



## Electronic Request for Proposal

### SECTION A – SOLICITATION/CONTRACT FORM

**OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE CMB WEBSITE <http://www.niaid.nih.gov/contract/default.htm> FOR ANY POSSIBLE SOLICITATION AMENDMENTS THAT MAY BE ISSUED. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE.**

<b>Purchase Authority: Public Law 92-218, as amended.</b>			
<b>NOTE: The issuance of this solicitation does not commit the government to an award.</b>			
<b>RFP Number:</b> NIH-NIAID-DAID-03-25	<b>Just In Time:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	<b>Small Bus. Set-Aside</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <b>8(a) Set-Aside</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <b>NAICS Code:</b> 541710 <b>Size Standard:</b> 500 employees	<b>Level of Effort:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <b>Total Effort:</b> <input type="checkbox"/> N/A <input type="checkbox"/>
<b>TITLE:</b> <p style="text-align: center;">HIV Clinical Research Management Support</p>			
<b>Issue Date:</b> July 22, 2002	<b>Due Date:</b> October 22, 2002 <b>Time:</b> 4:00 PM, EST	<b>Technical Proposal Page Limits:</b> <input checked="" type="checkbox"/> Yes (NTE 100 Pages) <i>(see "<a href="#">How to Prepare and Submit Electronic Proposals</a>")</i>	
<b>ISSUED BY:</b> _____ Barbara A. Shadrick Senior Contracting Officer Contract Management Branch, DEA NIH, NIAID 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, MD 20892-7612		<input checked="" type="checkbox"/> <i>We reserve the right to make awards without discussion.</i>	
		<b>NO. OF AWARDS:</b> <input checked="" type="checkbox"/> Only 1 Award <input type="checkbox"/> Multiple Awards	<b>PERIOD OF PERFORMANCE:</b> 5 years beginning on or about 06/02/2003
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 SECTION J - Attachments)			
The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.			
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## **INTRODUCTION / STATEMENT OF WORK / NOTES TO OFFERORS**

### **Introduction HIV Clinical Research Management Support DAIDS-03-25**

The AIDS pandemic has impeded the health, economic development, and political stability of many of the world's poorest and most vulnerable populations. In recognition of this global threat and to prevent the spread of HIV infection and other bio-organisms, the National Institute of Allergy and Infectious Diseases (NIAID) and the Division of AIDS (DAIDS) sponsors the conduct of Phase I-III trials testing vaccines and therapeutics, as well as preventive modalities (e.g. microbicides). DAIDS has extensive clinical trial networks and development contracts for the scientific development and testing of such products. These include the Adult AIDS Clinical Trials Group (AACTG), the Pediatric AIDS Clinical Trials Group (PACTG), the HIV Prevention Trials Network (HPTN) and the HIV Vaccine Trials Network (HVTN). In addition to these networks, DAIDS has fostered the development of vaccines and the testing of these products through industry partnerships, investigator initiated projects (R01s), and through inter-agency agreements with the Centers for Disease Control, and Department of Defense. With a maturing pipeline of clinical trials and an increased focus on clinical trial conduct in international settings, DAIDS will need to augment its current clinical trials management capacity, especially in international settings. Additionally, DAIDS is the Investigational New Drug (IND) sponsor for many of its current trials.

Therefore, with this Request for Proposal (RFP), DAIDS is seeking a contractor to provide comprehensive clinical trial management for a variety of clinical research efforts. Specific tasks performed within this contract will vary and will be trial-specific. For example, the contractor may provide quality assurance monitoring and medical writing for one Phase III trial within an established vaccine network; data management and site management support for an industry- sponsored Phase II trial; and an entire spectrum of clinical trials support services (design, initiation, management) for a third trial, initiated by an investigator (R01). The contractor must have the capacity and capability to work with DAIDS-specified grantees and contractors, and must possess the ability to establish necessary linkages (administrative, logistical, operational, Information Technology (IT), etc) as required for sound clinical trial management.

The primary activities under for this contract include:

- A) Research Program Management
- B) Site Assessment/Preparation/ Management/ Evaluation
- C) Clinical Trial Conduct
- D) Information Management Support

Specific responsibilities of the contractor are described in the Statement of Work below:

Statement of Work  
HIV Clinical Research Management Support  
RFP DAIDS-03-25

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## **STATEMENT OF WORK**

Independently, and not as an agent of the Government, the contractor shall furnish all the necessary qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the work set forth below.

### **A. RESEARCH PROGRAM MANAGEMENT**

**Provide both general and protocol specific clinical research management and associated activities.**

#### **1. Clinical Research Management**

Establish a team to provide clinical research management associated with the planning, implementing and conduct of Phase I, II, and III HIV clinical trials. Geographic areas for international trial conduct shall include, but are not limited to, Africa, Asia, Eastern Europe and India. The Contractor shall (but not be limited to) the following:

- a. Provide overall coordination and day-to-day management of a global portfolio of Phase I, II and III HIV trials with an emphasis on HIV Preventive Trials.
- b. Assemble Phase I, II, and III protocol specific teams to provide clinical research management activities related to a given trial; protocols will be provided by the DAIDS Project Officer.
- c. Program Report: On a monthly basis, track and report on key programmatic and protocol-specific activities as designated by the Division of AIDS (DAIDS) Project Officer (PO). This report shall be due two weeks after the end of each month. These activities shall include (but not limited to):
  - 1) Individual trial progress
  - 2) Individual project progress
  - 3) Meeting activity
  - 4) Financial expenditures by trial
  - 5) Administrative issues, obstacles, future plans
- d. Identify needs to be fulfilled by other sources as requested and approved by the DAIDS PO. Examples of other sources shall include (but are not limited to):
  - 1) Site Management Organizations
  - 2) Non-Governmental Organizations
  - 3) US and Foreign Academic Institutions
  - 4) Non-profit Organizations
- e. Provide video and teleconference support for projects/clinical trials at the request of the DAIDS PO including, but not limited to:
  - 1) 1-800 and international dial-in numbers
  - 2) Videoconference support for meetings
  - 3) Agenda dissemination
  - 4) Invitations/scheduling of attendees
  - 5) Meeting minute preparation with review and approval processes

#### **2. Logistical Support**

Establish a multi-faceted logistics center to provide programmatic and protocol-specific logistical assistance in many areas related to the conduct of Phase I, II and III clinical trials. The areas shall include but not be limited to:

a. Comprehensive Meeting Support for a variety of meetings (to include but not be limited to):

- 1) Investigator Meetings
- 2) Data and Safety Monitoring Meetings
- 3) Protocol Meetings
- 4) Scientific Workshops
- 5) DAIDS Meetings related to clinical trials and efforts supported by this contract
- 6) Conferences
- 7) Protocol Kick-Off Meetings

This comprehensive meeting support will include but will not be limited to:

- 1) Meeting arrangements to include venue booking and meeting coordination.
- 2) Agendas – to be promulgated and disseminated upon DAIDS PO approval.
- 3) Travel and accommodations (not to include Government employees).
- 4) Graphics and audiovisual support.
- 5) Simultaneous translation during meeting (may include Spanish, French, Chinese, Portuguese).
- 6) Document preparation, review and advance distribution.
- 7) Document translation.
- 8) Meeting summary reports for DAIDS designated meetings (e.g. large workshops, conferences).
- 9) Minute preparation and distribution upon DAIDS approval for Protocol Team Meetings and other DAIDS specified meetings related to contractual efforts.
- 10) Meeting participation.
- 11) Data and Safety Monitoring Board Meetings (DSMB) (including in international settings, identification and invitation of members and materials preparation).

b. Study and Program Material Distribution:

- 1) Prepare trial-specific and overall program support documents and materials including, but not limited to, recruitment materials, study specific binders, procedural manuals, team listings and directories.
- 2) Recommend the most appropriate mechanism(s) (to include web-based distribution) for document distribution.
- 3) Proof documents prior to distribution for errors, all materials must be pre-approved by the DAIDS PO.
- 4) Distribute documents and materials at the direction of the DAIDS PO.
- 5) Create list serves for distribution.

c. Call Center

The Contractor shall set up a Call Center to assist in the initiation and management of domestic and international clinical trials to provide multiple study functions. These activities (including, but not limited to) shall be to:

- 1) Provide a 1-800 number within this call center (8 hrs per day, Monday through Friday with U.S. or local in-country holidays observed) in the U.S. with trained personnel.
- 2) Provide regional toll free numbers in international settings staffed with multilingual personnel.
- 3) Develop Call Center Standard Operating Procedures within one month after DAIDS PO request.
- 4) Develop and implementing tools to collect and track regulatory documentation to register sites for Phase I, II and III trials.
- 5) Provide site nomenclature (site tracking numbers) with automated ability to prohibit enrollment without appropriate documentation. Produce site numbering reports with progress updates (i.e. which sites have completed registration) on a monthly basis and post on a web based mechanism to give “live data” to the DAIDS PO and the sites.
- 6) Broadcast messages via e-mail regarding site status (enrolled, disenrolled, on hold).
- 7) Establish, at the request of the DAIDS PO, an interface from the Call Center to an existing DAIDS contractor for a drug/vaccine distribution center to release test article upon site registration. Documented SOPs for appropriate processes and product release procedures should be available to DAIDS upon one month of award of contract.
- 8) Provide checklists of requirements to inform investigator of site registration requirements.

- 9) Provide Interactive Voice Response System or similar system for recruitment and automated diary collection if required by trial.
- 10) Answer, refer and report questions from site investigators to appropriate sources.

d. Study File Management and Archiving Services:

Provide study file management and archiving services in a facility (e.g. locked storage room for files) with limited access. Activities (including, but not limited to) shall be to:

- 1) Under the guidance of the DAIDS PO, establish and maintain study master trial files.
- 2) Establish and maintain study and contract administrative files (including, but not limited to items such as):
  - a) Quarterly reports
  - b) Monitoring reports
  - c) Assessment reports
  - d) Evaluation reports
  - e) Internal Quality Assurance activities and reports
- 3) Within four (4) weeks of contract award, provide an SOP to the DAIDS PO on the required contents of a protocol master file.
- 4) As specified by the DAIDS PO, archive and catalogue files.
- 5) Store files for the time period to be specified by the DAIDS PO.
- 6) Under the guidance of the DAIDS PO, facilitate an orderly transition of files with appropriate cataloguing and the archiving of administrative and research records.

### 3. Training

Provide a variety of training with an emphasis on delivering training in international settings and in multiple languages to include but not limited to Spanish, Portuguese, French and Chinese. Simultaneous translation may be required at training sessions. Training activities (including, but not limited to) shall be to:

- a. Perform needs assessment to determine the training requirements of personnel and the most suitable and efficient mode of providing training (e.g. Telephone, on-site, written materials, web). Develop a training request form and an SOP for request(s) and DAIDS approvals. Types of training (include, but are not limited to):
  - 1) Protocol specific training
  - 2) Good Clinical Practices Training
  - 3) Site specific training (based on needs)
  - 4) FDA audit training
  - 5) Scientific training on specific topics
  - 6) Human Subjects Protection
  - 7) Informed Consent
  - 8) MedDRA (the Medical Dictionary for Regulatory Activities)
  - 9) International Air Transport Association (IATA) training or Saf-T-Pak for shipping of biohazardous substances
- b. Develop, distribute and update training materials. Training materials and updates will be presented to the DAIDS PO for approval prior to distribution.
- c. Develop a web-based mechanism to catalogue, maintain and update training materials for easy web access and utilization by sites.
- d. Provide training through web-based media to facilitate training in domestic and international settings.
- e. Establish a central training documentation mechanism to record and report status of training activities for clinical investigators and staff, via a training website including, but not limited to, the identification of training requirements and associated frequency, the completion of training, and the expiration of training.

#### 4. **Staffing (Trial Sites)**

Provide staffing to trial sites, including sites in resource constrained areas, on an as needed basis. Assignments may vary from short-term to long-term. Types of staff include, but are not limited to:

- a. Monitor
- b. Site Manager
- c. Study Coordinator
- d. Laboratory technician
- e. Project Administrator
- f. Data Entry clerk
- g. Data Manager

#### 5. **Infrastructure Support**

As needed, provide a variety of support mechanisms in resource constrained settings (Africa, India, Asia, Eastern Europe) to assist with infrastructure development for the establishment of highly functional clinical trial units. Develop an SOP and a process for a site to request such support; all requests must be approved by the DAIDS PO. Equipment (including, but not limited to) shall include:

- a. Computers (see IT support)
- b. Telephones
- c. Videoconference capability (if site is so designated)
- d. Personal Digital assistants
- e. Laboratory equipments (e.g. centrifuges, freezers, laminar flow hoods)
- f. General facilities upgrade (e.g. generator, fax machine, Xerox machine, room design and renovations)

### **B. SITE ASSESSMENT/PREPARATION/MANAGEMENT/EVALUATION**

Provide comprehensive support for the assessment, preparation, management and evaluation of sites participating in DAIDS Phase I, II and III HIV trials. Activities shall include, but not be limited to:

#### 1. **Site Assessment**

- a. Identify clinical research sites with the capabilities to initiate and conduct specified clinical trial(s).
- b. Develop, utilize and analyze site capability questionnaires, pre- and post- assessment checklists (infrastructure needs, staffing needs, administrative needs, etc.) and reports to assess site capability and readiness for clinical trials (prior to site initiation for a specific trial).
- c. Upon DAIDS approval, send an initial assessment team to review the site. The team shall assess areas to include, but not be limited to, the clinical unit, pharmacy, laboratory, data management and recruitment.
- d. Provide annual site assessments that shall include, but shall not be limited to, a review of regulatory procedures, organizational procedures, pharmacy, laboratory, data management and other clinical trial related efforts. The DAIDS PO may request these annual assessments at a greater frequency.
- e. Report results from site assessment visits and making recommendations on site viability, describing site strengths and weaknesses to DAIDS. Reports are expected within two weeks of the last day of the visit.
- f. Upon DAIDS approval, propose plans for and conduct visits for remedial site actions and/or infrastructure development.

#### 2. **Site Preparation**

Prior to site initiation, new sites shall require a site preparation visit for the dissemination and training of site organizational tools (Standard Operating Procedures, volunteer contact form, screening log, training log, signature log) for trial conduct. Activities (including, but not limited to) shall be to:

- a. Establish a site preparation team (distinct and separate from the Contractor’s monitoring group) to visit sites and perform training as required.
- b. Perform site preparation visits at the request of the DAIDS PO. Follow-up visits may be requested by the DAIDS PO.
- c. Formalize a site preparation visit and report template for approval by the DAIDS PO. Site Preparation reports are expected within two weeks of the last day of the visit and shall include executive summaries and problems/resolution listings.
- d. Design web mechanisms to electronically track site visit problems/resolution(s) with the ability to report on the status of such problems/resolutions.
- e. Prepare and distribute organizational aids (in required languages such as French, Spanish, Portuguese and Chinese) to all sites. The Contractor shall (including, but not limited to):
  - 1) prepare a list of essential documents,
  - 2) prepare regulatory binders with suggested table of contents,
  - 3) prepare sample grid of responsibility for each site
  - 4) prepare sample, “generic” site Standard Operating Procedures with suggested table of contents
  - 5) provide additional organizational tools such as specimen tracking checklists, patient screening logs, telephone contact forms.
- f. Obtain signed Letter of Agreements and other legally binding documents (e.g. clinical trial agreements, confidentiality agreements, transfer of responsibilities) prior to trial initiation.
- g. Work with the DAIDS to generate a final checklist that will communicate that a site is capable, trained and is functioning in concurrence with Good Clinical Practices (GCP), International Conference on Harmonization (ICH), Office of Human Research Protection (OHRP), local in-country ethics approvals, and other applicable regulations to ensure successful trial initiation and conduct.

### 3. Site Management

Provide ongoing site management for all phases of clinical trial conduct. Activities (including, but not limited to) shall be to:

- a. Provide ongoing advisory assistance and Quality Assurance (QA) assistance (e.g. assistance in developing quality assurance measure, quality assurance checklists) to site(s) such as responding to requests for training or explanations of protocol and/or administrative procedures. Site Management/Site Advisory Personnel may not function in the role of Site Monitor of the same site(s).
- b. Track and report, to the DAIDS PO, key site and protocol activities and study metrics or variables in order to produce monthly visit reports by site and by trial to be submitted within two weeks after preparation. Metrics/variables will be determined by the DAIDS PO with input by the Contractor. Report content, distribution method and frequency shall be available on the web and shall be approved by the DAIDS PO (with monthly hard copy to DAIDS PO). MS Project GANTT charts shall be generated for each trial and updated at least monthly. Activities include, but are not limited to:
  - 1) Accrual by trial and by site.
  - 2) Retention by trial and by site.
  - 3) Protocol listings.
  - 4) Milestones and timelines.
  - 5) Financial status by trial and by effort.
  - 6) Regulatory clearance status by site and trial.
  - 7) Critical issues by site and by trial.
  - 8) Safety listings by trial and by site.
  - 9) Monitor visit summaries by trial and by site.
  - 10) Monitor visit deficiencies/listings.
  - 11) Number of volunteer visits by site and by trial.
  - 12) Number of volunteers screened by site and by trial.

- c. Provide ongoing communication support and materials (multiple language capability) to the sites. All communication materials must be approved by the DAIDS PO prior to dissemination. Activities (including, but not limited to): shall be to:
- 1) Assist site in the preparation of communication plans.
  - 2) Assist sites in the preparation of each Protocol Initiation “Questions and Answers” to the Press.
  - 3) Assist sites in the preparation of Press Releases.
  - 4) As specified by DAIDS PO, prepare clinical trial volunteer education materials (video may be included).
  - 5) As specified by DAIDS PO, prepare recruitment and retention materials to include web-based mechanisms, and patient/volunteer reward/incentives (such as designing and providing T-shirts, water bottles, backpacks and other culturally appropriate incentives).
  - 6) Following input and approval to be provided by the DAIDS PO, prepare radio and television commercials with suggestions of relevant content/message.
  - 7) Prepare other printed media (such as “Understanding Vaccines” or “HIV disease/treatment/prevention”).
  - 8) Prepare pamphlets in a variety of languages for a wide range of HIV clinical trials for lay audiences and with DAIDS input/approval.
  - 9) As directed by the DAIDS PO, interact with and contribute to the NIAID Vaccine Communications Steering Group for Vaccine-related communications.
  - 10) Initiate and maintain a link to [www.clinicaltrials.gov](http://www.clinicaltrials.gov), providing review and editorial assistance for protocol preparation summary and update of all DAIDS protocols (active and pending) in this database. All information must be approved by the DAIDS PO. Protocol summaries shall be written and approved and placed on the website at least six (6) weeks prior to trial initiation. Information for access to this website will be given by the DAIDS PO.
- d. Investigator Management – Investigator management activities (including, but not limited to): shall be to:
- 1) Recruit investigators and sites for trials on an ongoing basis through websites as well as through investigator communications such as mailings and selected conferences.
  - 2) Establish web-based advertisement and additional mechanisms (e.g. trade magazines) to communicate availability of new trials to potential investigators, academic institutes and research organizations.
  - 3) Maintain and update a searchable database (by investigator, specialty, site, geographic region, number of trials performed) of potential investigators and sites with open access to DAIDS. This shall be an ongoing effort with monthly updates of additions to the DAIDS PO. The first listing shall be due within four (4) months of contract award and shall contain a listing of all potential HIV investigators within the major geographic areas discussed. DAIDS will also provide to the Contractor its current listings of investigators and sites.
- e. Community Assistance –
- 1) Assist the sites in the establishment and maintenance of Community Advisory Boards (CAB).
  - 2) Provide administrative assistance to the CABs, at the request of the CABs and with approval of the DAIDS PO. Activities shall be to (including but not limited to):
    - a) arrange, attend and prepare meeting minutes on a monthly basis;
    - b) disseminate material as requested; and
    - c) as directed by DAIDS PO, arrange travel for the CABs to attend meetings where CAB representation is required/encouraged.

#### 4. Site Evaluation

As determined by the DAIDS PO, perform site evaluations on a bi-annual to annual basis. Evaluation shall be an ongoing, proactive effort that shall be to (including, but not limited to):

- a. Establish written procedures, policies and guidelines for the standardized evaluation of sites and disseminate this information to the sites. All materials must be approved by the DAIDS PO.

- b. Develop quantifiable mechanisms to track site quality and productivity such as:
  - 1) enrollment,
  - 2) data quality,
  - 3) protocol adherence,
  - 4) operational compliance, and
  - 5) Good Clinical Practices Adherence.
- c. Identify key site performance variables and minimum standards of performance for a site. The contractor shall, within 24 hours, identify to the DAIDS PO any site not meeting minimum standards and shall assist the site(s) in remedial actions when necessary and when requested and approved by DAIDS. The DAIDS may request other actions such as site shutdown or site hold, that will be implemented by the Contractor.
- d. Produce site comparison reports on a monthly, quarterly and annual basis to be delivered as requested by the DAIDS PO. Reports shall contain various graphic representations of the data for ease of comparison such as bar charts, means and averages. Report format shall be approved by the DAIDS PO.

### **C. CLINICAL TRIALS CONDUCT**

#### **Plan, initiate and conduct DAIDS Phase I, II, III trials**

Trials will be funded by DAIDS and sponsored either by DAIDS or pharmaceutical company partners or conducted within a DAIDS-funded Network. Certain tasks associated with the conduct trials may be provided by a partner or other DAIDS contractors and grantees (e.g. monitoring, or data management). Accordingly the Contractor must be willing to partner with additional entities in order to provide a seamless interface for communication and information flow. Therefore, as stated, trial support will vary and may range from a broad array of tasks for the Contractor to perform for a trial to only one task for the Contractor per a specific trial. Trial support (including, but not limited to) shall consist of:

#### **1. Document Generation**

A variety of documents will be needed throughout the life cycle of a trial and in support of the development and testing of new pharmaceutical products. Independent scientific input for these documents will not be incumbent upon the Contractor; however, the Contractor will work with a variety of DAIDS scientific/medical staff as well as with other Contract/Grantee staff.

- a. The Contractor shall bring the necessary review and technical expertise from multiple units such as the Contractor's medical unit, monitoring unit, project management unit, data and statistical unit, quality assurance and regulatory affairs unit in the promulgation, revision and finalization of documents (with commensurate literature searches).
- b. The Contractor shall furnish comprehensive medical writing SOPs for documents associated with clinical trials conduct within two months of contract award. Deadlines for the documents will vary upon the task. Documents produced (including, but not limited to) shall be:
  - 1) Protocols, amendments,
  - 2) Investigator brochure and updates,
  - 3) Study manual(s),
  - 4) Source documentation guidelines,
  - 5) Study specific procedures,
  - 6) Case report forms with data management review and case report instructions,
  - 7) Informed consent forms,
  - 8) Statistical Analysis Plan,
  - 9) Monitoring Plan,
  - 10) Draft tables and listings,
  - 11) Final tables and listings,
  - 12) Statistical report,
  - 13) Study reports for a range of scientific and lay audience(s), and
  - 14) Clinical Study Reports (trial conclusion).

## 2. Trial Planning

Procedures, systems and documentations shall be in place prior to a trial initiation to assure adherence with DAIDS Guidelines as well as applicable regulatory and host country regulations. At the direction of the DAIDS PO, the Contractor shall be responsible for a selected range of tasks (to include, but not be limited to):

- a. Provide Members and Assemble Protocol Team.
- b. Finalize documents.
- c. Establish a date for Investigator Meeting (arrangements to be provided by the Management Support component).
- d. Generate protocol working timeline, milestones and GANTT chart.
- e. Coordinate IRB (and selection/coordination of Central IRB if applicable) and International Ethics Committee submission(s) (interface with Call Center).
- f. Provide and file validation of systems (such as database systems).
- g. Provide template to DAIDS PO for protocol specific activity report.
- h. Provide randomization schedule.
- i. Provide Quality Assurance Plan per trial.
- j. Provide project management for the trial initiation, to include at a minimum:
  - 1) Set up trial master file,
  - 2) Set up communication and Project plan,
  - 3) Provide team rosters,
  - 4) Define day-to-day interaction with DAIDS and other contractors,
  - 5) Determine if Study Newsletter will be needed, what frequency, and working with communications to produce the study newsletter,
  - 6) Select and manage contracts for Central Laboratory for safety laboratory and specialized laboratory for special labs (viral load, PCR),
  - 7) Act as a liaison with Drug/Vaccine shipment center for shipment and follow-up on shipments,
  - 8) Determine date for kick-off meeting, and
  - 9) Conduct Kick-off Meeting with logistical arrangements provided by the Management support component.

## 3. Regulatory Support

The Contractor shall provide a broad range of regulatory support throughout the cycle of Phase I, II and III trials. Types of regulatory support and consulting shall include, but not be limited to:

- a. Pre-Investigational New Drug (IND) support and materials compilation,
- b. Pre-IND teleconference support,
- c. IND support and materials compilation,
- d. End of Phase II support, compilation of materials and presentation assistance,
- e. New Drug Application (NDA) application/compilation of materials,
- f. Biologics License Application (BLA) application/compilation of materials,
- g. Listing of international ethics committees where trials are to be conducted (for example, how many and what ethics committees does South Africa have for HIV drug trials),
- h. Submission times required for international submissions (by country),
- i. Attendance and advice at routine and non-routine FDA meetings,
- j. Assistance in the preparation, compilation and submission of non-US Marketing applications, and
- k. Performance and Issuance of Audit certificate upon completion of audit.

## 4. Monitoring and Quality Assurance Support:

The Contractor shall:

- a. Provide routine monitoring visits and GCP visits for sites including ability to travel to difficult areas and with as little as four (4) weeks notice by the DAIDS PO.

- b. Provide Quality Assurance of the monitoring. Review of monitoring reports generated by a third party in cases when monitoring for a trial may not be required by the Contractor. Monitors/Auditors shall be identified at the start of each trial and shall be identified in the contract as “Key Personnel” while performing these duties. Because Monitors/Auditors are to be identified as key, the DAIDS PO must approve all CVs, which shall be forwarded to the Project Officer six (6) weeks in advance of all monitoring visits.
- c. Provide separate and distinct reporting chains for all Monitoring and Quality Assurance units.
- d. Provide a Contractor’s internal monitoring SOPs within four (4) weeks after contract award.
- e. Provide a copy of Contractor’s own internal Quality Assurance plans within four (4) weeks after contract award.
- f. Conduct Monitor visits and more comprehensive Quality Assurance/GCP visits. Frequency and duration of visits will vary by trial and will be defined by a monitoring plan developed by the Contractor and approved by the DAIDS PO. [A typical trial will be monitored every 8-12 weeks with visits of 3-4 days duration.]
- g. Conduct Quality Assurance Visits/GCP visits that may take 1-2 weeks depending on the reason for the visit. The Monitor shall make recommendations as to percent of charts to be reviewed as well as key variables. The Contractor shall review and assess monitoring reports and follow tasks to resolution based upon reports generated by a third party Contractor. In support of monitoring and QA activities, the Contractor shall (including, but not be limited to):
  - 1) Perform various monitoring or QA visits:
    - a) Protocol/Site Qualification Visit (or telephone qualification if directed),
    - b) Protocol Initiation Visit,
    - c) Interim Visit,
    - d) Close-out Visit,
    - e) Quality Assurance/GCP Visit,
    - f) For cause audit/visit,
    - g) Audit (for purposes of issuance of Audit Certificate), and
    - h) Pre-FDA audit inspection.
  - 2) Conduct Site Visits that shall include a minimum of the following:
    - a) Letter to Investigator,
    - b) Defined record review (agreed upon between DAIDS and Contractor),
    - c) Assess the site’s internal Quality Assurance procedures,
    - d) Review of pre-determined number of Case Report Forms (CRFs) and Informed Consents,
    - e) Adherence to GCP,
    - f) Adherence to Source Documentation Guidelines,
    - g) Completeness of regulatory binder,
    - h) Pharmaceutical product accountability,
    - i) Facility Operations,
    - j) Follow-up actions (if authorized by the DAIDS), and
    - k) Detailed monitor report with executive summary.
  - 3) Forward a monitor report to the DAIDS PO within two (2) weeks after a routine monitoring visit. Notify the DAIDS PO within 24 hours of discovery of serious deficiency while still on site. Reports should be formatted so that executive summaries of issues are given on the first page of the report as well as critical protocol information (number of trial, number of volunteers per trial, number of charts selected, percent reviewed). Monitoring report “shells” will be reviewed and approved by the DAIDS PO prior to use.
  - 4) Act as the report reviewer for reports generated by third party contractors. In these instances, work with grantees/contractors to secure monitoring reports and import the data/information into a database using commercial software. Generate an SOP for monitor report review within four (4) weeks after contract award.

- 5) Design, implement and manage a web-based database to track monitoring visits and action items, deficiencies, and resolution(s). Tracking should be performed by:
  - a) patient/volunteer record,
  - b) syntheses of information,
  - c) problems and trends at sites or trends within studies,
  - d) regulatory deficiencies,
  - e) pharmaceutical storage/dispensing deficiencies,
  - f) informed consent violations,
  - g) protocol violations,
  - h) operational non-compliance (lack of SOPs, eroding infrastructure), and
  - i) investigator and/or DAIDS/Contractor correspondence (storing electronic copies of actual correspondence).
  
- 6) Provide monthly reports of monitoring deficiencies (by site and by protocol) with recommendations to DAIDS PO (or designee) and work with site to correct deficiencies. Reports shall be due the 5<sup>th</sup> (fifth) of each month. Assistance shall include, but not be limited to:
  - a) design, manage and update of a database to note monitoring problem trends and flag unresolved problems,
  - b) communication with sites to correct deficiencies,
  - c) provision of additional training or local support to correct problems,
  - d) provision of visits from an operational “assistance” team (separate from the routine monitoring team), and
  - e) answering protocol specific questions or general questions, or forward the question to the appropriate resource (e.g. such as a regulatory question from the site will be forwarded to the Contractor’s regulatory expert).

## 5. Data Collection and Management

Modify and/or develop a comprehensive data collection, management and transmission system to handle all aspects of data associated with Phase I, II and III trials. Modify and/or develop other related procedures to manage clinical data for Phase I, II and III studies and furnish all necessary hardware and software to be used by Contractor and the sites. Different data management tools (including web-based tools) may be used depending on the type of trial, the Sponsor of the trial (e.g. DAIDS or Pharmaceutical partner) as well as recommendations by the Contractor and other partners. Data management systems must be validated and the Contractor shall be expected to provide the proof of validation before trial implementation. Comprehensive SOPs for data collection and management shall be due within two (2) weeks after award of the contract. Associated activities (including, but limited to) shall require the Contractor to:

- a. Document and utilize a system of data management procedures to assure the quality and timeliness of data submitted by clinical sites throughout a study and to assure the accuracy and reliability of the databases managed by the Contractor to include the production of the final data set and “database lock”. Study-specific data management plans shall be established for trials.
- b. Keep all subject records (both hard copy and electronic) in a confidential manner. Certain types of summary data shall also be kept confidentially in compliance with current NIH Women, Gender and Minority policies. Procedures must be employed to ensure that access to all such data is given only to staff members who have been determined by DAIDS and the Contractor to view the data. The system must allow for access at different security levels.
- c. Establish reliable electronic communication links with DAIDS and with clinical sites that permit sending e-mail and sharing word processor and data files. Web sites for protocol and program communication(s) should be implemented with appropriate secured access. Maintain compatibility with standard software.
- d. Track, verify and file CRFs with appropriate QC checking of the CRFs and translation of text entries into the CRFs. The contractor will work with the sites and responsible parties to issue and resolve data queries in a timely manner.

- e. Accommodate special and routine data processing requests and data transfers using commercial software such as SAS. Perform the appropriate QC of the final dataset before transferring to the DAIDS PO.
- f. Provide technical support and data management support and advice to the sites. Some sites may require intensive data management support and training, that shall be provided by the Contractor at the request of the DAIDS PO.

#### 6. **Biostatistical Assistance**

The Contractor shall provide biostatistical assistance as requested by the DAIDS PO, or the PO designee. SOPs pertaining to the Biostatistical processes applied during clinical trials must be provided within five (5) days after request (e.g. “breaking the blind SOP or randomization SOP or DSMB data review). Assistance shall include but not be limited to:

- a. Protocol Design for Phase I, II, and III HIV trials,
- b. Interim analyses for ongoing trials,
- c. DSMB report preparation,
- d. Data summary, tables and listings for clinical study reports and other requested reports,
- e. Randomization schemas/listing(s),
- f. Generate biostatistical section of Clinical Study Report, and
- g. Generate input as requested for additional reports.

#### 7. **Product/Agent Distribution**

In accordance with all applicable guidance and regulations, the Contractor shall store, distribute and manage the accountability and stocking/dispensation of study drugs or vaccines. The Contractor shall furnish general repository activities to provide the storage of cells and serum from clinical trials participants (as needed). Activities related to product storage and management/dispensation shall be (including, but not limited) to:

- a. Maintain, manage and distribute study drug to U.S. and international sites, in accordance with all applicable guidance and regulations,
- b. Insure that appropriate quality control mechanisms are in place as they relate to shipping, storage, management and destruction. Securing the appropriate import/export licenses and assuring appropriate handling and storage conditions, drug accountability and cold chain.
- c. Utilization of state-of-art shipping containers (may be provided through DAIDS) and temperature monitors to insure appropriate storage and shipping.
- d. Review and approve each site’s pharmacy capabilities prior to shipment.
- e. Maintain product supply accountability with monthly total reports -- supply out/supply in, supply total -- in order to balance accountability on a monthly basis and to insure that each trial participant will be assured of the presence of study drug.
- f. Within one (1) month after the award of this contract, provide the DAIDS PO with a manual of SOPs that demonstrates appropriate compliance and sound management of product storage and distribution.

#### 8. **Project Management**

At the request of the DAIDS PO and prior to trial initiation, provide a Project Manager for each clinical trial. These Project Managers will be identified as “Key Personnel” under the contract. Submission of Curricula Vita to the DAIDS PO shall be required. Innovative project management and clinical trials management tools are encouraged if compatible with commercial software. In addition to overall clinical trial project management, project management tasks shall be (but not be limited) to:

- a. Assemble protocol teams (regulatory, biostats, medical writing, safety monitoring, data management, monitoring, site management, etc.),
- b. Generate communication plans,
- c. Generate protocol responsibility grids,
- d. Outline transfer of obligations for team and site staff,
- e. Provide team listings,
- f. Provide team notebooks and reference materials (distribution through logistics component),

- g. Establish an individual website for team communications, electronic notes and broadcast communications (electronic trial file) for each trial in conjunction with the IT department,
- h. Provide Quality Assurance for deliverables to the DAIDS PO,
- i. Serve as central trial resource for the DAIDS and the team,
- j. Liaison with the sites and DAIDS PO for site assessment, management and evaluation issue,
- k. Meet with DAIDS PO or designee on a predetermined schedule with minimal frequency of monthly meetings after trial initiation,
- l. Work with the monitoring team on the percentage of records monitored and make recommendations for adjustments when necessary, in conjunction with the DAIDS PO.
- m. Edit study newsletter if requested by DAIDS PO,
- n. Generate and update protocol or project timelines utilizing MS Project software,
- o. Generate monthly progress reports of technical progress, monitoring issues, enrollment and screening, number of CRFs entered, number of CRFs cleaned, numbers of outstanding queries, training requests, training sessions, additional administrative and technical issues. Report is due the 5<sup>th</sup> (fifth) of the following month.
- p. Organize and coordinate team meetings (including logistics such as notifications, securing dial-in numbers)
- q. Provide and file minutes of each protocol team meeting after approval of DAIDS PO or designee
- r. Maintain telephone records of key contacts and key decisions
- s. Communicate trial issues or problems to the DAIDS PO within 24 hours of notification or sooner, if possible.
- t. Track and report key metrics via web-based media.
- u. Design, develop and update GANTT charts on a monthly basis via the web for the DAIDS PO
- v. Serve as the central “information specialist” for the trial

## 9. Safety Monitoring

Provide all safety monitoring including the design, development, implementation and maintenance of a global Adverse Event/Serious Adverse Event (AE/SAE) Reporting system. Associated activities shall be (but not limited) to:

- a. Code all reported adverse event terms into a standardized international terminology, MedDRA (the Medical Dictionary for Regulatory Activities).
- b. Abstract adverse event information into a centralized database.
- c. Provide for medical review of AE/SAE, reportability meeting and assessment, and generate draft and final safety reports.
- d. Provide SOPs for AE review, AE/SAE flow process with charts for site use and clarity.
- e. Provide 24 hours/7 days per week physician coverage/consultation to the sites as well as to DAIDS and trial staff.
- f. Define an interface/communication plan and guidelines prior to study initiation as it relates to safety reporting in the event safety monitoring may be provided by DAIDS and existing contractor(s).
- g. Develop, implement and maintain quality control/assurance procedures and ongoing training of clinical site staff to ensure consistency, completeness and accuracy of SAE reporting.
- h. Standard SAE practice and reporting procedures shall be submitted to the NIAID PO within four (4) weeks after contract award.
- i. Transmit Serious Adverse Event (SAE) reports to DAIDS personnel and additional designated entities such as IRBs, DSMBs, other entities to be determined. Transmit immediately to DAIDS Medical Officer(s).
- j. Provide weekly safety listings to DAIDS PO. Due on the following Monday.
- k. Provide an interface with other DAIDS contractor(s) for the collection of safety information.
- l. Ensure compliance with current regulatory and requirements both in the U.S. and in other countries where the trial is conducted. Compliance shall include the areas of safety surveillance, safety strategy, representation and communication with regulatory authorities.
- m. Provide support to DAIDS Medical Monitors in managing adverse events (e.g. report preparation, narratives, assessment)
- n. Assist and manage a transition should the Contractor become responsible for the safety monitoring of all DAIDS protocols.

## 10. Laboratory Procedures for Clinical Research

Provide laboratory assistance to on-site labs as well as central laboratory support and specialized laboratory support. At the request of the DAIDS PO, or designee, activities provided shall be (but not be limited) to:

- a. Establish and develop “global” standard procedures for collection, labeling, shipping and storage of laboratory specimens. Utilization of electronic methods such as bar coding is encouraged to streamline laboratory procedures.
- b. Assist sites in the establishment and maintenance of individual site laboratory SOPs.
- c. Assist in international laboratory infrastructure development to include identification of equipment needed, training in laboratory procedures, and actual laboratory set-up. Laboratories may be regional or site-by-site.
- d. Assess the adequacy of laboratory quality control procedures and assist clinical site laboratories in the development of SOPs and quality assurance procedures.
- e. Perform GLP or routine audits to site laboratories with action plan for item resolution.
- f. Visit sites on an “as needed” basis to insure the appropriate conduct of safety laboratories and specimen shipping.
- g. As requested by the DAIDS PO, establish a proficiency-testing program for selected laboratory tests.
- h. Provide central laboratory support for the conduct of routine safety laboratory tests, quality assurance and project management of specified trials.
- i. At the request of, and with facility designation by the DAIDS PO, the Contractor shall negotiate agreements with specialized laboratory facilities to provide routine or specialized immunogenicity tests (ELISA, ELISPOT, antibody neutralization) and/or protocol laboratory assessments such as viral load or CD4 tests.
- j. Coordinate and implement quality assurance training and quality assurance programs for laboratories.

## 11. Shipping

Assist DAIDS with the shipping of laboratory specimens during the conduct of clinical trial(s). This assistance shall be (but not be limited) to:

- a. Provide specialized operational support when necessary for specimen shipping.
- b. Work with specified DAIDS personnel on shipping processes and provide personnel with understanding of U.S. customs and international shipping, import/export practices.
- c. Track shipments and trouble-shoot when specimen-shipping problems arise.
- d. Advise as to shipping timelines and problems in particular areas with an emphasis on clinical trial related materials from/to Africa, Asia, Eastern Europe and India.
- e. Procure shipping containers and commercial shippers for the transfer and shipping of international samples, with the approval of the DAIDS PO.
- f. Monitor International Air Transportation Association (IATA) certification and compliance for clinical sites.

## **D. INFORMATION MANAGEMENT SUPPORT (DATABASE DEVELOPMENT)**

**Provide State of Art Information Technology Support for large scale, international clinical trials.**

### 1. System Requirements/Specification

- a. Develop databases to meet the informational needs as defined in this contract using commercial off-the-shelf software to be compatible with DAIDS standards and with other existing and planned DAIDS applications. Access to these databases shall be given to the DAIDS.
- b. The system(s) shall be consistent with:
  - 1) Code of Federal Regulations,
  - 2) NIAID Informatics Standards,
  - 3) Industry Standards, and
  - 4) Health Insurance Portability Protection Act (HIPPA) standards for data integrity, confidentiality and security.

Additionally, the Contractor shall provide, at a minimum, the following activities:

- 1) assure that clinical trials data is entered into the database with identifying numbers only,
- 2) transfer legacy data into new databases,
- 3) establish necessary linkages with DAIDS contractor(s) and grantee(s) to facilitate clinical trials management and transfer data upon direction of the DAIDS PO,
- 4) establish a link with existing grantee networks; and
- 5) provide enterprise capabilities to integrate and to have interoperability of the databases under this contract.

## 2. **HIV Trials Database**

- a. Use [www.clinicaltrials.gov](http://www.clinicaltrials.gov) to establish an interface to produce protocol activity reports that will include protocol summaries and accrual to date information as well as site participation information.
- b. Provide reviews of submitted information on a regularly scheduled basis to maintain accuracy.
- c. Establish canned reports to furnish to DAIDS upon request. Examples of such reports include:
  - 1) Protocol listing by country
  - 2) Investigator listing by site
  - 3) Volunteer recruitment by country
  - 4) Phase of trial by country
  - 5) Protocol summary reports

## 3. **IT Systems to Facilitate International Trial Implementation**

Prepare, develop and maintain websites to facilitate communications and conduct of Phase I, II and III clinical trials. Websites must be approved by the DAIDS PO. Website and associated IT activities shall be (include, but not be limited) to:

- a. Provide IT systems to facilitate trial implementation and trial management.
- b. Propose web-based systems and innovative IT options for trial management such as Personal Digital Assistants and other wireless technologies.
- c. Provide laptops and hardware as needed per trial and per site, particularly in resource- constrained countries.
- d. Propose and utilize mechanisms such as PC based web meetings, internet facilitated meetings and videoconferencing capabilities to enhance communication and decrease Investigator travel.

## **E. CONTRACT TRANSITION**

Develop a written transition plan, subject to DAIDS PO approval, to ensure the timely and orderly transfer of all or part of this project to a designated entity six months prior to completion of this contract.

The transition plan shall include the following items, at a minimum, and any additional information the Contractor believes to be required for an orderly transition:

1. Schedule for delivery of data, datasets, databases, and/or systems developed under this contract to the DAIDS PO or designated entity, including study files, call center, websites
2. List of open trials and actions needed to ensure their continuation or completion during the transition period
3. List of INDs and any actions or reports due during the transition period and plan for their submission
4. List of incomplete remedial site actions or open safety issues and plan for their resolution
5. List of infrastructure support provided and any scheduled support to be provided during the transition period
6. List identified but unfulfilled training needs necessary for implementation of ongoing or anticipated trials

**[END OF STATEMENT OF WORK]**

## Notes To Offerors and Additional Technical Proposal Instructions

### HIV Clinical Research Management Support DAIDS-03-25

#### 1. OFFEROR COSTING OF A PHASE III TRIAL

Due to the nature of this contract, workload (# and types of trials) are not known at this time. Offerors are requested to provide an estimation of costs for a Phase III trial of three year duration at twenty sites throughout Africa. Assume that a full protocol team and “general management” team is in place in the United States. Assume that all services necessary for the initiation, conduct and close-out of a Phase III trial will be provided by the Contractor. Assume no payments to investigator(s) are required. You may add additional assumptions and tasks for your cost estimate. Please describe any additional tasks that you add.

<b>Trial Metric or Task</b>	<b>Additional Information</b>
Sites	20
Duration	3 years
Subjects	4000
CRF total/subject	15 per subject
Medical monitoring	5% SAE expected
Immediately reportable SAE	3%
Trial duration	3 years
Investigator Meetings	3 - 1 per year in Africa
Protocol team kick-off meeting	US meeting of protocol team
Protocol team meeting (teleconference)	100 teleconferences over 3 years
Regulatory review of protocol and ICF	3 iterations
Medical review of protocol and ICF	3 iterations
Biostatistical input/Stat Analysis Plan/report	Include 1 DSMB report preparation, 1 full statistical report
Study Manual	3 iterations
Investigator Brochure update	3 iterations
Source Document Guidelines	3 iterations
Randomization schedule	
Finalize protocol and ICF	3 iterations
CRF design and printing	Include data management and medical review
Project training	4 regional trainings for 3 days (Africa)
Regulatory Documentation Collection	20 sites
Site Registration/Call Center	20 sites
Recruit 10 sites	10 sites are already identified
Qualification visits	3 days duration at 10 sites
Initiation visits	3 days duration at 20 sites
Interim Monitoring	4 days per visit to 20 sites
Monitoring frequency	Every 4 weeks, two monitors
Site specific training (new sites)	10 visits for 7 day periods
GCP training	2 regional 3 day trainings
Site Evaluation visit	1 visit per year per site (operational personnel)
Site remedial visit	4 visits per year for 5 days each
Review, report and track monitoring reports	Separate entity from
Complete Data Management	Develop screens, checks, validation, programming, review, coding, listings, 5 data queries per subject, database audit, archiving,
Study Project Management	Throughout study
Clinical Study Report	3 iterations
Quality Assurance Audit	20 sites – 2 visits per site at 1.5 year interval

## 2. OFFEROR COSTING OF STAND ALONE TASKS

As noted throughout the contract, DAIDS may request only specific services per trial, e.g. develop a protocol, or make a GCP visit, rather than full clinical research management services for a trial (as outlined in the above exercise). Therefore, DAIDS also requests that Offerors provide reasonable cost estimate(s) for the below “stand alone” tasks, accompanied with reasonable explanations/ assumptions and suggestions. These tasks represent a sampling of single tasks, which may be requested at any time during this contract. Please provide an estimated cost for each task given below. These tasks (assume HIV/AIDS therapeutic or vaccine prevention trial) are:

- Protocol Development and Informed Consent (entire process from design to finalization, distribution to sites, FDA, quality assurance).
- Development and approval of Study Manual
- Development and approval of Case Report Forms (including completion instructions)
- Investigator’s Meeting
- Interim monitoring visit (3 day trip, include travel) and report
- Ethics Committee Submissions and approval
- Preparation and Submission of Non-US Application/Notification
- Database set-up for Phase III trial
- Database lock (including QC, cleaning)
- Serious Adverse Event Reporting for Phase III healthy volunteer vaccine trial
- Annual FDA report
- GCP Audit Report
- Clinical Study Report (with full stats report) – assume Phase II HIV therapeutic

### **SAMPLE RESPONSE TO ABOVE REQUEST:**

#### **Task: Investigator’s Meeting**

**Offeror:** Provide a Cost Estimate of Task \_\_\_\_\_

**Assumption:** For a Phase III trial in Africa, 30 Investigators, 3 days, setting in Four Star Hotel in Kampala, Uganda. US team of 10 traveling to Africa. 30 Investigators traveling within Africa.

**Offeror Suggestion to add:** Add a ½ day workshop as a GCP/Informed Consent Refresher. Provide an SOP how-to handbook and electronic templates

#### **Subtasks that make up the primary task of Investigator meeting:**

- Organize, planning and logistics of meeting (including traveling of 100 attendees)
- Travel costs are pass-through costs to DAIDS.
- Coordinate agenda and speakers/topics
- Presentation of monitoring and project management
- Attendance at meeting (list who from “project team” would attend)
- Produce and disseminate minutes

## 3. UNIFORM ASSUMPTION – INFRASTRUCTURE SUPPORT:

Paragraph A.5. of the Statement of Work requires the Contractor to provide Infrastructure Support in the form of equipment purchases (e.g., computers, telephones, personal digital assistants, laboratory equipment), videoconferencing capability and general facilities upgrades (e.g., generator, fax machine, copy machine, room design and renovations). **Because the extent of this requirement is unknown, all Offerors are directed to include in their Technical and Business Proposals, a Uniform Assumption of \$900,000 per year for infrastructure support.**

**Reporting Requirements  
HIV Clinical Research Management Support  
RFP DAIDS-03-25**

**REPORTING REQUIREMENTS AND OTHER DELIVERABLES**

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

The Contractor shall provide quarterly sample acquisition reports as well as two semi-annual reports per year that include, at a minimum, the information specified below. All reports shall be submitted as hard copies, and in electronic form, as computer files, in Microsoft Word™ version 7.0 for Windows and Microsoft Excel™ version 7.0 for Windows, with formats readable with an IBM-type personal computer. Files shall be sent by Email or on computer discs (CDs) by U.S. mail or courier service. All reports shall be archived on 3.5 inch discs or other appropriate media for delivery to the Government at the completion of the contract.

TECHNICAL REPORTS

1) Quarterly Sample Acquisition Reports

The Contractor shall submit Quarterly Sample Acquisition Reports that summarize:

- progress to date in each task area;
- listings of protocol(s) and activities;
- listings of major contract(s);
- listing of personnel; and
- narrative of future plans and impediments to progress.

The first reporting period shall consist of the first full quarter of performance plus any fractional part of the initial month of the contract and be due on the 30<sup>th</sup> of the month following each quarterly period. Thereafter, the reporting period shall consist of each calendar quarter.

2) Semiannual Reports

The Contractor shall submit Semiannual Reports that summarize the activities completed by the Contractor in the preceding six-month period. The first reporting period consists of the first full six-month of performance plus any fractional part of the initial month of the contract and shall be due on the 30<sup>th</sup> of the month following each semiannual reporting period. Thereafter, the reporting period shall consist of each six-month calendar period. A Semiannual Report shall not be required when submitting the Final Report.

Semiannual reports shall be composed of:

- a) A cover page containing:
  - i) contract title and number;
  - ii) period of performance being reported;
  - iii) contractor's name and address; and
  - iv) date of submission.
- b) A table of contents.
- c) Summary tables of results during the preceding six-month period.
- d) A discussion of technical and administrative problems encountered, their resolution or proposed corrective action; explanation of differences between planned progress and actual progress.
- e) Selected other additional information as may be required by the Project Officer.

3) Final Report and Summary of Salient Results

This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with ARTICLE F.1. DELIVERIES of this contract. A semiannual report will not be required for the period when the Final Report is due.

The Final Report shall be prepared in the same format and contain the same information required for the Semiannual Report and in addition provide:

- a) a brief description of any unfinished projects;
- b) a status report on transition or shut down activities; and
- c) a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

4) Annual Site Visit

During the final quarter of each contract year, the Contractor shall host a site visit review for NIAID contract and program staff. This meeting shall be attended by the Contractor's Lead Administrator and all Key Personnel. These presentations shall include summaries of all goals or milestones reached during the review period and include a description of all problems encountered that will impact the achievement of particular goals as outlined in the Contractor's research plan. The Administrator, and project staff representing each project and sub-project shall describe goals and objectives for the coming year. Additionally, application of the policies and procedures for monitoring the direction of specific projects shall be presented. A report of the plan for, and results of, this site visit shall be prepared by the Contractor and submitted to the Project Officer (in hard copy and digital medium) and the Contracting Officer (original hard copy) within 30 days of completion of the site visit.

5) Other Deliverables (to Project Officer only)

The second table, below, identifies the other deliverables that are identified throughout the Statement of Work, Article C.2., that are to be submitted only to the Project Officer during the entire contract period of performance.

6) Distribution

It remains the responsibility of the Contractor to assure receipt by the Government official listed below of all deliverables by the established due dates. If the Contractor is unable to deliver the items specified hereunder within the period of performance, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of anticipated delays with reasons therefore.

<b>Deliverables to Program Officer and Grants Management Specialist</b>			
<b>Deliverable</b>	<b>No. of Copies</b>	<b>Addressee</b>	<b>Due Dates</b>
Quarterly Sample Acquisition Report	3 1 (Original)	Project Officer Contracting Officer	On the 30 <sup>th</sup> of the month following each quarterly period. The first report shall be due on/before _____.
Semiannual Report	3 1 (Original)	Project Officer Contracting Officer	On the 30 <sup>th</sup> of the month following each six-month period. The first report shall be due on/before _____.
Annual Site Visit	3 1 (Original)	Project Officer Contracting Officer	Within 30 calendar days after the completion of each site visit.
Final Report and Summary of Salient Results	3 1 (Original)	Project Officer Contracting Officer	On/before the completion date of the contract.

<b>Other Deliverables (to Project Officer only)</b>			
<b>Item</b>	<b>Description</b>	<b>Due Date</b>	<b>Reference in SOW</b>
Monthly Program Report	Track and report key programmatic and protocol-specific activities.	Within 2 weeks after each month.	A.1.c.
SOP	Required contents of a protocol master file	Within 4 weeks of contract award.	A.2.d.3)
Site Assessment Visit Report	Results and recommendations on site viability.	Within 2 week of last day of site visit.	B.1.e.
Site Preparation Reports	Include executive summaries and problems/resolutions listings.	Within 2 weeks of last day of site visit.	B.2.c.
Monthly Site Management Visit Report	By site and trial, to include key site and protocol activities and study metrics or variables.	Within 2 weeks of last day of site visit.	B.3.b.
Searchable database listing	A listing of all potential HIV investigators within the major geographic areas discussed.	First listing due 4 months after contract award. Thereafter, due monthly.	B.3.d.
Site Comparison Reports	Contains various graphic representations of data.	Monthly, Quarterly and Annually (as requested by P.O.)	B.4.d.
Internal Monitoring SOPs and QA Plans		Within 4 weeks after contract award.	C.4.d. C.4.e.
Monitor Report		Within 2 weeks after routine monitoring visit	C.4.g.3)
SOP for Monitor Report Review		Within 4 weeks after contract award.	C.4.g.4)
Monthly Monitoring Deficiencies Report	By site and by protocol.	5 <sup>th</sup> of each Month	C.4.g.6)
SOPs	Data collection and management.	Within 2 weeks after contract award.	C.5.
SOPs	Biostatistical processes applied during clinical trials	Within 5 days after request.	C.6.
Manual of SOPs	Compliance and management of product storage and distribution	Within 1 month after contract award.	C.7.f.
Monthly Report – Project Mgmt.	Technical progress, monitoring issues, enrollment, etc.	5 <sup>th</sup> of each Month	C.8.o.
SAE SOPs	Practices and procedures	Within 4 weeks after contract award.	C.9.h.
SAE Reports		Transmit immediately to DAIDS Medical Officer(s)	C.9.i.
Weekly Safety Listings		Due on the following Monday.	C.9.j.
Transition Plan	As described in this section.	6 months prior to the completion date of the contract.	E.1. – E.6.

**PART I - THE SCHEDULE**

**SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL**

**A Sample Uniform Contract Format may be found at the following website:**

<http://www4.od.nih.gov/ocm/contracts/rfps/sampkt.htm>

**[Disregard SECTION I and J of this sample. Those SECTIONS have been incorporated as part of this RFP.]**

## **PART II – CONTRACT CLAUSES**

### **SECTION I - CONTRACT CLAUSES**

**THE FOLLOWING PAGES CONTAIN A LISTING(S) OF GENERAL CLAUSES WHICH WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS RFP. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSES LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.**

**BECAUSE THIS IS A STREAMLINED RFP, ARTICLES 1.2. AND 1.3., WHICH IDENTIFY ANY AUTHORIZED ADDITIONS, SUBSTITUTIONS AND/OR MODIFICATIONS TO THE GENERAL CLAUSES, WILL BE BASED ON THE TYPE OF CONTRACT/CONTRACTOR AND WILL BE DETERMINED DURING NEGOTIATIONS.**

**ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)**

This contract incorporates the following clauses 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. Also, the full text of a clause may be accessed electronically at this URL: <http://www.arnet.gov/far/>.

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

<u>FAR Clause No.</u>	<u>Date</u>	<u>Title</u>
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over \$100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over \$100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over \$100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over \$100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over \$100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over \$100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over \$500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over \$100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Feb 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over \$100,000)

52.219-9	Jan 2002	Small Business Subcontracting Plan (Over \$500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over \$500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over \$100,000) (NOTE: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over \$100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over \$500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs

52.242-13	Jul 1995	Bankruptcy (Over \$100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over \$100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over \$100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays

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

<u>HHSAR Clause No.</u>	<u>Date</u>	<u>Title</u>
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH  
AND DEVELOPMENT CONTRACT – Rev. 05/2002]

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

### SECTION J - LIST OF ATTACHMENTS

The following Attachments are provided in full text with this Solicitation:

**[PACKAGING AND DELIVERY OF PROPOSALS](#)** (Attached to this listing)

**[HOW TO PREPARE AN ELECTRONIC PROPOSAL](#)**: (Attached to this listing)

**[PROPOSAL INTENT RESPONSE SHEET](#)** [SUBMIT ON/BEFORE: [September 23, 2002](#)] (Attached to this listing)

[NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

#### **RFP FORMS AND ATTACHMENTS:**

THE RFP FORMS/ATTACHMENTS LISTED BELOW ARE AVAILABLE IN A VARIETY OF FORMATS AND MAY BE VIEWED OR DOWNLOADED DIRECTLY FROM THIS SITE:

<http://www.niaid.nih.gov/contract/ref.htm>

#### **APPLICABLE TO TECHNICAL PROPOSAL (INCLUDE THESE DOCUMENTS/FORMS WITH YOUR TECHNICAL PROPOSAL):**

- Technical Proposal Cover Sheet
- Technical Proposal Cost Information
- Summary of Related Activities
- Optional Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration [When applicable, all institutions must have the form reviewed and approved by their Institutional Review Committee.]
- Government Notice for Handling Proposals
- Targeted/Planned Enrollment Table
- Annual Technical Progress Report Format for Each Study

#### **APPLICABLE TO BUSINESS PROPOSAL (INCLUDE WITH YOUR BUSINESS PROPOSAL):**

- NIH-2043, Proposal Summary and Data Record
- Small Business Subcontracting Plan Format *[if applicable]*
- Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours
- Offeror's Points of Contact

#### **TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):**

- Inclusion Enrollment Report
- NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts
- NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)
- Safety and Health, HHSAR Clause 352.223-70
- Privacy Act System of Records

**PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL**

Listed below are delivery instructions for the submission of both PAPER and ELECTRONIC COPIES of your proposal.

**PAPER SUBMISSION:** *The paper copy is the official copy for recording timely receipt of proposals. You are required to submit one original paper copy of your proposal along with the number of extra copies required below.*

**ELECTRONIC SUBMISSION:** *In addition to the paper submission, you are required to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical.*

**SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.**

**Shipment and marking of paper copies shall be as indicated below:**

**A. EXTERNAL PACKAGE MARKING:**

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

**"RFP NO. NIH-NIAID-DAIDS-03-25  
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"**

**B. NUMBER OF COPIES:**

The number of copies required of each part of your proposal are as specified below.

**Technical Proposal:** One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).

**Business Proposal:** One (1) unbound signed original and 5 unbound copies.

**C. PAPER COPIES and CD-Rom or ZipDisk to:**

<b>If Hand Delivery or Express Service</b>	<b>If using U.S. Postal Service</b>
Barbara A. Shadrick Senior Contracting Officer Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Barbara A. Shadrick Senior Contracting Officer Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, 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).

## HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

**PAGE LIMITS** -- THE **TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 100 PAGES** [INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. **ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.**

**Note that although no page limit has been placed on the Business Proposal, offerors are encouraged to limit its content to only those documents necessary to provide adequate support for the proposed costs.**

**ELECTRONIC SUBMISSION** – To submit a proposal electronically under this RFP, offerors will need to prepare the proposal on a word processor or spreadsheet program (for the business portion) and convert them to Adobe Acrobat Portable Document Format (.pdf). THE TECHNICAL PROPOSAL AND BUSINESS PROPOSAL MUST BE CONTAINED ON SEPARATE FILES which must be identified as either TECHNICAL or BUSINESS and include some recognizable portion of the ORGANIZATION NAME.

Please note that the electronic submission does not replace the requirement to submit a signed, unbound original paper copy of both your Technical and Business Proposal, along with any required unbound duplicate copies. These paper originals should be mailed or hand-delivered to the address provided in this attachment and must be received on/before the closing date and time.

There is no limit to the size (MB) of the two electronic PDF files to be submitted; however, the size of the technical proposal is limited to the page limitation language outlined above. For purposes of assessing compliance with the page count, technical proposals will be viewed using the print function of the Adobe Acrobat Reader, Version 4.0 (or higher).

### **Formatting Requirements:**

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- Paper size should not exceed 8-1/2 x 11. Larger paper sizes will be counted as 2 pages.
- Limit colors to 256 colors at 1024 x 768 resolution; avoid color gradients.
- Simplify the color palette used in creating figures.
- Be aware of how large these graphics files become. Large files are discouraged.
- Limit scanned images as much as possible.
- Limit appendices and attachments to relevant technical proposal information (e.g., SOPs, pertinent manuals, non-scannable figures or data, resumes, letters of commitment/intent).

### **SUBMISSION OF “PROPOSAL INTENT TO RESPOND SHEET”:**

Upon receipt of the proposal intent to respond sheet, offerors will be provided, via e-mail correspondence, with specific electronic access information and electronic proposal transmission instructions. For this reason, it is imperative that all offerors who are intending to submit a proposal in response to this RFP contact the Contract Specialist identified in this RFP and complete and submit the attached “Proposal Intent Response Sheet” by the date provided on that Attachment.

**CREATE ADOBE PDF ONLINE** -- Adobe will allow you to create 5 documents on a trial for free. If you want to use the site regularly it costs \$10/month or \$100/year. Please link to the following URL for information:

<https://createpdf.adobe.com/index.pl/3847995518.39272?BP=IE>

**LOG-IN / TRANSMISSION INSTRUCTIONS:**

1. Log-in Site: Will be provided by the Contract Specialist upon receipt of the "Proposal Intent Response Sheet"
  2. Log-in Name: Will be provided by the Contract Specialist.
  3. Log-in Password: Will be provided by the Contract Specialist.
4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.
- You must have Explorer 3.1 or higher.
  - It is essential that you use antiviral software to scan all documents.
  - Click on "Sign On" and enter your log-in name and password.
  - Click on "Browse" to locate your saved files on your computer.
  - Click on "Upload Proposal" after you have located the correct file.
  - After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
  - If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
  - If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

**USER ACCESS TO THE POSTING SITE WILL BE DENIED AFTER THE RFP CLOSING DATE AND TIME PROVIDED WITH THIS RFP OR ITS MOST RECENT AMENDMENT(S).**

## PROPOSAL INTENT RESPONSE SHEET

**RFP No.:** NIH-NIAID-DAIDS-03-25

**RFP Title:** HIV Clinical Research Management Support

Please review the attached Request for Proposal. Furnish the information requested below and return this page by September 23, 2002. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

**Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.**

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:

CMB, NIAID, NIH

Room 2230

6700-B Rockledge Drive, MSC 7612

Bethesda, MD 20892-7612

Attn: Barbara A. Shadrick

RFP-NIH-NIAID-DAIDS-03-25

FAX# (301) 480-5253

Email : [bs92y@nih.gov](mailto:bs92y@nih.gov)

**PART IV – REPRESENTATIONS AND INSTRUCTIONS**

**SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS**

**Representations, Certifications, and Other Statements of Offerors or Quoters (Negotiated).**

1. REPRESENTATIONS AND CERTIFICATIONS

The Representations and Certifications required by this particular acquisition can be accessed electronically from the INTERNET at the following address:

<http://rcb.cancer.gov/rcb-internet/forms/rcneg.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 THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.**

## SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

### 1. GENERAL INFORMATION

#### a. INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION [FAR Clause 52.215-1 (May 2001)]

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

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

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

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

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

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

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

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

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

- (ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--
  - (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
  - (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
  - (3) It is the only proposal received.
- (B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.
- (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
- (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
- (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.
- (4) Unless otherwise specified in the solicitation, the offeror may propose to provide any item or combination of items.
- (5) Offerors shall submit proposals in response to this solicitation in English, unless otherwise permitted by the solicitation, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the solicitation.
- (6) Offerors may submit modifications to their proposals at any time before the solicitation closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.
- (7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.
- (8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.
- (d) *Offer expiration date.* Proposals in response to this solicitation will be valid for the number of days specified on the solicitation cover sheet (unless a different period is proposed by the offeror).

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

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

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

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

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

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

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

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

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

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

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

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

- (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.
- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.
- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) The Government may disclose the following information in postaward debriefings to other offerors:
  - (i) The overall evaluated cost or price and technical rating of the successful offeror;
  - (ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
  - (iii) A summary of the rationale for award; and
  - (iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

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

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

**b. NAICS CODE AND SIZE STANDARD**

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

- (1) The North American Industry Classification System (NAICS) code for this acquisition is 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 System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.**

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

It is anticipated that ONE AWARD will be made from this solicitation and that the award will be made on/about June 2, 2003.

It is anticipated that the award(s) 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].

**d. ESTIMATE OF EFFORT**

It is expected that a completion type contract will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the effort to be approximately 216,320 labor hours in Year 1. It is important to note that there may be the following increase to the effort:

- Year 2 – approximately 26% increase to monitoring and project management;
- Year 3 – approximately 65% increase to monitoring, project management, site evaluation, regulatory, training and investigator meetings;
- Year 4 – approximately 35% increase to monitoring, project management and site management;
- Year 5 – approximately 30% increase to monitoring, project management site management.

This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

**e. COMMITMENT OF PUBLIC FUNDS**

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

**f. COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

**g. RELEASE OF INFORMATION**

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

**h. COMPARATIVE IMPORTANCE OF PROPOSALS**

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

**i. PREPARATION COSTS**

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

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

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

Brenda J. Velez  
Contracting Officer  
Contract Management Branch, DEA  
National Institute of Allergy and Infectious Diseases  
6700-B Rockledge Drive, Room 2230, MSC 7612  
BETHESDA MD 20892-7612

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

(End of Provision)

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

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

(End of provision)

**1. USE OF INTERNET WEB SITE ADDRESSES (URLs) IN PROPOSALS**

Unless otherwise specified or required in NIAID solicitations, internet Web Site addresses (URLs) may not be used to provide information necessary to the conduct of the review of the proposal. Direct access to an internet site by a Reviewer who is examining and reviewing the proposal on behalf of the NIAID could compromise their anonymity during the review process. If a URL contains information pertinent to the proposal content, the offeror must provide access to the website via a temporary website portal which allow reviewers the capability to view and interact with the site.

The proposal must clearly identify the URLs to be accessed and the procedure for accessing the temporary website portal. Access must not require the identity of the individual.

## 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 addressees, and marked as indicated in the Attachment entitled, PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

##### I. COVER PAGE

Include RFP title, number, name of organization, identification of the proposal part, and indicate whether the proposal is an original or a copy.

##### II. TECHNICAL PROPOSAL

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

##### III. BUSINESS PROPOSAL

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

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

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

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

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

TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS).) However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

**(5) Alternate Proposals**

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 procurements, grants, and other business related activities unless such use is impracticable or is likely to cause significant inefficiencies.

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

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

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

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

**(9) Human Subjects**

**IMPORTANT NOTE TO OFFERORS: The following 6 paragraphs [(9) through (14)] shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "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 (JANUARY 2001)

- 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 of Protection from Research Risks (OPRR), National Institutes of Health (NIH), 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 National Institutes of Health 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 consideration with OPRR\*, (telephone: 301-496-7014\*), is recommended.
- e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR\* 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. Prospective Contractors proposing research that involves human subjects shall be contacted by OPRR\* and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.
- f) It is recommended that OPRR\* be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

\*\*\*\*Note: *The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7014. For more information, the OHRP website may be accessed at <http://ohrp.osophs.dhhs.gov/> Copies of the DHHS Regulations for the Protection of Human Subjects, 45 CFR Part 46, are also available on line at: [http://www.access.gpo.gov/nara/cfr/waisidx\\_01/45cfr46\\_01.html](http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html).*

### Instructions to Offerors Regarding Protection of Human Subjects

\*\*\*\*(Note: *The requirements in this paragraph (10), may be supplemented when necessary, based on the specific requirements of the solicitation.*) \*\*\*\*

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.

**(10) 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. In addition, 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\\_profes\\_protect.html](http://www.centerwatch.com/order/pubs_profes_protect.html). 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.

## (11) Inclusion of Women and Minorities in Research Involving Human Subjects

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

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

[http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm)

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research" (<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**<sup>1</sup> require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide:

[http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm),  
Definitions - Significant Difference),

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 in Section J, Attachments, entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities.**

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 format for the Annual Technical Progress Report for Clinical Research Study Populations (See Section J - List of Documents, Exhibits and Other Attachments of the RFP) entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.**

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<sup>1</sup>See NIH Guide [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm) for the Definition of an “NIH-Defined Phase III clinical trial.”

## (12) Inclusion of Children in Research Involving Human Subjects

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

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

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

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

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

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

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

### **Justifications for Exclusion of Children**

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

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

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

### **Definition of a Child**

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

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

### **(13) 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.

#### **(14) Care of Live Vertebrate Animals**

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

Notice to Offerors of Requirement for Adequate Assurance of Protection of Vertebrate Animal Subjects - (SEPTEMBER 1985)

The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at <http://www.grants.nih.gov/grants/olaw/olaw.htm>.

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

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

## **(15) Obtaining and Disseminating Biomedical Research Resources**

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

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions 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>.

## **(16) 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.

**(17) 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 this Institute's policy to conduct discussions with all offerors in the competitive range, the Institute 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 sources 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 Institute 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 the Institute's requirements. Synopses of awards exceeding \$25,000 will be published in the Commerce Business Daily and FedBizOpps.

**(18) Small Business Subcontracting Plan**

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

#### **(19) Extent of Small Disadvantaged Business Participation**

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$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. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

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

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

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

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

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

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

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

**(20) Reimbursement of Costs for Independent Research and Development Projects (Commercial Organizations Only)**

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

**(21) Salary Rate Limitation in Fiscal Year 2003 \*\***

Offerors are advised that pursuant to P.L. \_\_\*, no NIH Fiscal Year 2003 (October 1, 2002 - September 30, 2003) 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. \_\_\_\* applies only to Fiscal Year 2003 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. \_\_\_\* states in pertinent part:

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

**\*FY-2003 information is pending passage of legislation. Information regarding the FY-2003 rate can be found at: <http://www.opm.gov/oca/02tables/ex.pdf>. This currently shows FY02 data. A FY03 table will be created when legislation is passed.**

## (22) 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.

#### **(23) Past Performance Information**

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

A list of the last five (5) contracts completed during the past three (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 \_\_\_\_\_.

**\*\*\*\* (Note: The Contracting Officer will define "major subcontract" for individual acquisitions. A major subcontract could be defined, for example, as a subcontract that exceeds a certain dollar threshold.) \*\*\*\***

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.

#### 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:

1. 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
2. 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> .

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

**b) 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) Administrative Leader/Manager

List the name of the Administrative Leader/Manager 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 Administrative Leader/Manager who will be responsible for the overall implementation of any awarded contract. Discuss the qualifications, experience, and accomplishments of the Administrative Leader/Manager. 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 (SEE SECTION M).

**(3) Additional Technical Proposal Information**

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

**(4) Other Considerations**

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

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

- b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d) Other factors you feel are important and support your proposed research.
- e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

**(5) Information Technology Systems Security**

If this project involves Information Technology, the proposal must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The proposal will also need to include similar information for any subcontract proposed.

NOTE: OMB A-130 is accessible via web site: <http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html>

c. **ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS AND [EVALUATION INFORMATION](#)**

**THE FOLLOWING INFORMATION IS SPECIFIC FOR PURPOSES OF RESPONDING TO THIS RFP. ALL OFFEROR(S) SHOULD PROVIDE SPECIFIC DOCUMENTATION IN THEIR PROPOSAL WITH REGARDS TO THESE ITEMS.**

1. **Partnering**

Selected activities may be provided by a partner or other DAIDS contractors and grantees; therefore the contractor must be willing to partner with these contractors and provide an interface for communication and information flow. The ability to identify and work with partners to meet identified trial-specific and program management needs is necessary for successful completion of the scope of this contract. The contractor will be responsible for drafting a statement of work for each identified need, and upon approval from DAIDS, the contractor will compete and execute the agreement(s) with the recommendation of the DAIDS PO. This may involve identification of additional partners and initiation of agreements with entities such as Site Management Organizations (SMOs), international organizations and Non-Governmental Organizations (NGO)s as needed to perform clinical trials in diverse geographic settings. Approval of partners will be by the DAIDS PO.

2. **Trial Locales**

Various geographic areas for international trials may be involved in this contract. Potential trial sites may include, but are not limited to the following countries: Africa, Asia, Eastern Europe, India. Providing overall management of these sites would require a set of policies, procedures and staff to operate in a culturally acceptable manner in these countries.

3. **Location of Management Core**

It is considered vital to the effective management of this contract that the Management Core be located in close proximity to Bethesda, Maryland, in order to meet face-to-face with the DAIDS within two hours of notification (e.g. urgent situations). Employees other than the management core may be located throughout the United States and internationally. A typical management component might include the staff listed below under Key Personnel.

4. **Trial Management**

Case studies can be provided as documentation of trial management procedures (e.g. Phase III trial description, first patient enrolled through data-lock description) or other case studies in trial management.

5. **Key Personnel**

Several high-level or Key Personnel will be required for this contract.

Describe the experience and qualifications, as well as the percentage of the total time each will be committed to the project. Identify the composition of the task or work group, its general qualifications and recent experience with similar efforts. As a minimum, this effort will require different staff/areas of expertise at different times over the course of the contract. Please provide documentation to describe:

- Qualifications and experience as supported by academic degree(s) and expertise, specialized training, relevant collaborative work involving clinical research, proven ability to provide the necessary scientific leadership/management in designing, managing and coordinating clinical and research components of this multi-site and multi-disciplinary effort.
- Relevant work in planning and/or supporting clinical research as appropriate to the proposed role in the project.
- Availability for the proposed project.
- Managerial ability to achieve delivery or performance requirements as demonstrated by the proposed use of management and other personnel resources and to successfully manage the Project as demonstrated by the management plan and previous relevant experience.

The Offeror(s) are charged with providing a plan capable of identifying the need to add, replace, or remove scientific, management, clinical and technical staff, especially the proposed subcontractor(s), depending on progress or changes in scientific direction.

- a) **Administrative Leader/Manager** - expertise in research program management to include clinical trials with experience in infectious disease(s) and vaccines in international settings, and experience in managing similar large scale efforts with large, multiple trials. Three years minimum experience, minimum bachelor's degree, master's degree is preferable in health/public administration or related science.
- b) **Project Directors/Manager** – expertise in clinical research project management to include large scale clinical trials with an emphasis on international research and infectious diseases. Documented success to manage clinical research teams. Three years minimum experience, minimum bachelor's degree, master's degree is preferable in health/public administration or related science.
- c) **Senior Regulatory Director** – Expertise in regulatory affairs surrounding clinical trials in both the US and international settings, including FDA safety reporting requirements, IND annual updates, FDA formal meetings and experience in non-US marketing submissions. Expertise in Good Clinical Practices and application of Quality Assurance in clinical trials. Documented success in management of regulatory activities for large-scale pharmaceutical programs. Three years minimum experience, minimum bachelor's degree, master's degree is preferable in health/public administration or related science.
- d) **Lead Monitor** – expertise in the monitoring and oversight of monitoring of Phase I, II and III infectious disease and/or vaccine trials. Documented experience in the resourcing and monitoring of multiple large scale trials. Three years minimum experience, minimum bachelor's degree, master's degree is preferable in health/public administration or related science.
- e) **Senior Physician** – Board Certified in infectious diseases with vaccine experience preferred. Extensive clinical trials experience in international settings including safety monitoring, conduct and scientific/medical guidance into protocol development.
- f) **Senior IT Specialist** – Systems engineer with experience in IT infrastructure development and the development of programs to support the many aspects of clinical trials.
- g) **Lead Trainer** – Experience in the training of personnel, including non-US personnel, in Good Clinical Practices and other training needs associated with clinical trials. Three years minimum experience, minimum bachelor's degree, master's degree is preferable in health/public administration or related science. Documented success in implementation and conduct of clinical trials training programs.

#### 6. **Other Personnel (Non-Key)**

Offeror(s) should discuss the related experience and the role of other personnel. Provision of curriculum vitae(s) is not required.

- a) **Project Managers:** Identify and propose, as key personnel, additional staff in specialized areas such as clinical trials and research studies. These Project Managers must be active participants in this project in the area for which they will be serving on the Management Team. Offeror(s) should document relevant education and training, qualifications, expertise, vision, experience with similar projects/competence, suitable time commitment and ability to perform as a member of the proposed management team.
- b) **Subcontractors:** Documented relevant training, education, qualifications, expertise, experience, competence, and availability of the proposed staff, ability to perform their roles in the proposed effort with respect to the requirements of the SOW.
- c) **Technical and Administrative Staff/Subcontractors:** Documented relevant training, education, expertise, experience, competence and availability of the proposed staff to perform their roles in the proposed effort.

## 7. **Organizational Experience and Related Performance**

Documented experience and performance relevant to this study.

## 8. **Management and SOPs**

### a) Management Approaches and Plans

Offeror(s) are required to develop and submit complete working plans that describe how this contract and its activities will be implemented, managed, coordinated, and integrated. Scores will be based on completeness and feasibility. These plans relate to and need to include:

#### 1) Overall Management

- (a) Approach to Clinical Trial Project Management;
- (b) Manual of Standard Operations and Procedures;
- (c) Quality of performance; and
- (d) Staffing, responsibilities, lines of authority.

#### 2) Trial Management:

- (a) Training manual for and training of study personnel;
- (b) Data entry, quality control, management plan;
- (c) Data analysis plan describing the types and methods of analyses as well as a schedule for analyses;
- (d) Study initiation, tracking, and completion;
- (e) Recruitment, retention and follow-up of subjects.

#### 3) Specimen Management

### b) Standard Operating Procedures (SOPs)

SOP documents designate safe, sequential, numbered series of steps that allow tasks to be conducted in a standardized manner. SOPs are required procedures that include, but are not limited to, such things as: data collection and entry, drug usage, collection, processing, storage and shipping of biospecimens, etc. The Contractor monitors adherence to procedures and evaluates untoward events in terms of whether the procedure was followed or not. In the event of problems, the Contractor takes appropriate action based in part on an analysis of the SOP, i.e., revise the procedure, conduct quality control as required, and other measures as needed to resolve any detected discrepancies.

Offeror(s) are expected to provide SOP quality control plans with the proposal, to integrate them into the training program and manuals and to fully implement them.

### c) Forms

Offeror(s) are responsible for providing all forms needed for the study. These should be listed and provided with the proposal. Examples should include:

- 1) Typical Case Report Form
- 2) Adverse Events, FDA Submissions and SAE Tracking Systems
- 3) Biospecimen collection, tracking, and shipping

d) Computerized Data Management Systems

A number of databases are required under this contract and they must be integrated to achieve optimal benefit (e.g. Enterprise System). Offerors shall provide evidence of integrated systems or sufficient information on plans to develop such systems to ensure interoperability and integration of various databases in this contract.

Offeror(s) should provide adequate information on the proposed database(s); indicate the state of development and how it would be used at multiple sites. The enterprise system must include data tracking forms to monitor the flow of information and materials (biospecimens) from subject identification through creation of the final database. Forms shall include but not be limited to those required to track biospecimens, monitor the specimen transportation and shipping process, and document subject recruitment and participation rate.

Offeror(s) should demonstrate how the system tracks and integrates all clinical and monitoring data in a way that the information in various databases can be related at the enterprise level; generates reports of the status of the various activities of this contract as well as summary reports; generates reports on the status of data collection activities across subjects and research investigations, as well as other reports as required by the NIAID Project Officer.

e) Laboratory Research Studies

The offeror(s) should document their ability to collect biospecimens on all study participants based on past involvement in clinical trials. Describe how these biospecimens were identified, processed, packaged, stored, shipped, and tracked according to standard shipping and specimen policies.

d. **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.

To assist in the preparation of future cost estimates, the Projected Consumer Price Index may be accessed at: <http://rcb.nci.nih.gov/forms/cpi.htm>

(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)

Alternate I (October 1997). As prescribed in 15.408(l), substitute the following paragraph (b)(1) for paragraph (b)(1) of the basic provision:

- (b) (1) The offeror shall submit cost or pricing data and supporting attachments in the following format:

The format specified in paragraph L.2.c.(4) Cost and Pricing Data, subparagraph 3. Formats for Submission of Line Item Summaries shall be used for the submission cost information. Submission of all other cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

- (5) 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.

(6) Other Administrative Data

a) **Property**

(1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the 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, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

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

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

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

**c) Financial Capacity**

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

**d) Incremental Funding**

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

**HHSAR 352.232-75, Incremental Funding (January 2001)**

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

(End of provision)

e) **Facilities Capital Cost of Money, FAR 52.215-16, (October 1997)**

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

- (a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.
- (b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

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

- ] The prospective Contractor has specifically identified or proposed facilities capital cost of money in its cost proposal and elects to claim this cost as an allowable cost under the contract. Submit Form CASB-CMF (see FAR 31.205-10).
- ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(7) Subcontractors

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

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

Note: Organizations that plan to enter into a subcontract with an educational concern under a contract awarded under this 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/PDPclausecover.htm>

(8) Proposer's Annual Financial Report

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

(9) Representations and Certifications

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

(10) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

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

b) **Travel Policy**

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

## SECTION M - EVALUATION FACTORS FOR AWARD

### 1. GENERAL

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

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

### 2. HUMAN SUBJECT EVALUATION

This research project may involve human subjects. NIH Policy requires:

#### (a) Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by NCI 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 and provide a narrative 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 your discussion regarding the protection of human subjects from research risks 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 and/or clarify your position during such discussions and in your Final Proposal Revision (FPR). If, after discussions, your proposed plan for the protection of human subjects from research risks is still found unacceptable, 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 trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to 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 solicitations specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will provide a narrative that describes 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 information provided regarding Data and Safety Monitoring 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 and/or clarify your plan during such discussions and in your Final Proposal Revision (FPR). If, after discussions, the plan is still considered “unacceptable,” 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](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 address 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 address 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 information you provide in your proposal regarding the inclusion of women and minorities 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/exclusion of women/minorities is still considered “unacceptable” by the Government after discussions, 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’ narrative evaluation of the offeror’s response to this evaluation criterion, this section of the proposal may be rated “unacceptable” (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror’s response regarding the inclusion of children; or the plan is not in accordance with NIH policy guidelines) or “acceptable.”

If the 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.

3. **PAST PERFORMANCE FACTOR - [This criteria will not be evaluated by the Technical Peer Review Panel]**

**Evaluation of this component will not be conducted by the NIH Special Emphasis Panel (SEP).** An evaluation of offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal would not be selected for award based on the results of the evaluation of factors other than past performance.

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

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

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

The following rating method shall be used in the evaluation of past performance information:

+2 Excellent - Based on the offeror's performance record, no doubt exists that the offeror will successfully perform the required effort. Sources of information are consistently firm in stating that the offeror's performance was superior and that they would unhesitatingly do business with the offeror again.

+1 Good - Based on the offeror's performance record, little doubt exists that the offeror will successfully perform the required effort. Sources of information state that the offeror's performance was good, better than average, etc., and that they would do business with the offeror again.

None - No past performance history identifiable.

-1 Marginal - Based on the offeror's performance record, some doubt exists that the offeror will successfully perform the required effort. Sources of information make unfavorable reports about the offeror's performance and express concern about doing business with the offeror again.

-2 Poor - Based on the offeror's performance record, serious doubt exists that the offeror will successfully perform the required effort. Sources of information consistently stated that the offeror's performance was entirely unsatisfactory and that they would not do business with the offeror again.

4. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION - [This criteria will not be evaluated by the Technical Peer Review Panel.]**

**Evaluation of this component will not be conducted by the NIH Special Emphasis Panel (SEP).** The extent of the Offeror's Small Business and Small Disadvantaged Business Participation Targets will be evaluated for all "acceptable" proposals prior to establishment of the competitive range. **Assignment of these additional points could impact your final ranking.** In this phase of the project, the assessment of Small Business and Small Disadvantaged Business Participation will only be used to support the judgment by the Government as it considers all information relevant to the selection decision. The following criteria will apply:

<b>SDB CRITERIA</b>	<b>WEIGHT</b>
1. The extent of participation of Small Business concerns in terms of the value of the total acquisition taking into consideration the complexity and variety of the work Small Business concerns are to perform. Greater emphasis will be given for arrangements where the Small Business shall be performing work appropriate to the scientific objectives expressed in the statement of work.	<b>5 (Max. for SB)</b>
2. The extent of participation of SDB concerns in terms of the value of the total acquisition taking into consideration the complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.	<b>5 (Max. for SDB)</b>
<b>PLEASE NOTE: In accordance with the above criteria, the participation of capable Small Business concerns qualifies for a maximum of 5 points; the participation of capable Small Disadvantaged Business concerns qualifies for a maximum of 10 points.</b>	

5. **TECHNICAL EVALUATION CRITERIA**

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

**OFFEROR(S) AND REVIEWERS ARE ADVISED TO REFER TO [SECTION L.2.c.](#) OF THIS SOLICITATION PACKAGE FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION AND EVALUATION OF PROPOSALS.**

<u><b>CRITERIA</b></u>	<u><b>WEIGHT</b></u>
<b>1. PERSONNEL</b>	<b>(35 Points)</b>

**Contractor:**

Appropriateness and relevance of the training, experience and availability of the proposed Core Management Team to conduct the clinical research management activities called for in the Scope of Work especially with respect to the types and number of listed clinical trials, the therapeutic / preventive areas, trial locations and Phases.

Appropriateness, and relevance of the experience of the Core Management Team in conducting trials in at least one of the key geographic regions (Asia, Africa, Eastern Europe, India).

Strength, appropriateness and relevance of the international experience of the proposed personnel for tasks specified in the Scope of Work with special attention to cultural sensitivities in resource constrained countries.

Strength, relevance and appropriateness of provided explanations and/or Case Studies of clinical trials in resource-constrained settings.

Strength, appropriateness and relevance of the plan to provide a pool of experienced clinical trial monitors that can undertake arduous travel within 10 days notice.

Strength and appropriateness of the responsibilities and time commitments for key personnel in the organizational chart

Strength and appropriateness of the plan to meet the contractual requirement for face to face meetings in the Washington DC/Bethesda area within two hours notice.

#### **Subcontractor(s)**

Strength, relevance and appropriateness of the documented training, experience and capability of the proposed subcontractor(s) to perform the tasks called for in the Scope of Work with an emphasis on tasks conducted in international settings.

Strength, feasibility and appropriateness of the plan to include subcontractors, and/or to gain access to subcontractors located in resource-constrained areas.

## **2. TECHNICAL APPROACH / METHODOLOGY**

**(35 Points)**

Technical adequacy and feasibility of the proposed approaches and plan(s) to be used to conduct the tasks delineated in the SOW including options in the event that potential problems arise during the execution of this contract.

Technical adequacy of the documented Case Studies of past trials with respect to time of enrollment, time to datalock and management of an overall effort relevant to the tasks specified in the Scope of Work.

Adequacy, thoroughness and feasibility of the technical approaches and plans proposed for:

- organization of the Management component
- accurate translations
- training capabilities in a wide range of clinical trial related topics
- providing access to a Call Center in the U.S. and in Europe, Asia or Africa with associated relevant document collection experience
- access and to securely manage and archive files
- performance of a broad range of meeting support tasks
- development and operation of a logistics/distribution center for the dissemination of documents and other distributions
- access to short and long-term staffing needs in resource-constrained countries
- infrastructure development assistance in developing countries
- phase I, II and III site management activities
- communication assistance
- assisting in the development / operation of Community Advisory Boards
- producing a wide range of documents required through the life cycle of a product and associated trial
- managing the comprehensive conduct of Phase I, II and III trials with an emphasis on conduct in resource constrained countries.
- providing access to senior level regulatory support in routine clinical trial matters and managing the submission of non-U.S. Marketing applications
- monitoring and Quality Assurance to a comprehensive portfolio of Phase I, II and III HIV trials
- developing the databases
- collecting and managing data for Phase I, II and III trials
- accessing senior-level Biostatistical expertise

- providing product/agent distribution with an emphasis in distribution and storage in resource constrained countries
- conducting safety monitoring of Phase I, II and III trials
- providing assistance and Quality Assurance to resource-constrained clinical laboratories and access to safety laboratories.
- shipping laboratory specimens, world-wide, in support of Phase I, II and III trials
- providing and implementing a wide range of information technology tools and applications to support the tasks specific in the Scope of Work with emphasis on large scale, complex efforts.
- partnering

**3. ORGANIZATIONAL EXPERIENCE, RESOURCES AND FACILITIES**

**(30 Points)**

Appropriateness and availability of the proposed facilities, resources and equipment necessary to conduct the tasks specified in the Statement of Work including proximity of a Management Core to the Bethesda, MD area.

Strength and appropriateness of the documented experience in the comprehensive conduct (planning, initiation and conduct) of Phase I, II and III HIV clinical trials in domestic and international settings.

Strength and appropriateness of the documented experience in managing large complex clinical research programs.

Strength and appropriateness of the documented experience in subcontracting and / or establishing business relationship(s) with additional entities to include Contract Research Organizations (CROs), Site Management Organizations (SMOs), Pharmaceutical companies and non-governmental organizations (NGOs).

Documented willingness to partner with other companies, entities, organizations and groups as may be required by the Division of AIDS

Suitability of the transition plan to another contractor upon contract completion.

Adequacy, thoroughness and feasibility of the technical approaches and plans proposed for providing and implementing a wide range of Information Technology tools and applications to support the tasks specific in the Scope of Work with emphasis on large scale, complex efforts, including integrating the variety of databases called for in the SOW to providing for interoperativity and relation of data.

**TOTAL POINTS**

**(100 Points)**

[\[RETURN TO COVER PAGE OF RFP\]](#)