review Group (HPSCRG) for the Research Use of Human Embryonic Germ Cells," at: (http://grants2.nih.gov/grants/guide/notice-files/NOT-OD-02-049.html) to the contracting officer. This documentation will be forwarded for review and approval to the HPSCRG.

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

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

(15) **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.

(16) **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

(17) **Information Technology Systems Security**

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

The Statement of Work (SOW) requires the successful offeror to develop or access Federal automated information systems. Pursuant to the DHHS Information Security Program Policy (http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc), the following requirements apply:

(a) Information Type

[X] Administrative, Management and Support Information:

[ ] Mission Based Information:

(b) Security Categories and Levels

Confidentiality	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Integrity	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Availability	Level:	**[X]** Low	**[ ]** Moderate	**[ ]** High
Overall	**Level:**	**[X] Low**	**[ ] Moderate**	**[ ] High**

(c) Position Sensitivity Designations

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

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

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

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

Upon award, the contractor will be required to submit a roster of all IT staff working under the contract. The Government will determine the appropriate level of suitability investigation required for each staff member.

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

(d) Systems Security Plan

The offeror's proposal must:

(1) Include a detailed plan of its present and proposed systems security programs commensurate with the size and complexity of the requirements of the Statement of Work. Offerors must use: **NIH Systems Security Plan Template** (detailed) at:

http://irm.cit.nih.gov/security/secplantemp.doc; or
NIH Systems Security Plan Outline (outline only) at:
http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc.

OR

(1) Include a plan commensurate with the size and complexity of the requirements of the Statement of Work. The minimum areas to be addressed include, but are not limited to administrative, technical, and physical security as follows:

(i) Security Awareness Training
(ii) Logical Access Control
-Network (ex: firewall)
-System (ex: network OS, tcp wrappers, SSH)
-Application (ex: S-LDAP, SSL)
-Remote Access (ex: VPN)
-Monitoring and support (ex: IDS, pager, NOC)
(iii) Protection against data loss
-OS security (ex: patch management, configuration)
-Application security (ex: patch management)
-Database security
-Back-up and recovery
-Fault tolerance, high availability
(iv) Malicious Code Protection (ex: Antivirus, filtering of e-mail attachments, etc)
(v) Physical Security
-Access control (ex: locks, guards)
-Power conditioning and/or UPS
-Air conditioning
-Fire protection

Include an acknowledgment of its understanding of the security requirements.
Provide similar information for any proposed subcontractor developing or accessing an AIS.

The SSP that the offeror must submit with its proposal shall be finalized in coordination with the Project Officer no later than 90 calendar days after contract award.

(e) Information Systems Security Training

DHHS policy requires contractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor employee has completed the NIH Computer Security Awareness Training course(http://irtsectraining.nih.gov/) prior to performing any contract work, and on an annual basis thereafter, during the period of performance of the contract. The successful offeror shall maintain a listing of all individuals who have completed this training and shall submit this listing to the Project Officer.

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

(f) References

(19) DHHS Information Security Program Policy:
http://www.hhs.gov/read/irmpolicy/FINALHHSInformationSecurityProgramP.doc
(2) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(3) NIH Systems Security Plan Template: http://irm.cit.nih.gov/security/secplantemp.doc

(4) NIH Systems Security Plan Outline:
http://irm.cit.nih.gov/nihsecurity/Security_Plan_Outline.doc
(5) NIH Computer Security Awareness Training Course: http://irtsectraining.nih.gov/
(6) NIST Special Publication 800-16, Information Technology Security Training Requirements:
http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
Appendix A-D:
http://csrc.nist.gov/publications/nistpubs/800-16/AppendixA-D.pdf
(7) NIST SP 800-18, Guide for Developing Security Plans for Information Technology Systems:
http://csrc.nist.gov/publications/nistpubs/index.html
(8) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume I: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V1-final.pdf
(9) NIST SP 800-60, Guide for Mapping Types of Information and Information Systems to Security Categories, Volume II: http://csrc.nist.gov/publications/nistpubs/800-60/SP800-60V2-final.pdf
(10) NIST SP 800-64, Security Considerations in the Information System Development Life Cycle:
http://csrc.nist.gov/publications/nistpubs/800-64/NIST-SP800-64.pdf

c. BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

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

(2) Proposal Cover Sheet

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

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

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

(3) Information Other than Cost or Pricing Data

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

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

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

1. Direct Labor

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

2. Materials

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

3. **Subcontracted Items**

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

4. **Raw Materials**

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

5. **Purchased Parts**

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

6. **Fringe Benefits**

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

7. **Indirect Costs**

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

8. **Special Equipment**

If direct charge, list any equipment proposed including description, price, quantity, total price, purchase or lease, and the basis for pricing.

9. **Travel**

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

10. **Other Costs**

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

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

(a) Exceptions from cost or pricing data.

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

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

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

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

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

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

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

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

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

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

(End of provision)

(5) **Salary Rate Limitation in Fiscal Year 2006**

Offerors are advised that pursuant to P.L. 109-149, no NIH Fiscal Year 2006 (October 1, 2005 - September 30, 2006) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patient care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. 109-149 applies only to Fiscal Year 2006 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I* annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 109-149 states in pertinent part:

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

LINK TO EXECUTIVE SCHEDULE SALARIES: http://www.opm.gov/oca/06tables/indexSES.asp

***Note to Offerors:** The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year 2006 Executive Level I Salary rates.*

(6) **Small Business Subcontracting Plan**

If the proposed contract exceeds a total estimated cost of $500,000 for the entire period of performance, the apparent successful offeror shall be required to submit an acceptable subcontracting plan in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in the Solicitation, Attachment to this RFP is an example of such a plan.

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

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

c) The offeror understands that:

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

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

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

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

award of the contract.

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

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

d) Each plan must contain the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(7) **HUBZone Small Business Concerns**

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

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

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

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

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

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

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

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Subsector(s). The applicable authorized NAICS Subsector(s) for this project is (are) identified elsewhere in this RFP. A total target for SDB participation by the prime contractor, that includes any joint ventures and team members, shall be provided as well as a total target for SDB participation by subcontractors. In addition, offerors must provide information that describes their plans for meeting the targets set forth in their proposal. **This information shall be provided in one clearly marked section of the Business Proposal, which shall describe the extent of participation of SDB concerns in the performance of the contract.**

If the evaluation factor in this solicitation includes an SDB evaluation factor or subfactor that considers the extent to which SDB concerns are specifically identified, the SDB concerns considered in the evaluation shall be listed in any resultant contract. Offerors should note that addressing the extent of small disadvantaged business participation **is not in any way intended to be a substitute** for

submission of the subcontracting plan, if it is required by this solicitation. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Subsector 223

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

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

(9) **Qualifications of the Offeror**

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

a) **General Experience**

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

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

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

c) **Performance History**

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

d) **Pertinent Contracts**

Pertinent contracts is defined as a listing of each related contract completed within the last three years or currently in process. The listing should include: 1) the contract number; 2) contracting agency; 3) contract dollar value; 4) dates contract began and ended (or ends); 5) description of contract work; 6) explanation of relevance of work to this RFP; 7) actual delivery and cost

performance versus delivery and cost agreed to in the contract(s). For award fee contracts, separately state in dollars the base fee and award fee available and the award fee actually received. The same type of organizational experience and past performance data should be submitted.

e) **Pertinent Grants**

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

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

(10) **Other Administrative Data**

a) **Property**

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

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

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

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

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

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

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

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

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

c) **Financial Capacity**

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

d) **Incremental Funding**

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

HHSAR 352.232-75, Incremental Funding (January 2001)

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

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

(End of provision)

(11) **Subcontractors**

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

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

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

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

d) Information on their cognizant field audit offices.

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

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

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

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

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

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

(13) **Representations and Certifications**

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

(14) **Travel Policy**

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

SECTION M - EVALUATION FACTORS FOR AWARD

7. GENERAL

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

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.

8. 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 in the proposed research plan, or provide sufficient information on the research subjects to allow a determination by NIAID that a designated exemption is appropriate.

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

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

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

(b) **Data and Safety Monitoring**

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

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

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

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

(c) **Women and Minorities**

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

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

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

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

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

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

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups

and the rationale for selection of such subjects

- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:

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

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:

    - inclusion of those groups would be inappropriate with respect to their health,;or
    - inclusion of those groups would be inappropriate with respect to the purpose of the research.

- For NIH-defined Phase III clinical trials, reviewers will also consider whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

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

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

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

(d) **Children**

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

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

solicitation for further specific requirements on inclusion of children.

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

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

If the information provided in your proposal about the inclusion of children is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered "unacceptable" by the Government after discussions, your proposal may not be considered further for award.

9. **TECHNICAL EVALUATION CRITERIA**

OFFERORS AND REVIEWERS ARE ADVISED TO REFER TO APPENDIX A (ATTACHMENT 6) – Additional Technical Proposal Instructions OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION OF PROPOSALS.

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

CRITERIA	**WEIGHT**
CRITERION 1: TECHNICAL PLAN/APPROACH	**60 points**

The soundness, appropriateness, adequacy, and feasibility of: (1) the design of the proposed clinical trial; (2) documentation of access to and ability to recruit and retain adequate numbers of proposed study populations and proposed clinical trial timelines; and (3) the capabilities of the offeror and all proposed clinical trial sites.

1. Clinical Trial Design

   The design of the proposed clinical trial, including: potential to maximize the public health impact in the optimal treatment for the management of uncomplicated skin and soft tissue infection including wound infection, abscesses, folliculitis, cellulitis or erysipelas, among outpatients in areas where the prevalence of Community-Acquired Methicillin-Resistant Staphylococcus aureus (CA-MRSA) is high; proposed study design as provided for in the expanded Concept Synopsis, including: background. objectives, primary hypothesis, inclusion/exclusion criteria, study population, study arms, primary and secondary endpoints, follow-up time for study subjects, statistical methods and randomization.

2. Clinical Trial Timelines, Access to and Ability to Recruit and Retain Proposed Study Population(s)

   a. Proposed timelines for all steps involved, including protocol development, initiation, completion of enrollment, and analysis and publication of final study results, including past experience in meeting timelines for projects of similar size and complexity, obstacles and problems encountered during the conduct of these projects, and how they

were resolved.

b. Documented evidence of access to adequate numbers of study participants, based on the proposed clinical trial design, to meet target enrollment requirements as specified in the Statement of Work, and to meet the enrollment targets within the maximum period proposed for completion of enrollment.

c. Plan for the recruitment and retention of the study participants, a description of potential problems and obstacles to achieving the required enrollment targets, as well as proposed solutions to overcome identified problems/obstacles.

d. Organizational experience with a track record in the screening, recruitment and retention of study participants within the scope of the proposed clinical trial.

3. Clinical Trial Implementation, Oversight, Compliance with Federal Regulations and Collaboration with DMID Staff and Clinical Research Support Contractors

a. Capability to implement, and provide oversight for clinical trials as demonstrated by the Safety Monitoring Plan; the Data Management Plan; and the plan for monitoring study progress and ensuring conformance with Federal regulatory requirements, protocol-specific requirements, DMID policies and procedures.

b. Demonstrated experience in conducting clinical trials in compliance with Federal regulations, including experience with conducting Phase II/III clinical trials under INDs, and understanding of NIH and DMID policies for conducting research involving human subjects. Recognition of potential difficulties that may arise in performing the tasks required to comply with current regulations, and understanding of the close coordination necessary between the NIAID, this Contractor, and other NIAID contractors.

CRITERION 2: PERSONNEL AND STAFFING **20 points**

Adequacy and relevance of the training, expertise, experience and availability of personnel and appropriate levels of utilization of contractor/subcontractor (if any) required to plan and implement this project as described in the Statement of Work.

1. Principal Investigator and Clinical Investigators at participating sites

Medical training and experience relevant to the scope of the contract, including knowledge of the diagnosis, treatment and management of methicillin-resistant Staphylococcus aureus infections, experience in the design and conduct of clinical trials of infectious diseases, experience and skill in directing and providing oversight for clinical trials of similar size and complexity, and knowledge of applicable Federal regulations governing the conduct of research involving human subjects and compliance with Good Clinical Practices (GCP).

2. Other Professional Staff

a. Study Coordinators and other clinical research staff with R.N. degrees or other appropriate credentials and with experience demonstrating expertise in conducting clinical trials including GCP compliance.

b. Statistician to assist in the design of the protocol for all statistical support.

c. Data entry personnel with information management expertise to facilitate the transfer of relevant information to and from the Data Management contractor.

d. Laboratory personnel to perform identification and antimicrobial susceptibility testing for the isolates obtained from the study subjects in the clinical trial.

e. Clinical pharmacy personnel for the receipt, distribution and inventory of study drug(s).

f. Administrative personnel with demonstrated experience in management of research budgets and subcontract administration.

CRITERION 3: PROJECT MANAGEMENT AND OPERATIONS **10 points**

1. Adequacy of the organizational framework, with lines of authority and responsibility clearly demonstrated,

2. Adequacy of the proposed timelines for achieving contract objectives including the quality control methods to ensure the effective and efficient initiation, implementation and operation of contract requirements.

3. Adequacy of the proposed mix and balance of key personnel in relation to their specific responsibilities and time commitments.

4. Demonstrated experience in the management of research budgets and subcontract administration and performance monitoring.

CRITERION 4: FACILITIES AND RESOURCES **10 points**

Documented availability and adequacy of facilities, including clinical research outpatient, clinical pharmacy and clinical microbiological laboratory facilities, equipment and resources necessary to carry out all phases of the project,

TOTAL POSSIBLE POINTS: **100 points**

10. PAST PERFORMANCE FACTOR

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

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

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

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

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

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the offeror's performance.
The lack of a relevant performance record may result in an unknown performance risk assessment, which will

neither be used to the advantage nor disadvantage of the offeror.

5. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

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

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified.
(b) Complexity and variety of the work SDB concerns are to perform.
(c) Extent of participation of SDB concerns in terms of the value of the total acquisition.

6. EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy.

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

SOLICITATION ATTACHMENTS INCLUDED WITH THE RFP

The following pages include Attachments applicable to this RFP as specified in SECTION J - List of Attachments

PACKAGING AND DELIVERY OF THE PROPOSAL

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

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

A. EXTERNAL PACKAGE MARKING:

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

"RFP NO. NIH-NIAID-DMID-07-12
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. PAPER COPIES and CD-Rom to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Ross Kelley Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20817	Ross Kelley Contracting Officer Office of Acquisitions, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

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

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

C. NUMBER OF COPIES:

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

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

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

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

CREATING AND NAMING ELECTRONIC FILES:

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

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

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

EXAMPLE: XYX Company/07-12/Technical/Approach/8-15-06

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

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

EXAMPLE: XYX Company/07-12/Business/Staffing/8-15-06

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

PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

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

Document	Number of Copies	Page Limits
Technical Proposal and all Appendices	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Twenty (20) Compact Disks containing an electronic copy of the Technical Proposal (including all Appendices)	**Not to Exceed 160 pages**
Business Proposal	**PAPER** One (1) unbound SIGNED ORIGINAL. Five (5) unbound COPIES **ELECTRONIC FILES ON CD** Four (4) Compact Disks containing an electronic copy of the Business Proposal	N/A
Breakdown of Proposed Estimated Cost using Electronic Cost Proposal EXCEL Workbook	This Attachment to the Business Proposal should be submitted as a separate EXCEL file on the Business Proposal Compact Disk. **See Section J, Attachment entitled Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet to access the Excel Workbook.**	N/A

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-07-12
RFP Title: "CLINICAL TRIAL FOR COMMUNITY-ACQUIRED METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (CA-MRSA) INFECTIONS"

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **July 15, 2006**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

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

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

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

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

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

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

Attn: Ross Kelley
RFP-NIH-NIAID-DMID-07-12
FAX# (301) 480-4675
Email : RKellley@niaid.nih.gov

BACKGROUND

Clinical Trial for Community-Acquired Methicillin-Resistant *Staphylococcus aureus* (CA-MRSA) Infections RFP NIH-NIAID-DMID-07-12

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

Skin and soft tissue infections are diverse with respect to etiology, clinical manifestations, and severity, and are among the most common community-acquired and nosocomial infections in all patient age groups. Although many cases are self-limited, serious morbidity and mortality may result depending upon the patient's risk factors and hospitalization history, as well as the responsible etiologic agents. The most common bacterial pathogens that cause skin and soft tissue infections are staphylococci, streptococci and gram negative bacteria. The role of *Staphylococcus aureus* in this context is becoming increasingly important as both its resistance to antimicrobial therapies and virulence potential appear to be emerging rapidly.

Staphylococcus aureus causes a wide variety of infections, ranging from mild skin and soft-tissue infections to serious infections such as sepsis, endocarditis, osteomyelitis and toxic shock syndrome. *Staphylococcus aureus* is the most common cause of skin and soft tissue infection in the United States. Over the past 40 years, methicillin-resistant *Staphylococcus aureus* (MRSA) infections have become endemic in most U.S. hospitals and in hospitals worldwide. MRSA strains are resistant to all β-lactam antimicrobial agents, including the class of penicillinase-stable β-lactam antimicrobial agents such as methicillin and oxacillin which have been the drugs of choice in treating infections caused by *Staphylococcus aureus*. Consequently, vancomycin has been considered as the drug of choice in treating MRSA infections.

While MRSA infections have been recognized as a hospital-acquired infection that occurs in patients with established risk factors, such as recent hospitalization or surgery, residence in a long-term care facility, dialysis, and indwelling percutaneous medical devices and catheters, these strains have been uncommon in the community. However, over the past few years, community-acquired MRSA (CA-MRSA) infections have become commonplace in multiple locales in the United States and worldwide, striking healthy people with no known risk factors.

CA-MRSA strains differ from hospital-acquired MRSA strains in several aspects including the genotype, the production of toxins such as Panton-Valetine leukocidin, and their antimicrobial susceptibility pattern. Hospital-acquired MRSA strains are generally resistant not only to β-lactam antimicrobial agents but also to multiple classes of antimicrobials, with vancomycin and linezolid being the only effective antimicrobials currently being prescribed. Isolates of CA-MRSA however, are generally susceptible to off-patent antimicrobials such as clindamycin, trimethoprim/sulfamethoxazole, rifampin, and tetracycline/doxycycline in addition to vancomycin and linezolid.

With the increasing prevalence of CA-MRSA, outpatient management of uncomplicated skin and soft-tissue infection has become more complex. An uncomplicated skin and soft tissue infection is defined as the presence of wound infection, abscesses, folliculitis, cellulitis or erysipelas etc, among outpatients. Although most CA-MRSA isolates exhibit in vitro susceptibility to the following antimicrobials with oral formulations: clindamycin, trimethoprim/sulfamethxazole, rifampin and doxycycline, little is known about the effectiveness of such agents in treating uncomplicated skin and soft tissue infection. If any of these antimicrobials demonstrate clinical efficacy in treating skin and soft tissue infection caused by CA-MRSA, vancomycin might not be needed as the first-line therapy for these infections. Furthermore, whether initial therapy with an antimicrobial agent even affects the outcome of uncomplicated skin and soft-tissue infections is uncertain. Published data suggests that severe skin and soft tissue infections in hospitalized patients heal with adequate surgical drainage regardless of whether the antimicrobial agent given to the patient has in vitro activity against the pathogen. In order to reduce the inappropriate use of antimicrobials and the potential for additional development of antimicrobial resistance in *S. aureas*, it is imperative to determine the optimal management for skin and soft tissue infection in the era of emerging CA-MRSA infections. The contract to be awarded under this Request for Proposals (RFP) will advance the field of clinical management for skin and soft tissue infections caused by CA-MRSA through the conduct of a multi-site Phase II/III clinical trial to evaluate the efficacy of off patent oral antimicrobials and/or wound care for the treatment of outpatients with uncomplicated skin and soft tissue infection in areas in the U.S. where the prevalence of CA-MRSA is high.

DMID has entered into contracts with a number of organizations that provide clinical research support services and research and development tasks. The contractors with whom the successful offeror selected for this award are required to interact in order to perform certain clinical research support functions specified within the Statement of Work are described in Appendix C. In addition, Appendix D provides specific information on the electronic data capture system used by the DMID Data Management contractor.

One (1) award for a term of five (5) years is expected to be made in response to this solicitation. NIAID recognizes that no single organization or institution may have the expertise and facilities necessary to perform all of the required tasks. Therefore, subcontractors may be included when necessary to complete the work requirements. The Contractor shall be responsible for ALL work performed under this contract including that performed by all subcontractors.

STATEMENT OF WORK
Clinical Trial for Community-Acquired Methicillin-Resistant
***Staphylococcus aureus* (CA-MRSA) Infections**
RFPNIH-NIAID-DMID-07-12

INTRODUCTION

The Contractor shall be required to work with existing NIAID Division of Microbiology and Infectious Diseases (DMID) clinical research support contractors to carry out certain functions. The current contractors are listed below. The Contractor will be notified when awards are made for new or re-competed clinical research support contracts.

1) The DMID Data Management Contract (hereafter referred as the Data Management contractor) is currently with the EMMES Corporation and was awarded for the period from June 9, 2001 through June 28, 2008, under Contract Number N01-AI-15448 (http://spitfire.emmes.com/study/www_emmes_com/about/about.html). This contract provides several services for DMID-supported research including assistance in the design and development of data collection forms; lists of coded samples; and organizing, collecting, managing, interpreting, and reporting data. The Contractor shall collaborate with the Data Management contractor for data collection, management and analysis tasks.

2) The DMID Clinical Trials Management Contract (hereafter referred to as the CTM contractor) is currently with PPD Development, LP. and was awarded for the period from September 30, 2003 through September 29, 2008, under Contract Number N01-AI-30068 (http://www.ppdi.com/). PPD provides a central resource to the DMID and its extramural investigators to facilitate/support the conduct and management of the clinical research including the following: clinical site assessment, evaluation of clinical site for clinical research feasibility and capacity; clinical site preparation and clinical trial operations assistance; study document preparation and review; establishment and assistance to clinical sites with respect to internal quality control and quality assurance; provision of Good Clinical Practices training; external clinical site monitoring to include site initiation, interim and close-out visits and quality audit visits; centralized pharmacovigilance and safety monitoring; and information and document management through web-based systems.

3) The DMID Regulatory Support Contract is currently with Fisher BioServices (hereafter referred to as Regulatory Support contractor) and was awarded for the period from August 1, 2000 through August 30, 2008, under Contract Number N01-AI-05413 (http://fisherbioservices.com). Fisher BioServices provides regulatory support to the DMID including the preparation and maintenance of Investigational New Drug (IND) applications, consulting and audit for manufacturer of DMID products, and the management and operation of a clinical agent repository for distribution and tracking of IND products. The Contractor shall collaborate with the Regulatory Support contractor for clinical agent repository and regulatory support.

OVERALL OBJECTIVE AND SCOPE:

The objective of this contract is to advance the field of clinical management for uncomplicated skin and soft tissue infection caused by community-acquired methicillin-resistant *Staphylococcus aureus* (CA-MRSA) by determining the optimal outpatient treatment strategy. The Contractor shall provide the scientific, technical, and managerial infrastructure, facilities, and other resources required to design and conduct a multi-site Phase II/III clinical trial to determine the efficacy of off-patent oral antimicrobials and /or wound care for the treatment of outpatients with uncomplicated community-acquired skin and soft tissue infection in areas in the U.S. where the

prevalence of CA-MRSA is high. An uncomplicated skin and soft tissue infection is defined as the presence of wound infection, abscesses, folliculitis, cellulitis or erysipelas. Community-acquired methicillin-resistant *Staphylococcus aureus* infections are defined as the isolation of methicillin-resistant *Staphylococcus aureus* from the relevant disease process from subjects who have not been hospitalized within the previous fourteen (14) days.

NOTE: In order to preserve the efficacy of vancomycin and linezolid, evaluation of these two antimicrobials shall **NOT** be supported under this contract. In addition, clinical trials of invasive diseases (e.g., bacteremia, endocarditis, osteomylitis or pneumonia) or clinical trials with hospitalized patients shall **NOT** be supported under this contract.

TECHNICAL REQUIREMENTS

The Contractor shall, independently and not as an agent of the Government, furnish all services, qualified personnel, materials, equipment and facilities not otherwise provided by the Government under the terms of this contract. Specifically, the Contractor shall:

1. ESTABLISHMENT OF THE CLINICAL TRIAL INFRASTRUCTURE

Establish and direct the scientific and technical infrastructure to design and conduct a multi-site Phase II/III clinical trial to evaluate off-patent antimicrobials and/or wound care for the management of uncomplicated skin and soft tissue infection among outpatients in areas in the U.S. where the prevalence of CA-MRSA is high. The Contractor shall design and conduct the clinical trial in accordance with the clinical trial design features, clinical trial site and enrollment requirements, and timelines specified below.

a. Clinical Trial Design Features

1) The clinical trial shall maximize the possibility of impacting public health by clinical trial designs that could lead to a change in the standard of care for outpatients with uncomplicated community-acquired skin and soft tissue infections.

2) For the purpose of this contract, CA-MRSA infection is defined as the isolation of methicillin-resistant *Staphylococcus aureus* from the relevant disease process in subjects who have not been hospitalized within the previous fourteen (14) days.

3) The spectrum of diseases to be studied is limited to uncomplicated skin and soft tissue infections, including wound infection, abscesses, follicullitis, cellulitis or erysipelas, with a primary emphasis on those caused by CA-MRSA in an out-patient setting.

4) The clinical trial shall involve two (2) or three (3) arms to evaluate the efficacy of off-patent antimicrobials, such as clindamycin, trimethoprim/sulfamethoxazole, rifampin, and tetracycline/doxycycline.

5) If appropriate, wound care alone (e.g., incision and drainage of the wound) without any antimicrobial therapy may be included as one of the efficacy study arms.

6) Primary or secondary endpoints shall include, but not be limited to, progression to invasive disease (e.g., osteomyelitis, invasive soft tissue infection including but not limited to necrotizing fascitis, bacteremia, pneumonia, endocarditis, and meningitis).

7) Follow-up of subjects who do not respond to treatment or who progress to invasive disease and no longer stay in the protocol shall be included.

8) The subject population may include adult subjects alone, pediatric subjects (birth to 18 years of age) alone, or a combination of both adult and pediatric subjects.

9) The enrollment period shall be no more than three (3) years.

b. Clinical Trial Site Requirements

The clinical trial shall include a minimum of two (2) and a maximum of five (5) clinical trial sites. Each clinical trial site, including the Contractor, shall:

1) Operate in compliance with all Federal regulations and NIH policies applying to the conduct of all research involving human subjects including Title 21 CFR 50, 56 and 312, and Title 45 CFR 46.

2) Have access to one hundred and twenty (120) subjects with skin and soft tissue infection every three (3) months to ensure enrollment of a minimum of forty (40) subjects every three (3) months.

3) Provide clinical research staff with experience in the design and conduct of clinical trials in infectious diseases and training in Good Clinical Practice (GCP) necessary to conduct the clinical trial, including the Principal Investigator and all clinical investigators at participating trial sites who shall be medical doctors licensed to practice in the U.S and shall ensure that active licensure is maintained for the entire period of contract performance, and a Study Coordinator with a RN license or equivalent medical credentials.

4) Provide clinical research outpatient facilities for the screening and enrollment of study participants, the administration of study drug(s), the incision and drainage of wounds, and follow-up in accordance with the specific requirements of the clinical trial approved for implementation.

5) Provide clinical laboratory facilities and technical personnel to isolate, identify and perform susceptibility testing and storage at each individual site of pathogens present in the subjects at the time of enrollment.

6) Provide clinical pharmacy facilities and personnel for the receipt, storage, packaging, labeling, distribution, quality control and inventory of study drug(s) used in the clinical trial; and,

7) Work with the CTM, Data Management and Regulatory Support contractors for the provision of regulatory support, data management, site monitoring and meeting logistics.

c. Clinical Trial Timelines

The Contractor shall adhere to the following timelines in conducting the clinical trial:

1) Preparation of the Final Protocol and execution of the subcontract(s) with participating clinical trial sites shall be completed no later than twelve (12) months after the effective date of the contract.

2) Enrollment of the required number of study participants shall be completed no later than three (3) years after the effective date of the contract; and

3) Data analysis and manuscript preparation shall be completed within twelve (12) months of completion of enrollment.

2. PROTOCOL DEVELOPMENT AND CLINICAL TRIAL SITE ASSESSMENT

a. Develop the Draft Protocol, including case report forms, informed consent form(s) and Manual of Operations using the DMID Study Product Protocol Template http://www.niaid.nih.gov/dmid/clinresearch/protocol template.doc and the DMID Study Product Protocol Template: Working Shell: http://www.niaid.nih.gov/dmid/clinresearch/interventionalworkingshell.doc., and submit to the Project Officer within sixty (60) calendar days after the effective date of the contract.

b. Provide a statistician to assist in preparing the Draft Protocol of the clinical trial.

c. Revise the Draft Protocol as necessary to address DMID comments, within thirty (30) calendar days of DMID review.

d. The Draft Protocol shall be reviewed by an independent Data and Safety Monitoring Board (DSMB). The DSMB will be convened by NIAID no later than sixty (60) calendar days after approval of the Draft Protocol by DMID. The Contractor shall attend the DSMB meeting and respond to DSMB comments and revise the Draft Protocol as appropriate/necessary. The DMID will be responsible for all travel expenses associated with all DSMB meetings. The CTM contractor will coordinate logistical arrangements for all DSMB meetings.

e. Submit the revised Draft Protocol within fourteen (14) calendar days after the DSMB meeting to the Project Officer for review and approval. If necessary, revise and resubmit the revised Draft Protocol.

f. Within fourteen (14) calendar days of approval of the Final Protocol, submit the following materials for final review and approval by the Project Officer, the DMID Office of Clinical Research Affairs (hereafter referred as OCRA) and the DMID Office of Regulatory Affairs (hereafter referred as ORA):

1) A timeline and detailed milestones for the implementation, conduct and completion of the clinical trial and the analysis of final study data.
2) A plan for the recruitment and retention of the study participants, including potential problems/obstacles to achieving the required enrollment targets within the time frames specified and proposed approaches to overcome potential problems/obstacles.
3) A Quality Management Plan for the collection, internal quality control and management of study data of each participating clinical trial site.
4) A Data Management plan developed in collaboration with the Data Management contractor and the CTM contractor.
5) A Safety Monitoring Plan developed in collaboration with the Data Management contractor and the CTM contractor.

g. Clinical Trial Site Assessment Visit: Within ninety (90) calendar days of contract award, the OCRA, in conjunction with the CTM contractor, will perform a site assessment visit for each participating clinical trial site. The purpose of this assessment visit is to ensure the adequacy of the clinical trial site to conduct the clinical trial in conformance with Federal regulations, DMID policies and procedures, and protocol-specific requirements. The Contractor shall make available for the site assessment visit all appropriate

personnel, facilities and documentation as required by the Federal regulations and NIAID DMID policies for conducting clinical trials.

3. COMPLIANCE WITH FEDERAL REGULATORY REQUIREMENTS

a. IND Sponsorship and Preparation: DMID will serve as the IND sponsor and will submit the IND application to the U.S. Food and Drug Administration (FDA). The Contractor shall work with the ORA and the Regulatory Support contractor to prepare the IND application.

b. Institutional Review Board Approval: The Contractor shall obtain Institutional Review Board (IRB) approval of the Final Protocol at the Contractor's institution and shall ensure that all participating clinical trial sites obtain local IRB approval. Within thirty (30) calendar days following IRB approval, submit the following documentation for all participating clinical trial sites to the CTM contractor: the IRB-approved protocol, informed consent forms, case report forms and other Essential Documents including, the Principal Investigator's Curriculum Vitae, a copy of clinical licensure of Principal Investigator or appropriate Sub-Investigator from all participating clinical trial sites, Office of Human Research Protection Federal Wide Assurance numbers, Laboratory Certifications, Form FDA 1572, and Conflict of Interest Statements. Obtain and submit documentation of IRB approval for all participating clinical trial sites for all protocol amendments. Please refer to the CTM website at www.dmidctm.com/partners (password will be provided after award) for a complete list of the Essential Documents.

c. Interactions with the FDA: The Contractor shall participate in conference calls and meetings with FDA staff both pre- and post-IND submission and shall assist in the preparation of additional materials/data necessary for such conference calls and meetings. It is anticipated that one face-to-face meeting with the FDA shall occur with respect to the IND. The Contractor shall also work with the Project Officer and ORA to address FDA questions relating to the clinical trial within thirty (30) days of receipt.

d. FDA Reports: The Contractor shall provide the Project Officer, ORA and the Regulatory Support contractor with study data sufficient to file Annual IND Reports within thirty (30) calendar days of notification that Annual IND Reports are due and provide the Project Officer, ORA and the Regulatory Support contractor with study data sufficient to file a Final Study Report for submission to the FDA within six (6) months of completion of the study.

e. System of Records: The Contractor shall collect and maintain a system of records to ensure that all required documentation is on file as required by regulation. This includes all the Essential Documents and documentation demonstrating that all personnel at each clinical trial site have received Human Subject Protection Training.

4. CLINICAL TRIAL IMPLEMENTATION AND OVERSIGHT

The Contractor shall conduct the clinical trial in accordance with GCP guidelines (http://www.niaid.nih.gov/dmid/clinresearch/handbook.pdf), the clinical protocol, the Manual of Operations, and the Data Management Plan. The clinical trial shall proceed to the implementation phase only after Project Officer approval of the Final Protocol and completion of all pre-study initiation regulatory requirements. Implementation of the clinical trial shall also include the following requirements:

a. Investigators' Meeting: Within thirty (30) calendar days of Project Officer approval of the Final Protocol, the Contractor shall conduct a one (1) day Investigators' Meeting with all participating clinical investigators and study coordinators to present the clinical protocol, Manual of Operations, case report

forms and all other relevant documents for the initiation and conduct of the clinical trial. This meeting shall be held in the Washington DC area, and the Contractor shall be responsible for all logistical arrangements and expenses associated with the meeting, including travel expenses for all Contractor and subcontractor personnel.

b. Clinical Trial Site Initiation Visit: Within thirty (30) calendar days of Project Officer approval of the Final Protocol, the OCRA, in conjunction with the CTM contractor, shall conduct a one (1) day Site Initiation Visit at each participating clinical trial site. The overall purpose of this Site Initiation Visit is to ensure that all participating clinical trial sites are prepared to implement the approved Final Protocol in accordance with Federal regulations and requirements as well as DMID procedures and processes. The Site Initiation Visit shall include the following: inspection of the clinical facilities, equipment and other resources available for clinical trial implementation, including adequate space and other resources for the patient screening, enrollment, administration of study drug(s), and follow-up, the entry of confidential data on study participants and the secure storage of patient records, laboratory facilities for protocol-specific tests, and pharmacy facilities for the distribution of study products, and appropriate training of clinical investigators and other technical personnel with respect to GCP and adherence to Federal regulatory requirements governing the conduct of research involving human subjects. The Contractor shall ensure that clinical trial staff, facilities and necessary documents are available for the Site Initiation Visit and shall provide any written materials necessary to certify the capacity of all participating clinical trial sites to initiate the approved Final Protocol.

c. Protocol Amendments: The Contractor shall recommend to the Project Officer amendments to the clinical protocol, the Manual of Operations, and the informed consent form(s), including a written description of the proposed amendments and their rationale. All such amendments shall require approval by the Project Officer prior to implementation, as well as local IRB approval for all participating clinical trial sites.

d. Study Drug(s): Purchase and deliver to the Regulatory Support contractor adequate supplies of study drug(s) for all participating clinical trial sites forty-five (45) calendar days following approval of the Final Protocol. The Regulatory Support contractor shall package and distribute the study drug(s) to the participating clinical trial sites and maintain an inventory of study drug(s) at each participating clinical trial site. When necessary, purchase replacement study drug(s) if lots expire during the conduct of the clinical trial. In addition, the Contractor shall collaborate with the Regulatory Support contractor to assure adherence to appropriate guidelines for delivery of study drug(s) as specified in the approved Final Protocol.

e. Monitoring Clinical Trial Progress: The Contractor shall develop and implement a process for monitoring the progress of the clinical trial in conjunction with the CTM contractor. This shall include monitoring enrollment of eligible subjects for all participating clinical trial sites to ensure that the established target enrollment of a minimum of forty (40) subjects with uncomplicated soft tissue infection is achieved every three (3) months. The Contractor shall also be required to submit Quarterly Enrollment Reports to document the entry of an adequate number of eligible subjects into the clinical trial. In instances where quarterly target enrollment is not achieved, the Quarterly Enrollment Reports shall also include an explanation for the inability to meet quarterly target enrollment and proposed plans for ensuring that target enrollment can be increased adequately to comply with the timelines established for the conduct and completion of the clinical trial. Progress monitoring shall also include quarterly status reports and site-specific performance reports to address problems/deviations from protocol-specific requirements, proposed remedial actions to correct performance on the part of all participating clinical

trial sites, and plans to implement remedial actions when necessary, and shall be provided as a component of the Semi-annual and Annual Reports submitted to the Project Officer.

f. Clinical Site Monitoring: Clinical site monitoring for all participating clinical trial sites shall be conducted by the CTM contractor. The Contractor shall be responsible for accommodating clinical site monitoring/auditing visits and other activities, as directed by the Project Officer, to verify that the rights and well-being of the study participants are protected, the study data are accurate, complete and verifiable, and the conduct of the study is in compliance with GCP, the clinical protocol and applicable regulatory requirements. The Contractor shall make available for clinical site monitoring purposes all necessary facilities, personnel and records to support monitoring requirements during the active recruitment, dosing, follow-up and close-out phases of the clinical trial for all participating clinical trial sites. In addition, the Contractor shall implement remedial actions to address problems and issues in site performance identified through the clinical site monitoring process.

g. NIAID Data and Safety Monitoring Board (DSMB): Participate in the meetings, to be held in the Washington, D.C. area, and conference calls with the independent NIAID DSMB as required by the protocol and progress on study conduct. The Contractor shall, in collaboration with the Data Management contractor, provide all data and interim analyses requested by the DSMB. The CTM contractor shall be responsible for arranging DSMB conference calls and meetings. The Contractor shall be responsible for the travel expenses of Contractor staff related to DSMB meeting(s).

5. ANALYSIS, PRESENTATION AND PUBLICATION OF CLINICAL TRIAL RESULTS

a. Analyze the final study data with assistance from the Data Management contractor and provide final study data to the ORA for preparation of the Final Study Report to the FDA.

b. Present results from the clinical trial at scientific meetings. Abstracts, posters, and slide presentations require Project Officer approval and must be submitted to the Project Officer at least three (3) business days prior to presentation.

c. Within twelve (12) months after completion of clinical trial enrollment, the Contractor shall prepare a draft manuscript to report the final study results and submit the draft manuscript for Project Officer review and comment. The Contractor shall revise the draft manuscript as appropriate based on Project Officer review and submit the manuscript to a journal for peer review and publication. If Project Officer approval is not received within thirty (30) calendar days following submission, the Contractor may proceed with journal submission.

d. All publications and presentations must acknowledge NIAID support.

6. PROJECT MANAGEMENT AND OPERATIONS

a. Overall Project Management

The Contractor shall provide the scientific, technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, management and timely completion of all activities carried out under this contract, including activities carried out by subcontractors. Infrastructure at the Contractor's site shall include a Principal Investigator with responsibility for overall project management and communications, tracking, monitoring, reporting on project status and progress, and recommending and implementing modifications to project requirements and timelines, including projects undertaken by

subcontractors. This infrastructure shall also include administrative staff with responsibility for financial management and financial reporting on all activities conducted by the Contractor and all subcontractors. Additional project management and operations activities include coordinating the efforts of each clinical trial site and serving as a central point of contact for the Project Officer and the Contracting Officer.

b. Conference Calls and Meetings

1) Progress Review Conference Calls: Schedule, prepare agendas and background materials, make arrangements for and participate in conference calls to review progress as required to address scientific, performance, management and administrative issues that may arise during the development, implementation, and conduct of the clinical trial. At a minimum, there shall be monthly progress review conference calls. The CTM contractor shall be responsible for assembling and distributing necessary materials for all conference calls and shall prepare detailed summaries of discussions and action items. The conference call agenda shall be submitted to the Project Officer for final approval three (3) business days prior to each conference call. The Principal Investigator, clinical investigators and study coordinators at participating clinical trial sites, the Project Officer, and staff of the CTM contractor shall participate in all conference calls.

2) Annual CA-MRSA Meeting: One (1)-day annual meetings shall be held in the Washington, D.C. area throughout the contract period to evaluate progress and review clinical trial data and standard operating procedures. The annual meetings shall be attended by the Principal Investigator, all clinical investigators and study coordinators at participating clinical trial sites, the Project Officer, and the CTM contractor. The CTM contractor will be responsible for all logistical arrangements. The Contractor shall be responsible for preparing meeting agendas for Project Officer approval at least two (2) weeks prior to the meeting. The Contractor shall also be responsible for the travel expenses of all Contractor staff, including subcontractors, related to the meeting. The CTM contractor will be responsible for the preparation of detailed summaries of discussions and action items after each annual meeting.

[END OF STATEMENT OF WORK]

REPORTING REQUIREMENTS AND OTHER DELIVERABLES
Clinical Trial for Community-Acquired Methicillin-Resistant
***Staphylococcus aureus* (CA-MRSA) Infections**
RFP NIH-NIAID-DMID-07-12

a. **Technical Reports**

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

1) Format of Cover Page

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

a) Contract Number and Project Title
b) Period of Performance Being Reported
c) Contractor's Name and Address
d) Author(s)
e) Date of Submission
f) Delivery Address

2) Data Sharing Plan

Submit a Data Sharing Plan for providing data from Replication, Comparison, and Evaluation of Potentially Interfering Medical Conditions to the Scientific Community. The Plan shall contain a description of the proposed timelines for the Contractor to provide the data to the scientific community. An example of Data Sharing Plan is available at http://www.niaid.nih.gov/ncn/tool/datasharingex.htm.

3) Quarterly Study Status Report

After the initiation of enrollment, the Contractor shall submit a Quarterly Study Status Report. Each report shall include a brief summary of the work performed during the reporting period, including:

a) A Quarterly Enrollment Status Report of the clinical trial including numbers of subjects at each site and any protocol deviation/violation, proposed remedial actions to correct performance on the part of all participating clinical trial sites, and plans to implement remedial actions when necessary.

b) Technical and administrative issues encountered and corrective action taken during the clinical trial.

No Quarterly Report shall be due for the second and fourth quarter of each year when a Semiannual Progress Report and an Annual Progress Report shall be due.

4) Semiannual Progress Report

Each Semiannual Progress Report shall include a brief summary of the work performed during the reporting period, including:

a) A summary of the enrollment status of the clinical trial including numbers of subjects at each site and any protocol deviation/violation, proposed remedial actions to correct performance on the part of all participating clinical trial sites, and plans to implement remedial actions when necessary.
b) Technical and administrative issues encountered and corrective action taken during the clinical trial.
c) A Data Management Report to be presented at the Data and Safety Monitoring Board (DSMB) in a format to be determined by OCRA and members of the DSMB.
d) A Safety Report to be presented at the DSMB, the format to be determined by OCRA and members of the DSMB.

No Semiannual Progress Report shall be due when the Annual Progress Report or Final Report shall be due.

5) Annual Progress Report

Each Annual Progress Report shall include a brief summary of the work performed during the reporting period, including:

a) A summary of the enrollment status of the clinical trial including numbers of subjects at each site and any protocol deviation/violation, proposed remedial actions to correct performance on the part of all participating clinical trial sites, and plans to implement remedial actions when necessary
b) Technical and administrative issues encountered and corrective action taken during the clinical trial.
c) A Data Management Report to be presented at the DSMB meeting in a format to be determined by OCRA and members of the DSMB.
d) A Safety Report to be presented at the DSMB meeting, the format to be determined by OCRA and members of the DSMB.

No Annual Progress Report shall be due for the final year of the contract when a Final Report shall be due.

6) Annual Technical Progress Report for Clinical Research Study Populations

The Contractor shall submit information about the inclusion of women and members of minority groups and their subpopulations for each study being performed under this contract. The contractor shall submit this information in the format indicated in the attachment entitled, "Inclusion Enrollment Report," which is set forth in Section J of the contract. The contractor also shall use this format, modified to indicate that it is a final report, for reporting purposes in the Final Report. The contractor shall submit the report in accordance with ARTICLE F.1. DELIVERIES of the contract. In addition, the NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended, October, 2001 applies. If this contract is for Phase III clinical trials, see II.B of these guidelines. The Guidelines may be found at the following website: http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm. Include a description of the plans to conduct analyses, as appropriate, by sex/gender and/or racial/ethnic groups in the clinical trial protocol as approved by the IRB, and provide a description of the progress in the conduct of these analyses, as appropriate, in the Annual Progress Report and the Final Report. If the analysis reveals no subset differences, a brief statement to that effect, indicating the subsets analyzed, shall 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.

7) Invention Reporting Requirement

All reports and documentation required by FAR Clause 52.227-11 including, the invention disclosure report, the confirmatory license, and the government support certification, shall be directed to the Office of Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040 A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an Annual Utilization Report, and a copy of the Final Invention Statement, shall be submitted to the Contracting Officer. The Final Invention Statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the completion date of the contract to the Contracting Officer.

The Annual Utilization Report shall be submitted in accordance with ARTICLE F.1. DELIVERIES of this contract. The Final Invention Statement (see FAR 27.303(a)(2)(ii)) shall be submitted on the completion date of the contract to the following address:

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

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

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

8) Final Report

The Contractor shall submit a Final Report on/before the completion date of the contract that documents and summarizes the results of the entire contract for the period of performance. The Final Report shall provide a final report of the clinical trial in the format of a manuscript to be submitted to a peer-review journal. The Contractor shall submit, with the Final Report, a Summary (not to exceed 250 words) of Salient Results achieved during the performance of the contract.

b. **Technical Reports Delivery Schedule**

Copies of the technical reports shall be submitted as follows:

Item	Type of Deliverable	Recipients & Number of Copies	Due Date
1,	Quarterly Study Status Report	2 Paper Copies - PO 1 CD - PO 1 Original Paper – CO	First report due within ninety (90) calendar days after initiation of the enrollment; thereafter, due on/before the 15th of the month following each quarterly period during the enrollment period. This report will not be due when the Semiannual Progress Report, Annual Progress Report or Final Report are due.
2.	Semi-annual Progress Report	2 Paper Copies - PO 1 CD - PO 1 Original Paper - CO	First report due on/before the 30th of the month after each anniversary date of the contract. A Semiannual Progress Report is not due when an Annual Progress Report or Final Report is due.
3.	Annual Progress Report	2 Paper Copies - PO 1 CD - PO 1 Original Paper - CO	First report due on/before the 30th of the month after each anniversary date of the contract. An Annual Progress Report is not due when a Final Report is due.
4.	Annual Technical Progress Report for Clinical Research Study Populations	2 Paper Copies - PO 1 Original Paper - CO	First report due on/before the 30th of the month after each anniversary date of the contract.
5.	Annual Utilization Report	1 Copy - CO	Due on/before the 30th of the month following each anniversary date of the contract.
6.	Final Invention Statement	1 Copy – CO	Due on/before the completion date of the contract.
7.	All reports and documentation including, the invention disclosure report, the confirmatory license, and the government support certification	1 Copy - OPERA	As required by FAR Clause 52.227-11.
8.	Final Report with Summary of Salient Results	2 Paper Copies - PO 1 CD - PO 1 Original Paper - CO	Due on/before the completion date of the contract.

c. **Other Deliverables**

Satisfactory performance of the contract is defined as satisfactorily performing the Statement of Work and acceptable delivery of the following items:

Item	Type of Deliverable	SOW Paragraph Reference	Due Date	Recipient
1.	Draft Protocol	2.a	Due sixty (60) calendar days after award of contract	PO
2.	Case report forms, Manual of Operations, and informed consent forms	2.a	Within fourteen (14) calendar days of approval of the Final Protocol	PO

3.	Timeline for implementation of the clinical trial	2.f.(1)	Within fourteen (14) calendar days of approval of the Final Protocol	PO
4.	Plan for the recruitment and retention of the study participants	2.f.(2)	Within fourteen (14) calendar days of approval of the Final Protocol	PO
5.	Quality Management Plan with respect to the collection, internal quality control and management of study data of each participating site	2.f.(3)	Within fourteen (14) calendar days of approval of the Final Protocol	PO
6.	Data Management Plan	2.f.(4)	Within fourteen (14) calendar days of approval of the Final Protocol	PO
7.	Safety Monitoring Plan	2.f.(5)	Within fourteen (14) calendar days of approval of the Final Protocol	PO
8.	IRB-approved protocols, informed consent forms, case report forms	3.b	Due thirty (30) calendar days after IRB approval	PO
9.	Other Essential Documents including but not limited to the Principal Investigator's Curriculum Vitae, a copy of clinical licensure of Principal Investigator or appropriate Sub-Investigator from all participating sites, Office of Human Research Protection Federal Wide Assurance numbers, Laboratory Certifications, Form FDA 1572, and Conflict of Interests Statements to the CTM contractor no later than thirty (3) calendar days after IRB approval.	3.b.	Due thirty (30) calendar days after approval of the Final Protocol	PO
10.	Study data sufficient to file an IND Annual Report to the FDA	3.d.	Within thirty (30) calendar days of notification that an Annual Report is due	ORA Project Officer
11	Final Study Data for submission to the FDA	3.d	Within six (6) months of completion of the study.	ORA Project Officer
12	Study drugs	4.d	Forty-five (45) calendar days following approval of the Final Protocol	Regulatory Support Contractor

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

Project Officer:

DMID, NIAID, NIH, DHHS
6610 Rockledge Drive, Room 4107, MSC 6604
Bethesda, MD 20892-6604

Contracting Officer:

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

OPERA:

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

ORA:

Office of Regulatory Affairs
DMID, NIAID, NIH, DHHS
6610 Rockledge Drive, Room 6035, MSC 6603
Bethesda, MD 20892-6604

APPENDIX A
Clinical Trial for Community-Acquired Methicillin-Resistant
***Staphylococcus aureus* (CA-MRSAInfections**
RFP NIH-NIAID-DMID-07-12

APPENDIX A - ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS FORMAT FOR TECHNICAL PROPOSAL

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

The following additional Technical Proposal instructions reflect the requirements of the RFP and are meant to provide additional instructions as well as a uniform format for Technical Proposals. The information requested in these instructions should be used as a guide for formatting and preparing the Technical Proposal. Offerors should follow the instructions in Section L of the solicitation; include the information requested in this appendix.

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

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

Offerors are reminded that the total page limitation for the entire Technical Proposal package is 160 pages including all Appendices and Attachments.

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

TECHNICAL PROPOSAL – TABLE OF CONTENTS

SECTION 1:

A. PROPOSAL TITLE PAGE. Include RFP title and number, name of organization, DUNS number, proposal part, and identify if the proposal is an original or a copy.
B. PROJECT OBJECTIVES, NIH FORM 1688
C. GOVERNMENT NOTICE FOR HANDLING PROPOSALS
D. TABLE OF CONTENTS
E. PROPOSAL SUMMARY AND DATA RECORD (NIH-2043)

SECTION 2: TECHNICAL PROPOSAL OVERVIEW

Provide a brief overview of approximately three (3) pages that delineates the following:

- The overall clinical trial infrastructure, including Principal Investigator and institution, participating clinical trial sites and clinical investigators, and clinical research facilities, including clinical research outpatient, clinical research laboratory, and clinical pharmacy facilities; and

- A summary of the major design features of the proposed clinical trial.

SECTION 3: TECHNICAL PLAN/APPROACH

1. Clinical Trial Design

Submit an expanded Concept Synopsis of no more than ten (10) pages addressing the following design features of the proposed clinical trial headed as the following:

a. Background. Include the rationale(s) for the choices of the study arms selected
b. Objectives.
c. Primary hypothesis.
d. Study design including inclusion/exclusion criteria. Provide a plan for the procedure for performing or providing wound care, including the subpopulation of patients on which the procedure will be performed or provided, and whether or not any modifications to wound care will be made with any of the subpopulations.
e. Study population. Provide rationale(s) for the choice of the study population including age, gender, and demographics. Describe how the population meets the definition required in the Statement of Work.
f. Study arms.
g. Primary and secondary endpoints. Provide the definition of invasive infection to be adopted in the study, such as bacteremia, endocarditis, pneumonia, osteomyelitis, or invasive soft tissue infection.
h. Follow-up time for study subjects. Provide an algorithm indicating how patients are to be followed should invasive infection occur or should patients not respond to the therapy.
i. Statistical methods and randomization. Include in an algorithm for the method in which subjects are to be enrolled and randomized. The algorithm must include how the offeror plans to deal with prior antibiotic use if there is any. Include a sample size calculation, provide a rationale for this calculation, and state the relevance to outcomes desired for the target patient population that is being studied.
j. Potential problems and obstacles in implementing the proposed clinical trial and strategies to overcome identified problems and obstacles.

NOTE: The clinical trial design, as proposed in Section 3 of the Technical Proposal, will be used in the evaluation of scientific and technical merit, appropriateness and feasibility. The final clinical trial design and clinical protocol shall be subject to review, modification and approval by the Project Officer post award.

2. Clinical Trial Timelines, Access to and Ability to Recruit and Retain Proposed Study Populations

Provide the following documentation and plans for the offeror and all proposed clinical trial sites:

a. Proposed timeline for all steps involved, including protocol development, initiation, completion of enrollment, completion of clinical trial, and analysis and publication of final study results. Include a discussion of past experience in meeting timelines for projects of similar size and complexity, obstacles and problems encountered during the conduct of these projects, and how they were resolved.

b. Evidence of the incidence of local CA-MRSA for the offeror and for each proposed clinical trial site through summaries of microbiology logs or other information documenting the number of patient visits due to skin and soft tissue infection.

c. Evidence to document the ability to enroll forty (40) patients with CA-MRSA skin and soft tissue infection every three (3) months through submission of summaries of patient visit logs from the emergency room(s) and/or the clinic(s) for the offeror and for all proposed clinical trial sites to

demonstrate visits of one hundred twenty (120) patients with skin and soft tissue infections every three (3) months.

d. A plan for the recruitment and retention of the study participants and a description of potential problems and obstacles to achieving the required enrollment targets, as well as proposed solutions to overcome identified problems/obstacles.

e. Organizational experience with and a track record in the screening, recruitment and retention of study participants within the scope of the proposed clinical trial.

3. **Clinical Trial Implementation, Oversight, Compliance with Federal Regulations and Collaboration with DMID Staff and Clinical Research Support Contractors**

a. Provide the following protocol-related documents, plans and forms. These materials will be used in the evaluation of the Technical Proposal and may not be the final documents approved post award.

1) A draft Safety Monitoring Plan.

2) A draft Data Management Plan including processes and procedures for the collection, quality control and management of study data at the offeror's institution and at all proposed clinical trial sites.

3) A draft plan for monitoring study progress to ensure conformance with all Federal regulatory requirements, protocol-specific requirements, and DMID policies and procedures.

b. Describe previous organizational experience of the offeror and all proposed clinical trial sites in conducting Phase II/ III clinical trials in compliance with Federal regulations.

SECTION 4: PERSONNEL AND STAFFING

1. **Key Scientific and Technical Personnel**: Describe the training, experience, education, and qualifications, as well as the percentage of the total time each will be committed to the project. This includes scientific and technical staff of the offeror and any proposed subcontractors. Provide documentation to describe:

a. Key Scientific and Technical Personnel (limit CVs to 2-3 pages)
b. Qualifications and relevant training
c. Previous experience in the design and conduct of clinical trials in infectious diseases.
d. References to all relevant publications
e. Availability for the proposed project
f. Summary of ongoing and completed activities directly related to the requirements of this contract.

2. **Principal Investigator**

a. The scientific, technical and clinical expertise, training and experience in the design and conduct of clinical trials of infectious diseases.
b. Experience and expertise in the management, coordination and oversight of multi-site clinical trials of infectious diseases, including monitoring clinical site performance, adherence to regulatory requirements, and the development and implementation of remedial actions to resolve clinical site performance problems.

c. Ability to work with clinical research support contractors with respect to data management and quality

control, clinical site monitoring, and training of clinical research personnel.

3. **Other Personnel**

   The related experience and roles of other personnel proposed to address the requirements of the Statement of Work, including documentation to demonstrate expertise, appropriate training, experience, and availability of all such personnel of the offeror and all proposed subcontractors, including.

   a. Study Coordinators and other clinical research staff with R.N. degrees or other appropriate credentials and with experience demonstrating expertise in conducting clinical trials including GCP compliance.
   b. Statistician to assist in the design of the protocol and for all statistical support.
   c. Data management and data entry personnel with information technology expertise to facilitate the transfer of relevant information to and from the Data Management contractor.
   d. Clinical research laboratory personnel to perform identification and antimicrobial susceptibility testing for the isolates obtained from the study subjects in the clinical trial. Submit relevant documents such as laboratory certifications documenting the ability of the lab personnel to perform the microbiological tests specified in the Statement of Work.
   e. Clinical pharmacy personnel to provide for the receipt, labeling, distribution, quality control and inventory of study drugs. Submit evidence that a clinical pharmacy and staff is identified to conduct the clinical trial.

SECTION 5: PROJECT MANAGEMENT AND OPERATIONS

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

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

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

4. Provide a plan for managing subcontracts in accordance with FAR Clause 52.244-2 and for assessing subcontractor performance/progress, including procedures and approaches to resolving performance deficiencies and noncompliance with subcontract terms and conditions of award. This includes experience with identification and remediation of subcontractor performance.

5. Provide evidence of past experience in the management of research budgets, subcontract administration and performance monitoring for projects of similar size and scope.

SECTION 6: FACILITIES AND RESOURCES

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

1. Location and features of facilities (lease or ownership information should be provided) to be used for the project. Include a description of the clinical outpatient, clinical pharmacy, and clinical microbiology laboratory facilities and other resources that will be made available at the offeror's institution and at each proposed clinical trial site.

2. All support resources (including IT systems) that will be required to effectively complete the requirements of the contract.1.

SECTION 7: DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

1. **Human Subjects**

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

   a. Human Subjects

      Include plans for compliance with applicable domestic and international regulations on the use of human subjects (e.g. IRB submission and approval plans, consent procedures, etc.).

   b. Health Insurance Portability & Accountability Act (HIPAA)

      Include plans for compliance with HIPAA.

2. **Privacy Act**

   Section L of the RFP specifies the minimum documentation requirements for Privacy Act compliance. All related documentation should be included in the proposal in a clearly marked section.

3. **Biohazard Safety**

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

4. **IT Systems Security**

   The Technical Proposal should include a plan for IT Systems security.

5. **Sharing Research Data (Plan)**

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

APPENDIX B
Clinical Trial for Community-Acquired Methicillin-Resistant
***Staphylococcus aureus* (CA-MRSA) Infections**
RFP NIH-NIAID-DMID-07-12

APPENDIX B - ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS

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

Offerors are advised to give careful consideration to the statement of work, all reference material provided as appendices and attachments, and the technical evaluation criteria, and, the RFP as a whole, in the development of their proposals. The information requested in these instructions should be used as a guide for the development and formatting of the business proposal. Offerors should consider and include the information requested in this appendix, as well as **any other** information which will benefit the proposal.

BUSINESS PROPOSAL - TABLE OF CONTENTS

SECTION 1 – PROPOSAL COVER SHEET – FORM NIH-2043 (See Section J, Attachments)

SECTION 2 – COST OR PRICE SUPPORT

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

SECTION 3 – UNIFORM COST ASSUMPTIONS

These are the uniform cost assumptions that the offeror should make to prepare the business proposal.

1) **Technical Cost Assumptions**

Assume that 1,200 subjects will be enrolled in the clinical trial.

2) **Travel**

Offerors should include the following uniform assumptions:

Annual Meeting
1 trip to the Washington D.C. area once per year for one day, for 20 persons.

DSMB Meeting
2 trips to Washington D.C. for DSMB meetings for one day for 2 persons.

FDA IND Meeting
1 trip to Washington D.C. for FDA IND meeting for one day for 2 persons.

Scientific Meetings for presentation of study data

3 trips to Washington DC for three days for 1 person.

3) **Study Drugs**

Offerors should include a uniform assumption of $200,000 for study drugs in years 1 through 3 of the contract.

SECTION 4 - TABLE OF CONTENTS FOR DOCUMENTATION REQUIRED UNDER SECTION L OF THE SOLICITATION

A. **Small Business Subcontracting Plan**

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

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

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

C. **Past Performance Data, including references**

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

APPENDIX C: NIAID-Funded Clinical Research Support Services Contracts

Clinical Trial for Community-Acquired Methicillin-Resistant
***Staphylococcus aureus* (CA-MRSA) Infections**
RFP NIH-NIAID-DMID-07-12

NIAID/DMID holds contracts with companies that currently provide and will continue to provide regulatory, clinical site monitoring and data management and analysis support to DMID-funded clinical researchers. The contractors with whom the successful offerors is expected to interact in order to perform functions specified within the Statement of Work are described below. Notifications will be sent to the successful offerors of this competition when awards are made for new or recompeted contracts that provide support for these functions.

NIAID/DMID Data Management Contractor

EMMES Corporation, located in Rockville, MD, provides several services for DMID-supported clinical research programs including the following:

1. Provides statistical leadership and clinical trial design expertise for the development of protocols and analysis of study data;
2. Establishes and administers data collection, management, quality assurance and reporting systems;
3. Provides adverse event safety reporting system and reconciles with the pharmacovigilance (SAE) system maintained by another contractor;
4. Provides detailed record maintenance and timely reporting;
5. Provides inventory and tracking system for study specimens; and
6. Collaborates with DMID, research groups, individual Principal Investigators and contractors.

NIAID/DMID Clinical Trials Management Contractor

PPD Development, LP, located in Wilmington, NC, provides clinical trials management support to DMID and DMID investigators. PPD Development specific responsibilities include, but are not limited to, the following:

1. Clinical site assessment, evaluation of clinical site for clinical research feasibility and capacity;
2. Clinical site preparation and clinical trial operations assistance; study document preparation and review;
3. Establish and assist clinical sites with internal quality control and quality assurance;
4. Provide Good Clinical Practices training;
5. External clinical site monitoring to include site initiation, interim and close-out visits and quality audit visits;
6. Centralized pharmacovigilance and safety monitoring; and
7. Information and document management through web-based systems.

NIAID/DMID Regulatory Support Contract

Fisher BioServices Corporation, located in Rockville, MD, provides regulatory support services including:

1. Preparation and maintenance of Investigational New Drug (IND) applications;
2. Consulting and audit for manufacturers of NIAID/DMID products;
3. Management and operation of a clinical agent repository for distribution and tracking of IND products.

APPENDIX D: DATA SUBMISSION REQUIREMENTS

Clinical Trial for Community-Acquired Methicillin-Resistant *Staphylococcus aureus* (CA-MRSA Infections RFP NIH-NIAID-DMID-07-12

The EMMES Corporation serves as the Data Management contractor for the Division of Microbiology and Infectious Diseases (DMID), NIAID, NIH. The Data Management contract uses a variety of technologies to collect, manage, monitor and distribute study data and information. To interface with EMMES, a computer with Internet access is required. EMMES' AdvantageEDC^{SM} is accessible via the World Wide Web using Internet Explorer 5.5 or higher. Access to the system is password restricted and passwords are issued by EMMES to individual users.

Data are submitted to EMMES from participating sites via remote data entry (RDE). The core element of EMMES' web-based data management system is Internet Data Entry System (IDES). This system includes various tools for subject enrollment, data entry, case report form management and protocol monitoring. One tool integrated with this system is GlobalTrace^{SM}, a specimen tracking system that scans a unique barcode on each specimen aliquot and tracks each aliquot from a clinical site, while in-transit and arrival at a receiving repository and/or laboratory. A second tool within AdvantageEDC^{SM} is *Integrity.* This tool examines study data for inconsistencies and completeness and generates reports of anomalies. EMMES' data management system is validated and is compliant with §21 CFR 11.

The Data Management contract maintains an extensive collection of websites. Study materials, such as protocols, template consent forms, Manuals of Operations, and case report forms are posted to the website for investigators and study staff to download as needed. In addition, the websites serve to disseminate real-time study information, including overall accrual, accrual by site for multicenter studies, data queries, line listings of adverse events, deviation reports, etc. Users external to DMID, EMMES and the PPD monitoring group are restricted to only his/her site's data and only to the functions, e.g. enrollment, randomization, GlobalTrace, associated with the rights the user has been granted.

EMMES provides a training version of AdvantageEDC. The training site serves as a means to practice using system functions and utilities and is provided to familiarize new and potential users with its features. EMMES also provides AdvantageEDC and GlobalTrace training via web-cast. To access this feature, telephone, computer and high-speed internet access are required.