



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.

Purchase Authority: Public Law 92-218, as amended.			
NOTE: The issuance of this solicitation does not commit the government to an award.			
RFP Number: NIH-NIAID-DAIDS-03-26	Just In Time: [] Yes [X] No	Small Bus. Set-Aside [X]Yes []No 8(a) Set-Aside []Yes [X]No NAICS Code: 541710 Size Standard: 500 employees	Level of Effort: [] Yes [X] No Total Effort: [N/A]
TITLE: Regulatory Compliance Center			
Issue Date: MARCH 29, 2002	Due Date: JULY 15, 2002 Time: 4:00 PM, EST	Technical Proposal Page Limit of 150 pgs: [X] Yes (see " How to Prepare and Submit Electronic Proposals ")	
ISSUED BY: Barbara A. Shadrick Senior Contracting Officer 6700-B Rockledge Drive Room 2230; MSC 7612 Bethesda, MD 20892-7612		[X] <i>We reserve the right to make awards without discussion.</i>	
		NO. OF AWARDS: [X] Only 1 Award [] Multiple Awards	PERIOD OF PERFORMANCE: 7 years beginning on or about 03/31/2003
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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PART I - THE SCHEDULE

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

BACKGROUND / INTRODUCTION / NOTES TO OFFERORS
Regulatory Compliance Center (RCC)
DAIDS-03-26

INTRODUCTION

This is a contract to operate and manage the Regulatory Compliance Center ("RCC") to support a wide range of clinical research activities and programs administered by the Regulatory Affairs Branch (RAB), of the Division of AIDS ("DAIDS"), a component of the National Institute of Allergy and Infectious Diseases ("NIAID"). The NIAID is one of 27 Institutes comprising the National Institutes of Health ("NIH"), which is, in itself, a large health research agency within the Department of Health and Human Services ("DHHS"). The majority of the NIH research effort related to HIV infection and AIDS is managed by the NIAID. See web page for NIAID located at: <http://www.niaid.nih.gov>.

The Regulatory Affairs Branch serves as the Division of AIDS liaison to the Food and Drug Administration (FDA) and the Office of Human Research Protection (OHRP) for DAIDS- sponsored clinical trials. RAB develops regulatory policy for DAIDS clinical research and is responsible for regulatory oversight of all clinical trials groups and networks funded by DAIDS for HIV/AIDS treatment and prevention clinical trials. These groups include but are not limited to the Adult AIDS Clinical Trials Group (AACTG), the Pediatric AIDS Clinical Trials Group (PACTG), the Terry Bein Community Programs for Clinical Research (CPCRA), the HIV Prevention Trials Network (HPTN) and the HIV Vaccine Trials Network (HVTN). In addition, DAIDS provides regulatory support to the NIAID Intramural Research Program (IRP) and the Vaccine Research Center (VRC) for select protocols. With the expected expansion of international research, the RCC will have additional regulatory responsibility in this arena. For example, select clinical trials in the Comprehensive International Program of Research on AIDS (CIPRA) may require regulatory filings in countries receiving CIPRA grants. In some cases, IND applications in the United States may not be required and the ability to carry out regulatory work in other countries will be needed.

This critical contract must have state of the art regulatory, clinical and technical expertise and facilities to provide RAB with the support to facilitate the management of regulatory aspects of DAIDS-sponsored clinical trials. This contract will exist within a complex research environment and a consortium of multiple clinical trials groups that are increasingly complex and international in scope. International research is predominantly conducted in countries with high prevalence of HIV/AIDS. The DAIDS and its networks interact with a complex research environment composed of, but not limited to the following: clinical investigators and their institutions, statistical and data analysis centers, operational centers, the Food and Drug Administration (FDA), the Office of Human Research Protection (OHRP), the Fogarty International Center (FIC), other non-U.S. regulatory authorities, the pharmaceutical industry, local and national Institutional Review Boards/Ethics Committees (IRBs/ECs), domestic and international organizations involved in AIDS/HIV related research and prevention, patients with HIV/AIDS and their advocates, populations at risk for HIV infection and their advocates, and the NIH scientific and administrative personnel. The DAIDS-sponsored networks, through their research portfolios, make key decisions about HIV/AIDS treatment and prevention research and conduct numerous clinical trials of all phases. The research of each DAIDS network has the potential to strongly influence public health policies in The United States and other countries.

The clinical research organization supporting RAB will provide regulatory, clinical and technical expertise to enable DAIDS to fulfill its responsibilities as a sponsor of a large portfolio of clinical trials, many under DAIDS Investigational New Drug Application (IND). This contract also will manage several clinical trial areas related to the regulatory management of large (often international) trials not conducted under IND. These areas may include multiple government requirements for safety oversight and human subject protection. The contractor will manage a state-of-the-art Serious Adverse Experience (SAE) system for all phases of IND and non-IND studies and will communicate electronically and in other formats (conference call, group meetings, written communication, etc.) with statistical and data management centers, DAIDS medical officers, other NIH groups/contracts, industry, OHRP and the FDA. The contract will provide high level technical, medical and clinical ability to prepare and administer original INDs. In addition, the contract will provide the technical ability to conduct and write concept sheet and protocol reviews, summaries and related letters/documents for DAIDS. The protocol registration system for the participation of sites in DAIDS-sponsored trials and for the review of site informed consents will be managed by this contract. Other responsibilities will include, but will not be limited to, negotiating clinical trials agreements with the pharmaceutical industry, providing operational support for all agreements and letters of understanding required by DAIDS, providing in-country training/ seminars for international sites and groups sponsored by DAIDS, establishing and maintaining a computerized information system to produce reports and track existing and evolving information related to major responsibilities of the contract, provide and participate in electronic communication between DAIDS and the clinical trials groups, and provide rapid responses to inquiries from RAB related to all areas of contract responsibility.

OBJECTIVE:

Major project activities of the RCC will be managed by the Regulatory Affairs Branch, DAIDS, and will include the preparation, assembly and submission to the FDA, of IND submissions, amendments and annual reports; coordination of Serious Adverse Experience (SAE) reporting and evaluation for IND protocols and general management of the DAIDS safety reporting system for all protocols (IND and non-IND) conducted by the networks; initial collection and assessment of SAE reports; preparation of FDA Safety Reports and MEDWATCH reports; coordination of clinical protocol registration activities to ensure fulfillment of DAIDS regulatory obligation to the FDA as research sponsor; review of clinical protocols during the protocol development process to ensure compliance with all pertinent NIH, FDA, OHRP, and DHHS regulations including inclusion of minorities, children and underserved populations; review of protocol sample informed consents and site specific informed consents to ensure compliance with OHRP and FDA Human Subject Protection Codes and for compliance with DAIDS policy as the clinical trials sponsor; development of clinical trials agreements and other agreements as necessary between industry and DAIDS and other entities involved with DAIDS sponsored clinical trials. In addition, the RCC will provide scientific and technical support to the DAIDS Clinical Science Review Committee (CSRC) and the Prevention Science Review Committee (PSRC) for review of concept sheets and protocols developed by DAIDS-sponsored clinical trials groups and grantees. The RCC will provide regulatory support to DAIDS on a select basis for other protocols conducted by investigators or groups with grants such as R-O1s and U-O1s. The RCC will provide training to the clinical trials groups at the national meetings of the groups. In addition, the RCC will organize and lead other regulatory sessions/conference calls organized by the RAB at international and US locations for sites participating in therapeutic, vaccine and prevention studies sponsored by the DAIDS. For the centrally coordinated regulatory activities that the RCC supports, and in conjunction with various clinical trials groups data and statistical centers, the RCC will maintain complex study agent relational databases of adverse events and other parameters and a management information system for the rapid retrieval and distribution of information for DAIDS use and to generate ad hoc reports for the DAIDS.

BACKGROUND

The Regulatory Operations Contract (ROC) was awarded to Social & Scientific Systems, Inc. ("SSS") for a seven-year period commencing on October 3, 1995, and ending on October 2, 2002, to operate the Clinical and Regulatory Operations Center ("CROC"); the center's name was subsequently shortened to the Regulatory Operations Center ("ROC"). See web page for the ROC located at: <http://roc.s-3.com>.

The ROC provides regulatory and technical support for DAIDS-sponsored clinical research programs, including regulatory reviews in coordination with protocol development and other activities of RAB and the Networks sponsored by DAIDS: the Acute HIV Infection and Early Disease Research Program; the Adult AIDS Clinical Trial Group; the AIDS Clinical Trial Information Service; Centers for AIDS Research; HIV Prevention Trials Network; HIV Vaccine Trials Network; Multi-center AIDS Cohort Study; Pediatric AIDS Clinical Trials Group; Terry Bein Community Programs for Clinical Research on AIDS; and the Women's Interagency HIV Study.

Recently, the Division began supporting the expansion of AIDS clinical trials to international sites to answer difficult questions related to viral transmission and disease progression and to reach specific high- risk populations. In 1998, the ROC began providing regulatory support for international clinical trials in the HIVNET, a DAIDS- supported HIV prevention and vaccine trials network, subsequently known as the HPTN and HVTN. In 1999, a large, phase III, multi-centered therapeutic international clinical trial of 4000 subjects in twenty-two (22) countries (with almost 300 sites), entitled the "Evaluation of Subcutaneous Proleukin® in a Randomized International Trial (ESPRIT)", was launched under a DAIDS IND. This was the first time the Division had sponsored an international trial of this size and complexity. This expansion into a global arena, in addition to the already high volume of routine regulatory work, required additional funding of the existing regulatory operations contract. The new Regulatory Compliance Center will facilitate the regulatory, operational and technical tasks that require central coordination amongst multiple programs within the DAIDS.

The existing ROC will expire on October 2, 2002. Due to the expanded scope and complexity of DAIDS-funded clinical trials, the Division has identified the need for this new regulatory contract as part of the DAIDS therapeutic research and vaccine/prevention research programs. It is critical that a smooth transition of regulatory operations occur upon award of this contract to ensure continuation of trials without interruption and to maintain compliance with FDA, OHRP and other pertinent NIH and DHHS regulations. The new contract will be known as the Regulatory Compliance Center or the RCC.

The role and functions of the RCC, in terms of the quantity and mix of regulatory support activities, have evolved over the years in a manner that is consistent with the significant research and clinical advances made by investigators in the treatment of HIV disease and the increased levels of domestic and international vaccine and prevention research. Other notable developments include the increased use of automated databases to track protocols and treatments/vaccines/prevention agents, and the increased emphasis on international clinical studies (both IND and non-IND). The increase in international efforts has resulted in the addition of a significant number of clinical sites to existing and new networks. There currently are over eight hundred (800) DAIDS-sponsored sites in thirty-three (33) countries. DAIDS currently holds one hundred and twenty-one (121) INDS. Greater than 80% of the INDS are done with regulatory cross-reference filing from industrial partners supplying the study agents for DAIDS-sponsored trials. The work scope of the contract for the RCC reflects these evolutionary developments related to the growing complexity of government-funded human research. For those INDS including study agents that are not obtained from industrial collaborators, various DAIDS or NIAID-funded contracts provide support up to and including the pre-IND FDA meeting/conference call. At the time of the pre-IND call, the RCC begins the preparation of the IND.

Specific responsibilities of the Contractor are described in the Scope of Work.

In 2000, the Contracts Management Branch (CMB), NIAID, commenced an effort to adopt Performance-Based Service Contracting ("PBSC"), to the maximum extent practicable, on large research support contracts, in compliance with OFPP Policy Letter 91-2, as implemented in FAR Subpart 37.6--Performance-Based Contracting, FAR Subpart 16.4--Incentive Contracts, and FAR Subpart 11.1--Selecting and Developing Requirements Documents. The ROC contract was selected for conversion to PBSC using a cost-plus-award-fee ("CPAF") under FAR 16.405-2. A decision to re-name the contract the Regulatory Compliance Center ("RCC") was made at that time.

In summary, DAIDS treatment and prevention programs are responsible for managing the scientific components of the DAIDS-sponsored clinical research agendas. RAB/DAIDS is responsible for regulatory oversight of the DAIDS clinical trial/research portfolio. The RCC will provide regulatory and technical support to DAIDS to facilitate fulfillment of regulatory responsibilities to the FDA and OHRP in conducting DAIDS-sponsored clinical trials.

The scope of work for operation and management of the RCC includes eleven (11) performance elements:

1. Comply with General Contract Requirements (C.2.1)
2. Investigational New Drug ("IND") Applications Process (C.2.2)
3. Informed Consent Development and Review Process (IND and non-IND) (C.2.3)
4. Protocol Registration System of DAIDS-sponsored Clinical Trials (IND and Non-IND) (C.2.4)
5. Serious Adverse Experience ("SAE") Reporting System for DAIDS-sponsored Trials (IND and Non-IND) (C.2.5)
6. DAIDS Review Committees: Clinical Science Review Committee ("CSRC") and the Prevention Science Review Committee ("PSRC") (C.2.6)
7. Clinical Trials Agreements ("CTAs") and the Cooperative Research and Development Agreements (CRADAs) Process (C.2.7)
8. Maintain a Computerized Management Information System ("MIS")(C.2.8)
9. Maintain the RCC Standard Operating Procedures ("SOP") Handbook (C.2.9)
10. Other Regulatory Support Functions (C.2.10)
11. Provide for Orderly Transition to a Subsequent Contractor (C.2.11).

NOTES TO OFFERORS
Regulatory Compliance Center
DAIDS-03-26

GENERAL NOTES TO OFFERORS

1. As an aid in proposal preparation, a variety of documents describing the AACTG organization, standard operating procedures, instruction manuals and various DAIDS, NIH and FDA guidelines and regulations are attached to this Performance Work Statement (PWS).
2. The offeror may propose to continue existing systems and methods or propose new ones. In the latter case, the proposal must include a timetable for implementing, allowing time for review by the Project Officer and other DAIDS staff.
3. Describe in detail the responsibilities and level of effort of Contractor personnel who will be supporting the tasks delineated in the PWS. Describe in detail an administrative framework, including an organizational chart showing lines of authority and detailed work plan satisfactory for achieving contract objectives and maintaining quality control over the implementation and operation of the project. Documentation should also be provided on the decision-making authority of the Project Director and other key personnel and the percentage of time each staff member will contribute to the project. Curricula vitae (CV), international expertise, endorsements and descriptions of previous and current efforts should reflect length and variety of experience in similar tasks and should clearly demonstrate relevant training, experience and specific accomplishments. Documentation should include all previous and current projects of a similar nature, including the contract number, cooperative agreement or grant number, the supporting agency, the Project Officer and a description of the project.
4. For costing purposes, assume the RCC will need to coordinate transfer data to 5-6 data centers and obtain Serious Adverse Experience Forms and other regulatory documents from approximately one thousand sites, with approximately 50% of them overseas.
5. For language requirements, assume Spanish, French and Thai are major foreign languages at this time. Other languages, especially Chinese and Portuguese, may be needed in the future.

SPECIFIC NOTES TO OFFERORS

1. For planning purposes, estimate 3-4 individuals attending eight (8) national and twelve (12) international meetings per year for the purpose of providing training in DAIDS regulatory procedures. Approximately one fourth of the national meetings will be held in the Washington, D.C. area. Major training sessions with U.S. and international sites are also conducted by conference calls arranged by the contract. Estimate approximately 12 large (20 or more sites) international conference calls of one (1) hour duration each per year.
2. For planning purposes, it is estimated that approximately 2500 – 3500 submissions of protocol specific registration packages from sites will be processed each year. This involves 10-30 phone calls/day and response to approximately 30 to 100 e-mails/day from the sites, DAIDS and other authorized individuals/groups.
3. For costing purposes, estimate a portfolio of 120 INDs and 400 protocols that are active or in development. This includes 500 amendments (all types) to existing INDs and 90 annual reports per year. Assume that 10-20% of the protocols will not require INDs.
4. Approximately 50 Investigator Brochures (IBs)/year and 20 package inserts/year are sent to the contract by collaborating companies.
5. Approximately 350 pieces of correspondence to the FDA are prepared/year (excluding annual reports, safety reports and protocol reviews).
6. Estimate 80 Clinical Trials Agreements/year with approximately 50 companies.

7. Estimate 150 boxes of case report forms/year to be packed and shipped to Government archives. Estimate one-half to one hour of labor/box. Shipments up to 50 boxes may be sent on one order. Packing materials will be supplied by the DAIDS.
8. The database management package must be based on the relational model of database management, incorporate the industry-standard SQL language, allow multiple users to access the database simultaneously and include a report generator, ad hoc query capability, the ability to interface to higher order languages and security provisions to guard against unauthorized access to information. The system must provide for graphics capability as well as word processing capability using Word 7.0.

Describe in detail and provide justification for the specific database management system, operating systems, programming languages and software packages proposed. Describe the facilities and equipment, including mainframe and peripheral computer equipment, which will be available for the project when the contract is awarded. Describe proposed procedures for acquiring additional computer hardware and software (by purchase, lease, etc.) soon after the contract is awarded, if needed, and describes the proposed method for allocating all computer-related costs over the duration of the seven (7) year contract.

DEFINITIONS

Performance Based Service Contract (PBSC)

PBSC is a method of acquisition in which all aspects of the acquisition are structured around the purpose of the work to be performed rather than either the manner by which it is to be done or broad and imprecise statements of work. Performance based contracting emphasizes objective, measurable performance requirements and quality standards in developing a Statement of Work, selecting Contractors, determining contract types and incentives, and performing contract administration.

Performance Work Statement (PWS)

The contract Statement of Work (SOW), which is referred to as the Performance Work Statement (PWS), is the foundation of performance based services. The PWS describes the effort in terms of measurable performance standards (outputs). These standards include such elements as “what, when, where, how many, and how well” the work is to be performed.

The PWS describes the specific requirements the Contractor must meet in performance of the contract. It also specifies a standard of performance for the required tasks and the quality level the government expects the contractor to provide.

The PWS should contain consistent terminology. Use the same words throughout the PWS when addressing the same thing. This is particularly important when referring to technical requirements.

The performance work statement defines the Government's requirements in terms of the objective and measurable outputs. It should provide the vendor with answers to five basic questions: what, when, where, how many, and how well. It is important to accurately answer these questions in order to allow the vendor the opportunity to accurately assess resources required and risks involved.

Quality Assurance Surveillance Plan (QASP)

Performance standards and measures of contractor performance, is needed to determine if contractor services meet contract PWS requirements. Positive and/or negative performance incentives, based on QASP measurements, should be included. The PWS Performance Standards, QASP and Incentives are interdependent and must be compatible in form, style, and substance, and should be cross-referenced.

The quality assurance plan gives the Government flexibility in measuring performance and serves as a tool to assure consistent and uniform assessment of the contractor's performance. This plan is primarily focused on what the Government must do to ensure that the contractor has performed in accordance with the performance standards. It defines how the performance standards will be applied, the frequency of surveillance, the maximum acceptable defect rate(s), and the value of each performance requirement as a percentage of the overall contract. A good quality assurance plan should include a surveillance schedule and clearly state the surveillance methods to be used in monitoring the contractor's performance.

The acceptable quality level as defined in the quality assurance plan establishes a maximum allowable error rate or variation from the performance standard(s). Depending on agency level policy and procedures the quality assurance plan may or may not be included as part of the performance work statement in the contract; however, the methodology for evaluating performance of the contract must be included.

Performance Requirements

If there are number of tasks and deliverables, agencies should summarize them in a performance requirements summary (PRS). A PRS usually lists tasks, deliverables, standards, and quality levels.

Performance requirements are statements describing the required services in terms of output. They should express the outputs in clear, concise, commonly used, easily understood, measurable terms. They should not include detailed procedures that dictate how the work is to be accomplished. The following statements are examples of the kinds of information to be included in the performance requirements section:

One of the first steps in developing a Performance Work Statement (PWS) is identifying the agency's needs and addressing those needs with performance requirements. Performance requirements will be unique to each agency and the customers it serves. These requirements are statements describing the required services in terms of output. The requirements should be stated in clear, concise, commonly used, easily understood, measurable terms. Detailed procedures should not be included that dictate how the work is to be accomplished; rather, the requirements should allow the contractor the latitude to work in a manner best suited for innovation and creativity.

Performance Requirements Summary

The performance requirements summary can be presented as a matrix. This type of chart could be included in the performance work statement or placed elsewhere in the contract to summarize the requirements and display the relationships of each of the elements in the performance work statement. The summary chart is a tool that can easily summarize the elements presented in the performance work statement. Notice, that for each requirement there can be one or more standards, defined maximum allowable degree of deviation from the standard(s), method(s) of surveillance to determine adherence to the standard(s), and positive and negative incentives for meeting, exceeding, or failing to meet the standard(s).

Performance Standards

Performance standards establish the performance level required by the government. Each agency should ensure that each standard is necessary, carefully described, and not burdensome. Failure to do so can result in unnecessarily increased contract costs. Discretion must also be exercised in establishing the quality level at which performance standards are set. The minimum acceptable performance standard should rarely be 100 percent, since the standard directly affects the cost of the service. On the other hand, if the quality level is too low, however, it may act as a disincentive to good contract performance. Standards may be published or well recognized industry wide standards, or may be developed by the agency based on past workloads or best practices. Agency standards should have industry input to ensure that they are realistic and effective.

The performance standards establish the performance level(s) required by the Government. These standards are driven by the application system(s) being converted or developed. The agency should ensure that each standard is necessary, is carefully chosen, and not unduly burdensome. (See Performance Requirements Summary for a listing of examples of standards.)

Performance Incentives

Incentives should be used to encourage quality performance and may be either positive, negative, or a combination of both. Positive incentives are actions taken if the work meet or exceeds the standards. Negative incentives are actions taken if the work does not meet standards. Positive incentives should be set at challenging yet reasonably attainable levels. Incentives should be applied selectively to motivate contractor efforts that might not otherwise be emphasized, and to encourage efficiency. The definitions of standard performance, maximum positive and negative performance incentives, and the units of measurement should be established in the solicitation. They will vary from contract to contract and are subject to discussion during a source selection. Incentives should correlate with results. Follow-up is necessary to ensure that desired results are achieved, i.e., ensure that incentives actually encourage good performance and discourage unsatisfactory performance. Where negative incentives are used, the deduction should represent as closely as possible the value of the service lost. Avoid rewarding contractors for simply meeting minimum standards of contract performance, and create a balance between cost, performance, and schedule incentives.

Incentives should be used when they will encourage better quality performance and may be either positive, negative, or a combination of both; however, they do not need to be present in every performance based contract as an additional fee structure. In a fixed price contract, the incentives would be embodied in the pricing and the contractor could either maximize profit through effective performance or have payments reduced because of failure to meet the performance standard.

Incentives should be used when they will induce better performance and may be either positive, negative, or a combination of both. They should be applied selectively to motivate contractor efforts that might not otherwise be emphasized, and to discourage inefficiency. Incentives should apply to the most popular aspects of the work, rather than every individual task.

The definitions of standard performance, maximum positive and negative performance incentives, and the units of measurement should be established in the solicitation. The goal is to reward Contractors for outstanding work, but not penalize them for fully satisfactorily but less than outstanding work. Incentives are especially useful in efforts that are complex, have a high-dollar value, or have a history of performance or cost overrun problems.

Incentives should correlate with results. Agencies should avoid rewarding Contractors for simply meeting minimum standards of contractor performance, and create a power balance between cost, performance, and schedule incentives. The incentive amount should correspond to the difficulty of the task required, but should not exceed the value of the benefits the government receives.

Positive Incentives - Actions to take if the work exceeds the standards. Standards should be challenging, yet reasonably attainable.

Negative Incentives - Actions to take if work does not meet standards. The definitions of standard performance, maximum positive and negative performance incentives, and the units of measurement should be established in the solicitation. They will vary from contract to contract and are subject to discussion during a source selection. It is necessary to balance value to the Government and meaningful incentives to the contractor. Incentives should correlate with results. Follow-up is necessary to ensure that desired results are realized, i.e., ensure that incentives actually encourage good performance and discourage unsatisfactory performance.

Measurement Techniques

Measurement techniques should be clearly stated in the quality assurance plan (QAP). The QAP defines what the government must do to ensure that the contractor has performed in accordance with the PBSC performance standards. It is needed to ensure the government receives the quality of services called for under the contract, and pays only for an acceptable level of services. A good QAP should include a surveillance schedule and clearly state the surveillance method(s) to be used.

**Performance Work Statement (PWS)
Regulatory Compliance Center
RFP DAIDS-03-26**

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SECTION B SUPPLIES OR SERVICES AND PRICES/COSTS

B.1 BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This is a contract to operate and manage the Regulatory Compliance Center ("RCC") to support a wide range of clinical research activities and programs administered by the Regulatory Affairs Branch (RAB), of the Division of AIDS ("DAIDS"), a component of the National Institute of Allergy and Infectious Diseases ("NIAID"). The NIAID is one of 27 Institutes comprising the National Institutes of Health ("NIH"), which is, in itself, a large health research agency within the Department of Health and Human Services ("DHHS"). The majority of the NIH research effort related to HIV infection and AIDS is managed by the NIAID. See web page for NIAID located at: <http://www.niaid.nih.gov>.

B.2 ESTIMATED COST, FIXED FEE , AWARD FEE and OPTIONS

B.2.1 This is a Cost-Plus-Award-Fee (CPAF), Performance-Based Service Contract (PBSC), consisting of the following elements: Estimated Cost; Base Fee; Award Fee; Estimated Cost-Plus-Base Fee-Plus-Award-Fee and Options.

B.2.2 Base Period (Years 1 through 3)

B.2.2.1. The Estimated Cost of the BASE PERIOD is \$_____.

B.2.2.2 The Base Fee (for the BASE PERIOD) for this contract is \$_____ [note: target= 2% of est. costs]. The Government will pay the Contractor the Base Fee in equal monthly increments of \$_____, subject to the withholding provisions in Section B.1.6. The Contractor will be paid the Base Fee regardless of whether it earns any Award Fee during the period of contract performance.

B.2.2.3 The Award Fee (for the BASE PERIOD) for this contract is \$_____ [note: target=8% of est. costs]. This amount represents the MAXIMUM amount of potential Award Fee over the entire period of performance of the contract. The actual amount of Award Fee will be determined based on semiannual evaluations of the Contractor's performance conducted in accordance with procedures described in Exhibit J.5 and Exhibit J.6.

B.2.2.4 The Base Fee plus Award Fee (for the BASE PERIOD) for this contract is \$_____. Payment of Base Fee and the Award Fee shall be made as specified in this Schedule.

B.2.2.5 The Estimated Cost-Plus-Base Fee-Plus-Award Fee (for the BASE PERIOD) for this contract is \$_____. This represents the Government's MAXIMUM obligation under this contract.

B.2.3 Options

If the Government exercises its options pursuant to H.5. of this contract, the Government’s total obligation represented by the MAXIMUM of the Estimated Cost-plus-Base Fee-plus-Award Fee will be increased as follows:

	Estimated Cost (\$)	Base Fee (\$)	Award Fee (\$)	Estimated Cost + Base Fee + Award Fee (\$)
Base Period				
Year 1	\$	\$	\$	\$
Year 2	\$	\$	\$	\$
Year 3	\$	\$	\$	\$
Option 1:				
Year 4	\$	\$	\$	\$
Year 5	\$	\$	\$	\$
Option 2:				
Year 6	\$	\$	\$	\$
Year 7	\$	\$	\$	\$
Total (Including Options)	\$	\$	\$	\$

B.2.4 Total funds currently available for payment and obligated to this contract are \$_____, of which \$_____ represents the Estimated Costs, and of which \$_____ represents the Base Fee. There are no current funds obligated to this contract for Award Fee. If and when the Contractor earns Award Fee under this contract, the Contracting Officer will unilaterally modify this Section B to obligate funds in the amount of the Award Fee increment. For further provisions on funding, see the clause in Section I entitled Limitation of Funds (Apr 1984).

B.2.5 The Contracting Officer may obligate funds to the contract through a unilateral modification (without the concurrence of the Contractor).

B.3. PROVISIONS APPLICABLE TO DIRECT COSTS

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

B.4. ADVANCE UNDERSTANDINGS

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

[End of Section B]

SECTION C – WORK REQUIREMENT / DELIVERABLES

C.1. ACRONYMS

AACTG	Adult AIDS Clinical Trial Group
ADEERS	Adverse Event Expedited Reporting System
AFP	Award Fee Panel
AQL	Allowable error rate
CFR	Code of Federal Regulations
CIPRA	Comprehensive International Program of Research on AIDS
CMB	Contract Management Branch
C.O.	Contracting Officer
C.O.B.	Close of Business
CPAF	Cost-plus-award-fee
CPCRA	Terry Beirn Community Programs for Clinical Research on AIDS
CRADA	Cooperative Research and Development Agreements
CRFs	Case Report Forms
CROC	Clinical and Regulatory Operations Center
CRPMC	Clinical Research Products Management Center
CSRC	Clinical Science Review Committee
CTAs	Clinical Trial Agreements
DAIDS	Division of Acquired Immunodeficiency Syndrome
DHHS	Department of Health and Human Services
ESPRIT	Evaluation of Subcutaneous Proleukin® in a Randomized International Trial
FAR	Federal Acquisition Regulations
FDA	Food and Drug Administration
GCP	Good Clinical Practices
GFP	Government-Furnished Property
HIVNET	HIV Network for Prevention Trials
HPTN	HIV Prevention Trials Network
HVTN	HIV Vaccine Trials Network
IBs	Investigational Brochures
INDs	Investigational New Drug Applications
IRBs	Institutional Review Boards
IRP	Intramural Research Program
LOU	Letter of Understanding
MF	Master File
MIS	Management Information System
MO	Medical Officer
NDA	New Drug Application
NIAID	National Institute of Allergy and Infectious Diseases
NIH	National Institutes of Health
NDA	New Drug Approval
OFPP	Office of Federal Procurement Policy
OHRP	Office for Human Research Protection
PACTG	Pediatric AIDS Clinical Trials Group
PP	Past Performance
PBSC	Performance Based Service Contract
PI	Performance Incentives
PID	Patient Identification Number
PLA	Product Licensing Approval
P.O.	Project Officer
PR	Performance Requirement
PRS	Performance Requirement Summary
PSRC	Prevention Science Review Committee
PTN	Prevention Trials Network

PWS	Performance Work Statement
QA	Quality Assurance
QASP	Quality Assurance Surveillance Plan
RAB	Regulatory Affairs Branch
RAS	Regulatory Affairs Specialist
RCC	Regulatory Compliance Center
ROC	Regulatory Operations Center
SAE	Serious Adverse Experience
SOP	Standard Operating Procedures
VTN	Vaccine Trials Network
WARP	Weekly Accrual Report Package

C.2 WORK REQUIREMENTS/TASKS

The Contractor shall perform the work requirements/tasks as described in Sections C.2.1 through C.2.12, in accordance with the requirements in Sections C.3 through C.6, and in conformance with all other terms, conditions, and sections of the contract, whether printed in full text or incorporated by reference into the contract.

The Contractor shall furnish all labor, materials, parts, and equipment necessary to perform all work requirements in the contract, with the exception of property and other resources specifically designated as "Government-Furnished Property and Resources" and listed in Exhibit J.1 of the contract. Contractor-Furnished Property and Resources include, but are not limited to, the items listed in Exhibit J.2.

The Contractor shall use its best efforts to optimize achievement of the Performance Requirements and Performance Standards listed in Exhibit J.5.

C.2.1 General Contract Requirements (TASK AREA A)

C.2.1.1 Deliver Required Status Reports

The Contractor shall deliver the following five (5) categories of status reports as described in more detail, below, in accordance with the requirements of Section C.3.

C.2.1.1.1 Monthly Labor-Hour Report

The Contractor shall prepare and deliver a Monthly Labor-Hour Report.

This Report shall include the following information for each person expending labor-hours under this contract:

- Name of person;
- Labor category or categories;
- Hours worked by task area (identified in C.2.1 through C.2.12) within a labor category;
- Total hours worked by labor category and task area; and
- Total hours worked for the month.

The first Report consists of the first full calendar month including any fractional part of the initial month. This Report shall also include the same information in summary format for each labor category under the contract.

C.2.1.1.2 Quarterly Progress Report

The Contractor shall prepare and deliver a written Quarterly Progress Report. This Report shall include a description of the work accomplished during the period covered. The first reporting period consists of the first full three months of contract performance including any fractional part of the initial month. Thereafter, the reporting period shall consist of three full months.

The Quarterly Progress Report shall, at a minimum, include the following information:

- Overview of contract;
- Project activities by each task area as identified in Sections C.2.1 through C.2.12, with a separate section addressing each task in the same numerical order;
- Personnel changes; and
- RCC Organizational Chart.

C.2.1.1.3 Annual Report

The Contractor shall prepare and deliver a written Annual Report. This Report shall include a description of the work accomplished during a one-year period of contract performance. The Quarterly Progress Report shall not be required when an Annual Report is due.

The Annual Report shall, at a minimum, include the information prescribed in Section C.2.1.1.2, in addition to a summary of the Quarterly Progress Reports.

C.2.1.1.4 Final Report

The Contractor shall prepare and deliver a written Final Report. This Report shall include a description of the work accomplished during the entire period of contract performance. This Report shall be in sufficient detail to describe comprehensively the results achieved. The Contractor shall submit with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract. A Quarterly Progress Report and Annual Report shall not be required for the period when the Final Report is due.

The Final Report shall, at a minimum, include the information prescribed in Section C.2.1.1.2, in addition to a summary of the Annual Reports. This Report shall also include a section entitled "Special Activities" which describes activities and events experienced by the Contractor during the life of the contract that were both significant and unanticipated.

C.2.1.1.5 Written Agendas and Minutes for Meetings

The Contractor shall prepare and deliver to the Project Officer written meeting agendas and minutes for meetings conducted in accordance with Section C.2.1.3, below.

The **meeting agendas** shall include, at a minimum, the following information:

- Date, time, location, and participants for meeting;
- Type of meeting;
- Chronological list of topics to be discussed; and
- Designated spokesperson for each topic.

The **meeting minutes** shall include, at a minimum, the following information:

- Date, time and location of meeting;
- Chronological list of topics discussed, accompanied by a brief description of the salient points made under each topic;
- List of follow-up action items, with designated person(s) responsible for each item; and
- Date and time of next meeting (if applicable).

C.2.1.2 Deliver Required Data Reports **(TASK AREA A)**

The Contractor shall prepare and deliver the following 12 categories of data reports as described in more detail in the applicable referenced section of this performance work statement, and in accordance with the requirements of Section C.3:

1. Weekly IND Submission Summary (Section C.2.2.1.7)
2. Draft of Annual Report to FDA on INDs (Section C.2.2.2.3)
3. Quarterly IND Annual Report Table (Section C.2.2.2.3.1)
4. Weekly Accrual Report Package ("WARP") (Sections C.2.2.6 and C.2.4.2)
5. Monthly Status Report of Protocol Team Responses to FDA Comments and Data Requests (Section C.2.2.7)
6. Interim and Final FDA Safety Reports (Section C.2.5.10)
7. Weekly Report of Status of 15-day IND Safety Reports (Section C.2.5.11)
8. Summary Letter with CSRC or PSRC comments (Section C.2.6.1.4)
9. Weekly Tracking Reports for CTAs (Section C.2.7.5)
10. Protocol Registration Reports (Section C.2.7.6)
11. Drafts of Semi-Annual Revisions to the RCC SOP Handbook (Section C.2.9.2)
12. Regulatory Reviews of Protocols per SOPs (Section C.2.10.7).

C.2.1.3 Attend Required Meetings

The Contractor shall coordinate and attend the following meetings:

C.2.1.3.1 Biweekly Project Management Meeting

The Contractor shall coordinate and attend a biweekly (once every two weeks) project management meeting at the DAIDS, RAB, to be attended, at a minimum, by the Contractor's project director and its project managers for each of the task areas of the contract. [Note: The Chief, RAB/DAIDS, will designate government attendees in addition to the Project Officer.]

C.2.1.3.2 Bimonthly Contract Management Meeting

The Contractor shall coordinate and attend a bimonthly (once every two months) contract management meeting with RAB, to be attended, at a minimum, by the Contractor's Project Director. [Note: The Chief, RAB/DAIDS, will designate government attendees in addition to the Project Officer.]

C.2.1.3.3 Other Meetings as Required

The Contractor shall coordinate and attend other meetings as required to successfully perform the work requirements in the contract.

C.2.2 Investigational New Drug ("IND") Application Process (TASK AREA B)

C.2.2.1 Prepare, distribute and track DAIDS-sponsored Investigational New Drug Applications (INDs) in accordance with 21 CFR 312, Investigational New Drug (IND) Applications.

C.2.2.1.1 Provide technical assistance to RAB/DAIDS in the assembly of original and subsequent submissions of INDs to the FDA.

C.2.2.1.2 Contact various offices and committees as necessary in the NIAID, other NIH Institutes, academic investigators, protocol teams, contractors and pharmaceutical companies responsible for pre-clinical screening, animal toxicology, chemistry, pharmacology, literature research and clinical research in order to obtain, summarize, and if needed, analyze, information/data for use in potential new IND submissions. Request IND, NDA, PLA, or MF cross-reference authorization in writing when appropriate. Respond to regulatory requests from pharmaceutical companies and other groups such as protocol teams and investigators for IND or MF documentation from DAIDS-sponsored trials.

C.2.2.1.3 Access various scientific and information databases as necessary to retrieve scientific data for possible inclusion in a new IND or other regulatory file.

C.2.2.1.4 Prepare and maintain IND data for subsequent submission to the FDA after approval by the FDA Liaison in RAB/DAIDS. This includes such administrative tasks such as editing, indexing, assembling and duplicating the acquired data. **(TASK AREA B)**

C.2.2.1.5 Prepare and submit to the FDA the required protocol registration documentation, which consists of the FDA Form 1572 package and the Curricula Vitae ("CVs") of the key clinical personnel. **(TASK AREA B)**

C.2.2.1.6 Maintain files of all IND correspondence and submissions to FDA for DAIDS sponsored clinical trials; maintain files of all supporting DAIDS Master Files at the FDA. **(TASK AREA B)**

C.2.2.1.7 Prepare and deliver weekly IND Submission Summary to RAB, DAIDS.

C.2.2.1.8 Organize IND-related conference calls and meetings with FDA for DAIDS, contact companies and investigators for participation on calls/meetings and prepare summaries of FDA calls with major action items for the IND file. Enter and track major action items in a computerized system.

C.2.2.2 Prepare FDA-required IND sponsor's annual reports. These reports include narrative analysis and tabular summaries of all results of a drug or vaccine's development during the previous 12 months of the protocol. **(TASK AREA B)**

C.2.2.2.1 Retrieve and summarize information to be included in an annual report to the FDA. This information shall be drawn from, but is not limited to, chronologies, pharmaceutical company information, the latest protocol versions, schematics depicting the protocols, comparison charts of protocol requirements, reports and tables received from applicable data coordinating centers, statistical analyses, relevant abstracts, posters, papers and presentations, copies of adverse experience summary reports, and lists of all submissions to the FDA.

C.2.2.2.2 Prepare the narrative sections of the annual report, that describe historical background, protocol rationales, relevant safety issues, pertinent results, and future directions for the general investigations.

C.2.2.2.3 Prepare, track and submit a written draft annual report that includes the above elements to the DAIDS Medical Officers (MOs) on the IND and DAIDS FDA Liaison in RAB/DAIDS for review and approval.

C.2.2.2.3.1 Prepare and deliver on a quarterly basis to RAB/DAIDS an IND Annual Report Table that displays the following information: IND; Protocols; Anniversary Date; Delivery Date; Regulatory Affairs Specialist (RAS); Tables Due; Tables Received; To Quality Assurance (QA) Review; To Medical Officer (MO) and Regulatory Manager-Return; To Regulatory Affairs Branch (RAB)-Return; and To FDA.

C.2.2.2.4 Duplicate, submits to the FDA, and distributes the IND annual report(s) as directed by the DAIDS FDA Liaison in RAB/DAIDS. **(TASK AREA B)**

C.2.2.3 Obtain Investigator Brochures (IBs) and package inserts from collaborating pharmaceutical manufacturers and copy and distribute these to potential clinical investigators and DAIDS. Obtain updates to these materials as they become available and distribute them. When package inserts are needed for studies, obtain and manage them in the same manner.

C.2.2.4 Assist DAIDS in preparation and submission of responses to formal FDA correspondence relating to INDs held by DAIDS. This includes, but is not limited to, researching and assembling relevant information, incorporating protocol team responses in the letter, and submitting the final response for review and sign-off by the FDA Liaison in the RAB/DAIDS.

C.2.2.5 Furnish collaborating drug companies with copies of all IND-related submissions.

C.2.2.6 Prepare and deliver Weekly Accrual Reports Package ("WARP") (see also Section C.3.4.2) for all DAIDS-sponsored clinical trials conducted by networks (including IND and non-IND). This package shall include, at a minimum, the following information: Patient Accrual by IND and Protocol or Protocol only for non-IND studies; Protocol Overview; and Summary of Patient Accrual to Studies in DAIDS-sponsored Trials Groups.

C.2.2.7 Prepare and deliver the Monthly Status Report of Protocol Team Responses to FDA Comments and Data Requests. This report shall include, at a minimum, the following information: Date of Request; Documentation; Source of Information; IND Number; Protocol Number; Regulatory Specialist; Current Status; and Date of Reply. Prepare a tabular summary of protocols in development for the Biweekly Project Management Meeting (Section C.3.1.3.1).

C.2.2.8 All work shall comply with the substantive and procedural requirements of 21 CFR 312, Investigational New Drug (IND) Applications, and all other applicable FDA and NIH requirements and guidelines.

C.2.2.9 All clinical investigators shall comply with the requirements of 21 CFR 54, Financial Disclosure for Clinical Investigators, as it relates to registration protocols (i.e. protocols under IND intended for use in product approval by the FDA). The RCC, at the direction of RAB/DAIDS, will assist companies submitting information to the FDA related to 21 CFR 54 by providing the final list of sites participating in registrational protocol(s).

C.2.3 Informed Consent Development & Review Process (IND & non-IND) **(TASK AREA C)**

C.2.3.1 Prepare, maintain and distribute all DAIDS Informed Consent Templates used to prepare Sample Consents for all protocols sponsored by DAIDS. Maintain up-to-date DAIDS Informed Consent Templates on the web site. **(TASK AREA C)**

C.2.3.2 Perform regulatory review of the Protocol Sample Informed Consents at RAB-specified stages of protocol development (such as before PSRC/CSRC review, prior to FDA submission for IND protocols, and prior to site distribution). The RCC will provide advice as requested. RAB may request additional or different timeframes for review, if needed to complete special protocol projects undertaken by DAIDS. **(TASK AREA C)**

C.2.3.3 Perform regulatory review of all Informed Consents submitted by clinical sites after approval by their Institutional Review Boards ("IRBs") as required for protocol registration and in accordance with DAIDS Protocol Registration Policy and Procedure Manual (See Exhibit J.3). **(TASK AREA C)**

C.2.3.4 Prepare Spanish translations of the Sample Informed Consents for U.S. sites, and for sites outside the U.S. participating in treatment protocols and other protocols as designated by the Project Officer, RAB/DAIDS. Have accessibility to translators of all widely used foreign languages used in DAIDS-sponsored trials in order to provide, at DAIDS request, Sample Informed Consents in these languages. **(TASK AREA C)**

C.2.3.5 Prepare, update, maintain and distribute lists of risks associated with study agents, and, where indicated, with patient management guidelines for adverse events. Obtain approval of risks lists from pharmaceutical companies and DAIDS medical officers.

C.2.3.6 Plan and conduct training sessions at national and international meetings on informed consents.

C.2.3.7 Respond to international requests for implementation of non-US regulations used in addition to, or in conjunction with, 45 CFR 46 for overseeing the informed consent process.

C.2.3.8 All work shall conform to the substantive and procedural requirements of 21 CFR 50, Protection of Human Subjects, 21 CFR 56, Institutional Review Boards, and 45 CFR 46, Protection of Human Subjects.

C.2.3.9 Prepare, disseminate to DAIDS staff and clinical site investigators, and periodically update a summary of the substantive differences among diverse ethical codes applicable to DAIDS-sponsored trials (e.g. Helsinki, CIOMS, NBAC) insofar as these relate to regulatory compliance procedures involving protection of human subjects.

C.2.4 Protocol Registration System of DAIDS-sponsored Clinical Trials (IND and non-IND) **(TASK AREA D)**

C.2.4.1 Establish and maintain a computerized clinical protocol registration system for DAIDS-sponsored trials and their amendments. **(TASK AREA D)**

C.2.4.1.1 File and track registration documentation submitted by the clinical sites in accordance with DAIDS Protocol Registration Policy and Procedure Manual. **(TASK AREA D)**

C.2.4.1.2 Receive and assess adequacy of all registration documentation submitted, including the FDA Form 1572 package, the Curricula Vitae for IND studies, the site IRB approval of each protocol, other IRB approvals (if required), back-translations of informed consents (if required) and the IRB-approved consent forms for each protocol. Verify current OHRP assurance numbers of the sites when documentation is submitted. Advise submitting sites of corrective action required in the registration documentation submitted to the RCC.

C.2.4.1.3 Respond to queries on the status of the protocol registration process from sites, DAIDS and other authorized individuals/groups. Furnish status update to registrant and to the DAIDS.

C.2.4.1.4 Notify the NIAID Clinical Research Products Management Center ("CRPMC"), currently the DAIDS distribution center for drugs and biologics used in DAIDS-sponsored trials, or other designated organization that a site has been registered for a particular protocol so study agents may be ordered by site pharmacists.

C.2.4.1.5 Plan and conduct training sessions on protocol registration at national and international meetings, or through telephone conference calls, addressing implementation of the regulations of 21 CFR 50, Protection of Human Subjects, 21 CFR 56, Institutional Review Boards, and 45 CFR 46, Protection of Human Subjects.

C.2.4.2 Prepare and Deliver Weekly Accrual Report Package ("WARP"), a report summarizing protocol status by network/group and other pertinent information.

C.2.5 Serious Adverse Experience ("SAE") Reporting System for DAIDS-sponsored Clinical Trials (IND and non-IND) (TASK AREA E)

C.2.5.1 Evaluate and summarize adverse experience reports received from clinical sites by telephone, facsimile ("Fax") or electronic mail; query the sites to clarify information or to obtain follow-up information; abstract (e-mail) information regarding SAEs and forward to DAIDS medical and regulatory staff for review; reply to queries from DAIDS medical staff; provide medical assessment of relationship of the event to the study agent(s), and draft and distribute, by hard copy and/or electronic methods, Safety Reports, Safety Memos, Safety Alerts or Med Watch Reports about serious adverse experiences in accordance with the DAIDS Serious Adverse Experience (SAE) Reporting Manual(s) (see Exhibit J.3). **(TASK AREA E)**

C.2.5.2 Establish and maintain a computerized tracking system for the receipt, follow-up, reporting, and disposition of SAEs occurring during participation in DAIDS-sponsored clinical trials. Work performance and output shall comply with the DAIDS Serious Adverse Experience Reporting Manual(s) and DAIDS SOPs related to Serious Adverse Event Reporting. **(TASK AREA E)**

C.2.5.3 Establish and maintain a toll-free "800" telephone line and an "800" fax line capable of receiving SAE information 24 hours a day, 7 days a week. This may be accomplished by providing appropriately trained health care professionals during working hours and utilizing an answering machine after normal working hours and on weekends. When appropriate, use a WEB-based reporting system for select protocols. **(TASK AREA E)**

C.2.5.4 Maintain, update, print and distribute to participating clinical sites adverse experience reporting forms, standard operating procedures (SOPs) for collecting and processing SAE data, and the relevant DAIDS SAE Reporting Manual.

C.2.5.5 Generate and maintain periodic reports, accessible to the Project Officer and other authorized Government personnel, that document SAE reporting. This includes documentation of the accuracy and completeness of SAE Reports, time required for response to queries, and Contractor performance as measured by timely SAE disposition. Timely SAE disposition will be measured by compliance by the Contractor with the procedural and substantive requirements of the DAIDS SAE Reporting Manuals and applicable FDA requirements.

C.2.5.6 Coordinate and facilitate electronic data transfer of SAE data to the central database of each DAIDS network (usually established data centers affiliated with the network). Work with the data center to reconcile discrepancies between the SAE data reported to the RCC and that collected on the data center's case report forms (CRFs).

C.2.5.7 Within 24 hours of receipt, abstract and enter serious adverse experience data from the SAE form into the computerized, interactive SAE system maintained by the RCC.

C.2.5.8 Plan and conduct training sessions on SAE reporting for clinical site personnel at national meetings or by conference call.

C.2.5.9 Implement and maintain RCC internal quality control/quality assurance (QC/QA) procedures and ongoing training to ensure consistency, completeness, and accuracy of data abstraction and data entry so that coding, based on SAE data exported from the RCC to the data management center is accurate.

C.2.5.10 Prepare interim and final FDA Safety Reports or Med Watch Reports in accordance with the DAIDS Serious Adverse Experience (SAE) Reporting Manual(s) and DAIDS SOPS related to SAEs. These reports shall, at a minimum, contain the following information: Adverse Experience; Severity Grade; SAE; Protocol Title and Number; IND Number; Study Agent(s); Date of Report; PID; Summary of the event; Patient History and Clinical Evaluation; Assessment of Relationship of Study Agent to the Event; and Compliance Statement. Distribute the FDA Safety Reports to sites using the study agent(s) listed in the report in a timeframe according to DAIDS SOPS. Distribute other serious safety information, such as DAIDS Safety Alerts and safety information obtained from company collaborators in a timely manner according to DAIDS SOPS. Provide instructions to DAIDS sites about site responsibilities related to such reports. Provide monitoring contracts with pertinent information related to safety report identification. **(TASK AREA E)**

C.2.5.11 Prepare and deliver to RAB/DAIDS a weekly report of status of 15-day and 7-day IND Safety Reports.

C.2.5.12 Generate specified SAE/death tabulations and summary reports for specific studies, study agents, and by type of SAE, either periodically or upon request from the FDA or DAIDS. Provide quarterly safety summary reports to each network by study and agent.

C.2.5.13 All work related to SAE reporting for IND protocols shall conform to the requirements of 21 CFR 312, Investigational New Drug (IND) Applications. All SAE reporting for non-IND protocols shall correspond to criteria established by DAIDS SOPS.

C.2.6 DAIDS Review Committees: Clinical Sciences Review Committee ("CSRC") and the Prevention Science Review Committee ("PSRC") **(TASK AREA F)**

C.2.6.1 Provide administrative, technical and scientific support for the CSRC and the PSRC.

C.2.6.1.1 Receive and track materials (capsules, proposed concept sheets, protocols in various stages of development and protocol amendments) received for review by the CSRC or the PSRC via electronic reports. **(TASK AREA F)**

C.2.6.1.2 In consultation with DAIDS staff, establish the agenda for the CSRC and the PSRC reviews, which take place on a weekly or bi-weekly basis, and notify reviewers and presenters. Copy and distribute materials to meeting participants.

C.2.6.1.3 Draft, revise, based on DAIDS review, and distributes consensus reviews to designated groups and individuals. Track, maintain and distribute the final review to the appropriate groups and individuals.

C.2.6.1.4. Distribute Summary Letter of review with CSRC and PSRC Comments to appropriate groups.

C.2.7 Clinical Trials Agreements (CTAs), Letters of Understanding (LOUs) and Cooperative Research and Development Agreements (CRADAs) Process **(TASK AREA G)**

C.2.7.1 Maintain DAIDS standard CTA template(s) and send them to industrial collaborators (biologic or drug product manufacturers) at the direction of the RAB/DAIDS. **(TASK AREA G)**

C.2.7.2 Facilitate and support negotiation and finalization of initial CTAs and CRADAs between industrial collaborators or agencies and DAIDS. Negotiate subsequent CTAs and CRADAs with collaborators requiring multiple agreements with DAIDS.

C.2.7.3 Establish and maintain a tracking system for Letters of Understanding ("LOUs") addressing intellectual property issues between industrial collaborators and the sites. **(TASK AREA G)**

C.2.7.4 Maintain records of CTAs and LOUs, including the maintenance of a system for tracking the documents electronically through a database.

C.2.7.5 Prepare written weekly tracking reports of CTAs and CRADAs that include, at a minimum, the following information: Protocol Number; Study Agent/Company; CSRC/PSRC review and date; Notification Letter; Approval of the CTA by the company and DAIDS; Protocol Regulatory Review; Date CTA Signed and Mailed to Company; Date CTA Distributed to DAIDS and Investigators; and Comments.

C.2.8 Maintain Computerized Management Information Systems ("MIS") **(TASK AREA H)**

C.2.8.1 Establish and maintain an electronic data management information systems ("MIS") to schedule, track, report, store, modify, transmit, and dispose of all work and work products generated by the Contractor during the performance of work under this contract. This MIS shall be able to exchange information with those systems utilized by the DAIDS sponsored group/network Operations Offices, Data Management Centers, and the DAIDS. **(TASK AREA H)**

C.2.8.2 Establish, maintain, and document quality control procedures to ensure the substantive accuracy of all data entered into the electronic databases.

C.2.8.3 Produce and distribute reports that extract data from the MIS as requested by the Project Officer.

C.2.8.4 Maintain up-to-date documentation that describes the structure and operating characteristics of the MIS.

C.2.8.5 Ensure that the MIS allows multiple users of the network to access the system simultaneously. There shall be security provisions in place to guard against unauthorized access to system data. The MIS shall include virus protection that detects and prevents the spread of computer viruses from internal and external sources.

C.2.8.6 Develop and maintain a reliable and efficient web-site that serves as an information source for DAIDS staff and Investigator Group members and associated staff. The website should provide easy access to all guidance documents, manuals, templates, etc. related to regulatory issues of importance in DAIDS-sponsored clinical studies. The web site must also provide access to data from the RCC MIS in an easy-to-use, milestone-driven format that provides up-to-date information about the status of all protocol related regulatory processes supported by the RCC and the DAIDS RAB and PAB. **(TASK AREA H)**

C.2.8.7. Integrate and/or implement, as needed, a comprehensive clinical trials management system (or components thereof) as relates to the functions of the RCC.

C.2.9 Maintain the RCC Standard Operating Procedures (SOP) Handbook **(TASK AREA I)**

C.2.9.1 The Contractor shall maintain and revise as required but no less than semiannually (as of January 1 and July 1 of each year) the RCC Standard Operating Procedures (SOP) Handbook used by RCC personnel to carry out their responsibilities (see Exhibit J.3). All work under this contract shall be performed in accordance with the current version of the RCC SOP Handbook. **While some SOPs may be displayed on the contract's web site, the current hardcopy version of the RCC SOP Handbook is considered the official document for auditing purposes.**

C.2.9.2 The Contractor shall prepare and deliver to the Project Officer the Handbook revised to reflect current statutory, regulatory, and administrative requirements pertaining to the regulatory operations of the RCC under this contract. This document shall be posted in the restricted access of the web site. **(TASK AREA I)**

C.2.9.3 All proposed revisions to the RCC SOP Handbook should be submitted in draft form to the Project Officer for review and approval prior to being incorporated into the RCC SOP Handbook.

C.2.10 Other Regulatory Support Functions (TASK AREA J)

C.2.10.1 Review clinical site-monitoring reports, prepared by DAIDS monitoring contracts, and identify areas of potential concern that may require DAIDS action. As necessary, research relevant regulatory requirements. Forward reports with comments to DAIDS RAB for review and action/consultation with other DAIDS staff.

C.2.10.2 Archive completed case report forms (CRFs) obtained from sites no longer funded by DAIDS by following instructions and the SOP provided by RAB.

C.2.10.2.1 Box and ship completed CRFs received from de-funded sites for long-term storage in accordance with DHHS Regulations on Archiving and Storage of Official Records (Month, Year) (see Section 10.3). Retrieve CRFs as requested in writing by the RCC Project Officer.

C.2.10.3 Draft, copy, and distribute by electronic mail, Fax, U.S. mail or courier service, letters, documents or reports, to principal investigators, clinical site personnel, pharmaceutical companies, FDA, OHRP and other related agencies and personnel.

C.2.10.4 Periodically update a directory of names, position(s), addresses, phone/fax numbers, and E-mail/internet addresses of key regulatory/clinical personnel who interact with RAB in the FDA, OHRP, and pharmaceutical companies.

C.2.10.5 Assist DAIDS in responding to outside inquiries (both governmental and non-governmental) concerning regulatory activities covered by the scope of work of this contract.

C.2.10.6 Review all protocols and amendments for IND and non-IND studies. Ensure that modifications to protocols are in compliance with FDA regulations for IND studies and that all protocols comply with OHRP regulations and NIAID/NIH/DHHS pertinent regulations and requirements.

C.2.10.7 Prepare written regulatory reviews of final (full version) protocols prior to distributing full version protocols to the sites. These reviews shall include, at a minimum, the following information: General Protocol Comments and Sample Informed Consent/SAE Comments.

C.2.10.8 Assist the PO and other NIAID officials in responding to requests for information under the Freedom of Information Act (FOIA), with respect to any documents or records generated as work product by the Contractor under this contract.

C.2.10.9 Assist the PO and other NIAID officials in responding to requests for information by U.S. Congressional Oversight Committees, or other U.S. government inquiries, with respect to any work done (including documents or records generated as work product) by the Contractor under this contract.

C.2.11 Provide for Orderly Transition to a Subsequent Contractor / or to a New Contract

C.2.11.1 Develop a written transition plan, subject to Project Officer approval, to ensure the orderly transfer of all or part of this project to a subsequent Contractor.

C.2.11.2 Instruct employees of the new Contractor on all procedures in current use, including detailed instructions on the design and structure of the automated adverse event processing/tracking system and the automated site registration system.

C.2.11.3 Ensure that the Standard Operating Procedures Handbook is accurate and up-to-date, and provide a copy of this Handbook to the new Contractor.

C.2.11.4 Affect a smooth transfer of all data and data documentation to the subsequent Contractor.

During a period prior to completion of this contract, to be specified by the Project Officer, the Contractor shall develop a written transition plan, subject to Project Officer approval, to ensure the orderly transfer of all or part of this project to a designated Contractor or Subcontractor, if other than the incumbent.

The Contractor shall actively collaborate with subsequent contractors and subcontractors to implement a transition plan to ensure the transfer of all or part of the data collected by the current Contractor and Subcontractors necessary to the fulfillment of the current contract, as well as relevant software and equipment to effect the transition within a three-month period.

The Contractor shall carry on contractual operations at full staffing levels agreed to by the Project Officer until the completion of the contract.

C.3 CONSOLIDATED LIST OF STATUS REPORTS AND DATA DELIVERABLES

The Contractor shall deliver the status reports and data deliverables as described below.

C.3.1 Due Dates for Deliverables

The deliverables (status and data reports) listed below shall be delivered in accordance with due dates prescribed below. The content for each deliverable is specified in the cross-referenced section of Section C.3 indicated after each item.

Item #	Deliverable	Section	Format/Quantités	Due Date
No. 1	Monthly Labor-Hour Report	C.2.1.1.1	E-Mail plus one (1) hard copy	15th day of following month
No. 2	Quarterly Progress Report	C.2.1.1.2	Original plus three (3) copies	15th day of following month
No. 3	Annual Report	C.2.1.1.3	Original plus three (3) copies	15th day of following month
No. 4	Final Report	C.2.1.1.4	Original plus three (3) copies	15th day of following month
No. 5	Agendas and Minutes for Meetings	C.2.1.1.5	E-Mail -- (PO will designate recipients)	Agendas , no later than one (1) hour before meeting. Minutes , no later than 72 hours after meeting
No. 6	Weekly IND Submission Summary	C.2.2.1.7	E-Mail -- (PO will designate recipients)	Close of Business (C.O.B. Fridays)
No. 7	Draft of Annual Report to FDA on IND Anniversary Date	C.2.2.2.3	E-Mail -- (PO will designate recipients)	One month before IND anniversary date
No. 8	IND Annual Report Table	C.2.2.2.3.1	E-Mail -- (PO will designate recipients)	15th day of following month on a quarterly basis
No. 9	Weekly Accrual Report Package ("WARP")	C.2.2.6 C.2.4.2	E-Mail -- (PO will designate recipients)	Close of Business (C.O.B.) Fridays
No. 10	Monthly Status Report of Protocol Team Responses to FDA Comments and Data Requests	C.2.2.7	Original plus adequate copies	Bring to Biweekly Project Management Meeting (C.5.1.3.1)
No. 11	Interim and Final FDA IND Safety Reports	C.2.5.10	E-Mail -- (PO will designate recipients)	Interims no later than day 5 --Finals no later than day 13
No. 12	Weekly Report of Status of 15- & 7-day IND Safety Reports	C.2.5.11	E-Mail -- (PO will designate recipients)	Close of Business (C.O.B.) Fridays
No. 13	Summary Letter with CSRC and PSRC Comments	C.2.6.1.4	E-Mail plus Hardcopy	Seven (7) days after meeting
No. 14	Weekly Tracking Reports for CTAs in Development	C.2.7.5	E-Mail -- (PO will designate recipients)	Close of Business (C.O.B.) Fridays
No. 15	Protocol Registration Reports	C.2.4.1.3	E-Mail -- (PO will designate recipients)	Close of Business (C.O.B.) Fridays
No. 16	Drafts of Semiannual Revisions to the RCC SOP Handbook	C.2.9.2	Original plus three (3) copies	June 1 and January 1 of each year
No. 17	Regulatory Reviews of Final Protocols	C.2.10.7	Original plus three (3) copies	Seven (7) days after receipt of protocols

C.3.2 Addressees for Deliverables

Deliverable Nos. 1 through 4:

Contracting Officer
Contracts Management Branch (CMB), NIAID
Room 2230
6700-B Rockledge Drive - MSC 7612
Bethesda, MD 20892-7612

Deliverable Nos. 1 through 5:

Project Officer
DAIDS, NIAID
Regulatory Affairs Branch
Room 5232
6700-B Rockledge Drive - MSC 7620
Bethesda, MD 20892-7620

Deliverable Nos. 6 through 17:

Regulatory Affairs Branch Office
Central Mailbox
5th Floor
6700-B Rockledge Drive - MSC 7620
Bethesda, MD 20892-7620

C.4 DELIVERY SCHEDULE AND PERIOD OF PERFORMANCE

The Contractor shall perform all work in accordance with the delivery schedule and period of performance prescribed in Section F of this contract.

NOTE: Due dates for Status Reports and Data Deliverables are listed in Section C.3.1, and are prescribed in Section C.2 (the cross-references to Section C.2 are in Section C.3.1). They are not repeated in SECTION F.

C.5 PLACE OF PERFORMANCE

The Contractor shall perform all work in accordance with the place of performance prescribed in Section F of this contract.

C.6 EXHIBITS INCORPORATED BY REFERENCE

The Contractor shall perform all work in accordance with Exhibits J.1 through J.6 prescribed in PART III, LIST OF DOCUMENTS, EXHIBITS, AND OTHER ATTACHMENTS that are hereby incorporated by reference into this Performance Work Statement (PWS). The full texts of the Exhibits are located in Section J of this contract.

[End Section C]

SECTION D PACKAGING, MARKING AND SHIPPING

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

SECTION E INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, _____ is the authorized representative of the Contracting Officer.
- c. Inspection and acceptance will be performed at, _____.

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

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

FAR Clause No 52.246-8, INSPECTION OF RESEARCH AND DEVELOPMENT - COST REIMBURSEMENT (MAY 2001)

SECTION F DELIVERIES OR PERFORMANCE

F.1. PERIOD OF PERFORMANCE

- a. The period of performance of this contract shall be from _____ through _____.
- b. If the Government exercises its option(s), the period of performance will be increased as listed below:

Option Year Number	Option Period
Base Period	3 Years
Option 1	2 Years
Option 2	2 Years

F.2. DELIVERIES

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

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

F.3. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2
(FEBRUARY 1998)

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (AUGUST 1989) with ALTERNATE I (APRIL 1984).

FAR Clause 52.247-35, FOB Destination Within Consignees Premises (APRIL 1984).

[End of Sections D, E and F]

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

Contracting Officer
Contracts Management Branch (CMB)
National Institute of Allergy and Infectious Diseases (NIAID), NIH
6700B Rockledge Drive, Room 2230, MSC 7612
BETHESDA MD 20892-7612

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

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

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

G.4. INDIRECT COST RATES

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

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

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

G.5. GOVERNMENT PROPERTY

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

G.6. POST AWARD EVALUATION OF CONTACT PERFORMANCE

- a. Contractor Performance Evaluations

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluations will be prepared annually to coincide with the anniversary date of the contract.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. Any disagreement between the parties regarding an evaluation will be referred to an individual one level above the Contracting Officer, whose decision will be final.

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

b. Electronic Access to Contractor Performance Evaluations

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

http://ocm.od.nih.gov/cdmp/cps_contractor.htm

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

[End of Section G]

H.11. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

Information regarding procedural matters is contained in the NIH Manual Chapter 1754, which is available on <http://www3.od.nih.gov/oma/manualchapters/management/1754/>.

H.12. OBTAINING AND DISSEMINATING BIOMEDICAL RESEARCH RESOURCES

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

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

[End of Section H]

PART II SECTION I

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.

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</u> <u>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	Feb 1999	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	Feb 2002	Buy American Act - Balance of Payments Program – 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)
352.216-72	Oct 1990	Additional Cost Principles
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. 02/2002]

I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

ALTERNATE IV (OCTOBER 1997) of FAR Clause 52.215-21, REQUIREMENTS FOR COST OR PRICING DATA OR INFORMATION OTHER THAN COST OR PRICING DATA--MODIFICATIONS (OCTOBER 1997) is added.

FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN (JANUARY 2002) is deleted in its entirety.

FAR Clause 52.229-3, FEDERAL, STATE AND LOCAL TAXES (JANUARY 1991) and FAR Clause 52.229-5, TAXES - CONTRACTS PERFORMED IN U.S. POSSESSIONS OR PUERTO RICO (APRIL 1984), are deleted in their entirety, and FAR Clause 52.229-6, TAXES - FOREIGN FIXED-PRICE CONTRACTS (JANUARY 1991) is substituted therefor.

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

FAR Clause 52.249-14, EXCUSABLE DELAYS (APRIL 1984) is deleted and HHSAR Clause 352.249-14, EXCUSABLE DELAYS (APRIL 1984) is substituted therefor.

I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

FAR 52.215-17, Waiver of Facilities Capital Cost of Money (OCTOBER 1997).

FAR 52.217-9, Option to Extend the Term of the Contract (MARCH 2000).

"(a) The Government may extend the term of this contract by written notice to the Contractor within 60 days prior to the completion date of each option period; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 days before the contract expires. The preliminary notice does not commit the Government to an extension."

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 84 months (7 Years)."

FAR 52.219-6, Notice of Total Small Business Set-Aside (JULY 1996).

FAR 52.224-1, Privacy Act Notification (APRIL 1984).

FAR 52.224-2, Privacy Act (APRIL 1984).

FAR 52.227-14, Rights in Data - General (JUNE 1987)

FAR 52.227-17, Rights in Data--Special Works (JUNE 1987).

FAR 52.229-8, Taxes-Foreign Cost-Reimbursement Contracts (MARCH 1990).

FAR 52.230-2, Cost Accounting Standards (APRIL 1998).

FAR 52.230-6, Administration of Cost Accounting Standards (NOVEMBER 1999).

FAR 52.239-1, Privacy or Security Safeguards (AUGUST 1996).

FAR 52.242-3, Penalties for Unallowable Costs (OCTOBER 1995).

FAR 52.247-63, Preference for U.S. Flag Air Carriers (JANUARY 1997).

FAR 52.247-67, Submission of Commercial Transportation Bills to the General Services Administration for Audit (JUNE 1997).

FAR 52.251-1, Government Supply Sources (APRIL 1984).

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

HHSAR 352.223-70, Safety and Health (JANUARY 2001)

HHSAR 352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities (APRIL 1984).

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

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

NIH (RC)-7, Procurement of Certain Equipment (APRIL 1984) (OMB Bulletin 81-16).

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

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

This contract incorporates the following clauses in full text.

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

FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS AND COMMERCIAL COMPONENTS (DECEMBER 2001)

(a) **Definition.**

Commercial item, as used in this clause, has the meaning contained in the clause at 52.202-1, Definitions.

Subcontract, as used in this clause, includes a transfer of commercial items between divisions, subsidiaries, or affiliates of the Contractor or subcontractor at any tier.

(b) To the maximum extent practicable, the Contractor shall incorporate, and require its subcontractors at all tiers to incorporate, commercial items or non-developmental items as components of items to be supplied under this contract.

- (c) Notwithstanding any other clause of this contract, the Contractor is not required to include any FAR provision or clause, other than those listed below to the extent they are applicable and as may be required to establish the reasonableness of prices under Part 15, in a subcontract at any tier for commercial items or commercial components:
- (1) 52.222-26, Equal Opportunity (E.O. 11246);
 - (2) 52.222-35, Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era (38 U.S.C. 4212(a));
 - (3) 52.222-36, Affirmative Action for Workers with Disabilities (29 U.S.C. 793); and
 - (4) 52.247-64, Preference for Privately Owned U.S.-Flagged Commercial Vessels (46 U.S.C. 1241) (flow down not required for subcontracts awarded beginning May 1, 1996).
- (d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

[End of Section I]

PART III SECTION J
LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

LIST OF EXHIBITS:

<u>J.1</u>	Government-Furnished Resources.....	45
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<u>J.3</u>	Applicable Documents.....	45
<u>J.4</u>	Personnel Requirements.....	46
<u>J.5</u>	Performance Requirements Summary.....	47-50
<u>J.6</u>	Quality Assurance Surveillance Plan (QASP).....	51-53

LIST OF ATTACHMENTS:

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

<u>PACKAGING AND DELIVERY OF PROPOSALS</u>	54
<u>HOW TO PREPARE AN ELECTRONIC PROPOSAL:</u>	55-55
<u>PROPOSAL INTENT RESPONSE SHEET</u> [SUBMIT ON/BEFORE: <u>July 1, 2002</u>]	57

[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
- Government Notice for Handling Proposals

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

- NIH-2043, Proposal Summary and Data Record
- Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours
- Offeror's Points of Contact

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- 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
- Report of Government Owned, Contractor Held Property

EXHIBIT J.1 GOVERNMENT-FURNISHED PROPERTY AND RESOURCES

J.1.1 Government-Furnished Information

J.1.1.1 The Government will furnish the Contractor with written comments on all drafts of deliverables, and will furnish the Contractor with "sign-offs" by authorized Government representatives on work product generated by the Contractor that requires Government approval prior to its distribution to affected or interested third parties.

J.1.2 Government-Furnished Property (GFP)

All Government-furnished Property (GFP) identified above, and all Contractor-acquired property, title to which will vest in the Government under the provisions of Exhibit J.2 below, shall be maintained, managed, and accounted for in accordance with the clause at FAR 52.245-5 Government Property (Cost-Reimbursement, Time-and-Materials, or Labor-Hour Contracts) (Jan 1986), and the DHHS Publication entitled "Contractor's Guide for Control of Government Property," which is published electronically at the following internet address:
<http://knownet.hhs.gov/log/contractorsguide.htm>.

EXHIBIT J.2 CONTRACTOR-FURNISHED PROPERTY AND RESOURCES

The Contractor shall furnish all labor, materials, facilities, and equipment necessary to perform the work under this contract, except for property specifically listed and described in Exhibit J.1, above.

The Contracting Officer will authorize the Contractor in writing to acquire computer and related office equipment as necessary for performance of the work under this contract. The Contractor shall be reimbursed for such equipment as a separate reimbursable item of direct cost under the contract. The Government will acquire title to such equipment in accordance with the provisions of the Government Property Clause in this contract (FAR 52.245-5).

EXHIBIT J.3 APPLICABLE DOCUMENTS

The documents listed in this Exhibit are incorporated by reference into this contract as if printed in full text.

J.3.1 Applicable Statutes and Regulations

21 CFR 11, Electronic Records, Electronic Signatures	Use http://www.fda.gov/ for Access to
21 CFR 50, Protection of Human Subjects	Code of Federal Regulations.
21 CFR 54, Financial Disclosure for Clinical Investigators	
21 CFR 56, Institutional Review Boards	
21 CFR 312, Investigational New Drug Applications	
45 CFR 46, Protection of Human Subjects	http://ohrp.osophs.dhhs.gov/humansubjects

J.3.2 Applicable Directives, Instructions, Publications, and Forms

ROC Standard Operating Procedures ("SOP") Handbook -
[NOTE: This Handbook will be made available in a reading room during the solicitation phase.]
DAIDS Serious Adverse Experience (SAE) Reporting Manuals [Http://roc.s-3.com](http://roc.s-3.com)
DAIDS Protocol Registration Policy and Procedure Manual [Http://roc.s-3.com](http://roc.s-3.com)

EXHIBIT J.4 PERSONNEL QUALIFICATIONS

J.4.1 Key Personnel

J.4.1.1 Project Manager (**Key**)

The Project Manager shall possess a Ph.D., or equivalent, with a minimum of five (5) years in managing a clinical research organization, or in clinical trial management, that involved substantial interaction with the FDA.

J.4.1.2 Health Manager (**Key**)

The Health Manager shall possess a M.S. or equivalent with a minimum of three (3) years of experience in clinical trials management.

At least one of the key personnel shall possess significant international experience related to clinical trials management. In addition, one or all of the Health Coordinator, Health Specialist and Health Analyst positions shall have international experience related to clinical trials.

J.4.2 Other Personnel (Non-Key)

J.4.2.1 **Senior IT/Network Specialist**

J.4.2.2 **Senior Programmer Analyst**

J.4.2.3 **Senior Systems Analyst**

J.4.2.4 Technical Assistant

The Technical Assistant shall possess a B.S. or B.A.

J.4.2.5 Health Coordinator

The Health Coordinator shall, at a minimum, have a B.S. degree and be a Registered Nurse (R.N.)

J.4.2.6 Health Specialist

The Health Specialist shall, at a minimum, have a B.S. degree and be a Registered Nurse (R.N.)

J.4.2.7 Health Analyst

The Health Analyst shall, at a minimum, have a B.S. degree and be a Registered Nurse (R.N.)

J.4.2.8 IT/Network Specialist

J.4.2.9 Programmer Analyst

J.4.2.10 Systems Analyst

J.4.2.11 Paralegal

[End Exhibit J.4]

EXHIBIT J.5 PERFORMANCE REQUIREMENTS SUMMARY ("PRS")

The Performance Standards identified below apply to the referenced Performance Requirements in SECTION C. The Contractor's performance of the referenced requirements will be evaluated semi-annually (every six months) in accordance with the Quality Assurance Surveillance Plan (QASP) in Exhibit J.6. The results of this contractor evaluation will then be used to compute award fee increments in accordance with Exhibit J.6.

PERFORMANCE REQUIREMENT	PERFORMANCE STANDARD
<u>TASK AREA A</u> - General Contract Requirements	
C.2.1.2 Prepare and deliver 12 categories of data reports	(1) Demonstrates high quality writing skills (clear and concise prose, proper use of English syntax and grammar); (2) Submitted in timely manner; (3) Accurate and thorough treatment of subject matter
<u>TASK AREA B</u> - IND Application Processes	
C2.2.1.4. Prepare and maintain IND data for submission to the FDA after approval by the FDA Liaison	(1) Complies with procedural and substantive requirements of 21 CFR 312; (2) Does not result in IND holds by FDA resulting from contractor-caused deficiencies or omissions; (3) Could or does successfully pass FDA IND audit; and (4) Demonstrates high quality writing skills (clear and concise prose, proper use of English syntax and grammar)
C.2.2.1.5 Prepare and submit to FDA required protocol registration documents	(1) Complies with procedural and substantive requirements of 21 CFR 312; (2) Does not result in IND holds by FDA resulting from contractor-caused deficiencies or omissions; (3) Could or does successfully pass FDA IND audit; and (4) Demonstrates high quality writing skills (clear and concise prose, proper use of English syntax and grammar)
C.2.2.1.6 Maintain files of all IND correspondence and submissions to FDA	(1) Complies with procedural and substantive requirements of 21 CFR 312; (2) Does not result in IND holds by FDA resulting from contractor-caused deficiencies or omissions; (3) Could or does successfully pass FDA IND audit; and (4) Demonstrates high quality writing skills (clear and concise prose, proper use of English syntax and grammar)
C.2.2.2 Assist in preparation of FDA-required IND sponsor's interim and annual reports	(1) Complies with procedural and substantive requirements of 21 CFR 312; (2) Does not result in IND holds by FDA resulting from contractor-caused deficiencies or omissions; (3) Could or does successfully pass FDA IND audit; and (4) Demonstrates high quality writing skills (clear and concise prose, proper use of English syntax and grammar)
C.2.2.2.4 Duplicate, submit to the FDA, and distribute the annual report	(1) Complies with procedural and substantive requirements of 21 CFR 312; (2) Does not result in IND holds by FDA resulting from contractor-caused deficiencies or omissions; (3) Could or does successfully pass FDA IND audit; and (4) Demonstrates high quality writing skills (clear and concise prose, proper use of English syntax and grammar)

PERFORMANCE REQUIREMENT	PERFORMANCE STANDARD
<u>TASK AREA C - Informed Consent Development and Review Process</u>	
C.2.3.1 Maintain and provide to DAIDS Network /Group Operations Offices pertinent DAIDS Informed Consent Templates; make templates available to other investigator(s)/groups at the direction of RAB/DAIDS	(1) Complies with procedural and substantive requirements of 21 CFR 50, 21 CFR 56, and 45 CFR 46; (2) Distribution is current and according to RAB/DAIDS SOPs and direction
C.2.3.2 Perform regulatory review of Protocol Sample Informed Consents	(1) Complies with procedural and substantive requirements of 21 CFR 50, 21 CFR 56, and 45 CFR 46; (2) Demonstrates high quality writing skills (clear and concise prose, proper use of English syntax and grammar); (3) Meets RAB-designated time-frames and complies with pertinent RAB SOPs
C.2.3.3. Perform regulatory review of all Informed Consents	(1) Complies with procedural and substantive requirements of 21 CFR 50 and 45 CFR 46; (2) Demonstrates high quality writing skills (clear and concise prose, proper use of English syntax and grammar) and translation ability per RAB/DAIDS SOP
C.2.3.4. Prepare Spanish, French, and Thai translations of the Sample Informed Consent Forms	(1) Complies with procedural and substantive requirements of 21 CFR 50 and 45 CFR 46; (2) Demonstrates high quality writing skills (clear and concise prose, proper use of English syntax and grammar) and translation ability per RAB/DAIDS SOP
<u>TASK AREA D - Protocol Registration</u>	
C.2.4.1 Establish and maintain computerized clinical protocol registration system for DAIDS-sponsored trials	(1) Complies with procedural and substantive requirements of 21 CFR 50, 21 CFR 56, and 45 CFR 46; (2) Complies with DAIDS Protocol Registration Policy and Procedure Manual; (2) No lost paperwork; (3) No improper classification of information; (4) Response to site is timely; (5) Prompt notification to RAB of problems
C.2.4.1.1 File and track registration documentation submitted by the clinical site	(1) Complies with procedural and substantive requirements of 21 CFR 50, 21 CFR 56, and 45 CFR 46; (2) Complies with DAIDS Protocol Registration Policy and Procedure Manual; (2) No lost paperwork; (3) No improper classification of information; (4) Response to site is timely; (5) Prompt notification to RAB of problems

PERFORMANCE REQUIREMENT	PERFORMANCE STANDARD
<u>TASK AREA E - SAE Reporting System</u>	
C.2.5.1 Evaluate adverse experience forms/reports received from sites, and perform other tasks specified by RAB in analysis of information	(1) Complies with procedural and substantive requirements 21 CFR 312; (2) Complies with DAIDS SAE Reporting Manuals and RAB SOPs for IND and non-IND trials
C.2.5.2 Establish and maintain computerized tracking system for the SAEs	(1) Complies with procedural and substantive requirements 21 CFR 312; (2) Complies with DAIDS SAE Reporting Manuals; (3) Demonstrates ability to analyze and abstract complex medical information in timely and accurate manner
C.2.5.3 Establish and maintain the toll-free "800" telephone and fax line for SAEs	(1) Complies with procedural and substantive requirements 21 CFR 312; (2) Complies with DAIDS SAE Reporting Manuals; (3) Ensures that clinical sites adhere to requirements in DAIDS SAE Reporting Manuals
C.2.5.10 Prepare interim and final FDA Safety Reports	1) Reports are complete, timely and accurate; (2) Reports comply with DAIDS SAE Reporting Manuals and RAB SOPs; (3) Information about safety alerts/reports is communicated to the clinical sites in a timely and understandable manner; (4) Timely submission to FDA per 21 CFR 312
<u>TASK AREA F - DAIDS Review Committees</u>	
C.2.6.1.1 Receive and track materials from the CSRC and the PSRC <hr/> C.2.6.1.4 Distribute Summary Review Letter with CSRC & PSRC Comments	(1) Accurate tracking of materials; (2) Accurate review of proceedings of meetings <hr/> Letters are distributed within seven (7) days after the meetings
<u>TASK AREA G – CTAs & LOUs</u>	
C.2.7.1 Maintain DAIDS standard CTAs	Ensure the most current DAIDS CTA templates are being used.
C.2.7.3 Maintain DAIDS standard LOUs	(1) Ensure the most current DAIDS LOU templates are being used; (2) Ensure accurate transcription of comments by DAIDS and collaborating drug companies during the LOU negotiation process; (3) Ensure negotiated LOUs from sites are consistent with DAIDS LOU templates

PERFORMANCE REQUIREMENT	PERFORMANCE STANDARD
<u>TASK AREA H</u> – Computerized Management Information System (MIS)	
C.2.8.1 Maintain the electronic data management information system (MIS) used to track regulatory information and protocols	(1) 100% system back-up/redundancy; (2) Adequate and trained personnel to maintain system; (3) Capability to respond on 24-hours per day, 7-days per week, basis to questions, concerns, or problems raised by DAIDS personnel
C.2.8.6 Maintain a regulatory worldwide web site providing a reliable and efficient electronic link between the ARCC, the DAIDS, and the various clinical trial group sites	(1) Is well-designed; (2) Is easy to use and understand; (3) Has dynamic links to DAIDS major clinical trials networks; (4) Contains library of current DAIDS regulatory reference materials drawn from RCC SOP Handbook
<u>TASK AREA I</u> – Maintain the RCC SOP Handbook	
C.2.9.2 Prepare and deliver revised RCC SOP Handbook	(1) Complies with all current statutory, regulatory, and administrative requirements applicable to RCC functional performance areas described in Section C
<u>TASK AREA J</u> - Contract Financial Management	
Section I -- Comply with Limitation of Funds, Limitation of Costs and Allowable Cost and Payment Clauses Incorporated by Reference	(1) Contractor demonstrates the ability to control, manage, and report costs consistent with the requirements of FAR 52.232-20 Limitation of Cost (April 1984), FAR 52.232-22 Limitation of Funds (April 1984), and FAR 52.216-7 Allowable Cost and Payment (Mar 2000)

EXHIBIT J.6 QUALITY ASSURANCE SURVEILLANCE PLAN ("QASP")

J.6.1 Purpose of the QASP

The QASP is intended to accomplish the following:

- Define the roles and responsibilities of participating Government officials;
- Describe the process of quality assurance assessment; and
- Describe the process of computation of the award fee.

J.6.2 Quality Assurance Assessment

The Government will convene an Award Fee Panel (AFP) semiannually, within 21 days following completion of each six (6) full months of contract performance. The AFP shall consist of the Project Officer, designated in G.1 of the contract, who will serve as Chairperson, plus up to two DAIDS staff and/or outside experts in the subject matter of the contract.

The AFP will meet and assess the Contractor's performance over the preceding six-month period using the rating elements listed in the "Performance Requirement" column of Exhibit J.5, and the Performance Standards associated with the rating elements (right side column of Exhibit J.5). The Contractor's performance in each rating area will be evaluated adjectivally as Unsatisfactory, Satisfactory, or Outstanding, using the following definitions of Contractor performance:

Unsatisfactory: Level of performance that in the aggregate fails to meet the Performance Standard; Deficiencies are pervasive

Satisfactory: Level of performance that in the aggregate meets the Performance Standard; Deficiencies are minor and offset by outstanding elements of performance within the Standard

Outstanding: Level of performance that exceeds the minimum Performance Standard by a substantial margin; Deficiencies are nonexistent or extremely minor.

The AFP will meet and assess the Contractor's performance collectively. A consensus rating of the Contractor's performance in each rating area will be determined. The Contracting Officer and the Project Director will contact the Contractor to discuss an "Unsatisfactory" rating in any of performance rating areas prior to making a final determination on that element of contract performance.

This discussion may or may not result in a change in score by the AFP. The Contractor may respond in writing to each "Unsatisfactory" rating within 5 working days after the discussion, and the AFP will consider such responses before making a final rating determination. The Contractor may be invited to make a personal appearance before the AFP as part of this process.

The AFP will substantiate all individual adjectival rating scores, which they judge to be indicative of "unsatisfactory" or "outstanding" performance. Performance at the "satisfactory" level is expected from the Contractor and may not be documented in detail.

There are **24** measurable Performance Requirements ("PRs") in Exhibit J.4. They shall be grouped in **Task Areas** (which are consistent with the work breakdown structure in Section C.2) for fee allocation purposes as follows:

- Task Area A** (C.2.1) Includes C.2.1.2 [1 PR Total]
- Task Area B** (C.2.2) Includes C.2.2.1.4, C.2.2.1.5, C.2.2.1.6, C.2.2.2 and C.2.2.2.4 [5 PRs Total]
- Task Area C** (C.2.3) Includes C.2.3.1, C.2.3.2, C.2.3.3 and C.2.3.4 [4 PRs Total]
- Task Area D** (C.2.4) Includes C.2.4.1 and C.2.4.1.1 [2 PRs Total]
- Task Area E** (C.2.5) Includes C.2.5.1, C.2.5.2, C.2.5.3 and C.2.5.10 [4 PRs Total]
- Task Area F** (C.2.6) Includes C.2.6.1.1 and C.2.6.1.4 [2 PRs Total]
- Task Area G** (C.2.7) Includes C.2.7.1 and C.2.7.3 [2 PRs Total]
- Task Area H** (C.2.8) Includes C.2.8.1 and C.2.8.6 [2 PRs Total]
- Task Area I** (C.2.9) Includes C.2.9.2 [1 PR Total]
- Task Area J** (I.1) Includes I.2 and I.3. [1 PR Total]

In addition to an adjectival rating for each Performance Requirement, the AFP will give the Contractor an overall adjectival rating for each Task Area based on an average of the individual PR scores comprising that Task Area. The AFP will annotate such ratings with a written narrative that supports the rating.

J.6.3 Computation of the Award Fee for Each Six Month Period of Performance

SECTION B of the contract contains the following negotiated pricing elements for this contract based on a seven-year period of performance: Estimated Cost; Base Fee; Award Fee; Estimated Cost-Plus-Base-Fee-Plus-Award-Fee.

The Base Fee shall be paid in accordance with provisions in SECTION B, and is not subject to the performance incentives described in Exhibits J.5 and J.6.

The Award Fee amount in SECTION B will be divided into 14 equal monetary increments. Each increment represents the Maximum Award Fee available for each six-month period of evaluated performance. There is no carry-over of unearned award fee from one evaluation period to another.

The Contractor's adjectival rating in each Task Area as determined in SECTION J.6.2, above, will be converted by the AFP into a raw numerical rating, using the following ranges:

Unsatisfactory = 0 - 39

Satisfactory = 40 - 80

Outstanding = 81 - 100

These ranges are deliberately intended to be broad to allow the AFP substantial leeway in applying its collective subjective judgment regarding the degree to which the Contractor has achieved the desired performance standards prescribed in Exhibit J.5 (the Performance Requirements Summary) for that Task Area. However, the AFP must assign an overall numerical rating that is consistent with the written narrative that supports that rating.

The numerical rating for each Task Area will then be converted by the AFP to percentages of Maximum Award Fee using the following fee allocations (% reflects the weight of importance of key output tasks of the contract):

- Task Area B:** Numerical Rating x **.21** = ____ % of Maximum Award Fee (**IND Application Process**)
 - Task Area C:** Numerical Rating x **.15** = ____ % of Maximum Award Fee (**Informed Consent Development**)
 - Task Area D:** Numerical Rating x **.12** = ____ % of Maximum Award Fee (**Protocols**)
 - Task Area E:** Numerical Rating x **.20** = ____ % of Maximum Award Fee (**SAE Reporting**)
 - Task Area H:** Numerical Rating x **.08** = ____ % of Maximum Award Fee (**Computerized MIS**)
 - Task Area A:** Numerical Rating x **.08** = ____ % of Maximum Award Fee (**General Contract Requirements**)
 - Task Area F:** Numerical Rating x **.05** = ____ % of Maximum Award Fee (**Review Committees**)
 - Task Area G:** Numerical Rating x **.05** = ____ % of Maximum Award Fee (**CTAs, LOUs & CRADAs**)
 - Task Area I:** Numerical Rating x **.03** = ____ % of Maximum Award Fee (**Maintain RCC SOPs**)
 - Task Area J:** Numerical Rating x **.03** = ____ % of Maximum Award Fee (**Contract Financial Management**)
- Grand Total = ____% of Maximum Award Fee [**100% = Maximum Award Fee**]

The AFP will prepare a written Report containing all of the ratings, comments, and tabulations for the applicable period no later than 30 calendar days following the completion of each six-month period of performance being evaluated. The Contracting Officer will furnish the Contractor with a copy of this Report.

The Report will be delivered to the Contracting Officer as a recommendation for approval and final action. The Contracting Officer will make the final determination on all matters relating to the award fee. The award fee amount and the award fee determination methodology are unilateral determinations of the Contracting Officer made solely at the discretion of the Government.

The Contracting Officer will unilaterally modify Section B of the contract to obligate funds sufficient to pay the amount of award fee, if any, awarded to the Contractor for the applicable evaluation period. This modification will be issued no later than 30 calendar days following receipt of the Report for each six-month performance evaluation period. The Contractor may thereafter invoice the Government for that amount.

J.6.4 Award Fee Changes

The Government's plans for administering the award fee provisions of this contract are contained in Exhibits J.5 and J.6. The Contracting Officer may unilaterally modify this plan and these Exhibits prospectively, in whole or part, by unilateral modification issued no later than 15 days prior to the commencement of the next evaluation period. The one exception would be changes to the six-month evaluation periods, which may be made by mutual consent of the parties only.

[End Exhibit J.6 and SECTION J]

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-03-26
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:

If Hand Delivery or Express Service	If using U.S. Postal Service
Nancy M. Hershey Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Nancy M. Hershey Contract Specialist 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 150 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. IT IS RECOMMENDED THAT YOU LIMIT CVs TO NO MORE THAN 2-3 PAGES EACH.

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”:

Approximately TWO weeks prior to the due date of the proposals, all offerors who submitted a “Proposal Intent Response Sheet” will be provided 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 after 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 via telephone by the Contract Specialist after Log-in Name is provided.
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-03-26
RFP Title: Regulatory Compliance Center

Please review the attached Request for Proposal. Furnish the information requested below and return this page by July 1, 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: Nancy M. Hershey
RFP-NIH-NIAID-DAIDS-03-26
FAX# (301) 480-5253 or (301) 402-0972
Email : nh11x@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.nci.nih.gov/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. NOTICE OF SMALL BUSINESS SET-ASIDE

- (a) **General.** Bids or proposals under this procurement are solicited only from small business concerns. The procurement is to be awarded only to one or more such concerns, organizations, or individuals. This action is based on a determination by the Contracting Officer, alone or in conjunction with a representative of the Small Business Administration, that it is in the interest of maintaining or mobilizing the Nation's full productive capacity, or in the interest of war or national defense programs, or in the interest of assuring that a fair proportion of Government procurement is placed with small business concerns. Bids or proposals received from others will be considered non-responsive.
- (b) **Definitions.** The term "small business concern" means a concern, including its affiliates, which is independently owned and operated, is not dominant in the field of operation in which it is bidding on Government contracts, and can further qualify under the criteria set forth in the regulations of the Small Business Administration (13 CFR 121.3-8). In addition to meeting these criteria, a manufacturer or a regular dealer submitting bids or proposals in his own name must agree to furnish in the performance of the contract end items manufactured or produced in the United States, its territories and possessions, Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia, by small business concerns. Provided, that this additional requirement does not apply in connection with construction or service contracts.

c. 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.

d. 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 March 31, 2003.

It is anticipated that the award from this solicitation will be a multiple-year, cost-reimbursement, completion type performance based contract with a period of performance of seven (7) years [includes a 3-year base period and two 2-year options] and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. 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 estimated effort to be approximately 55,500 labor hours per year (~27 FTEs) -- (REFER ALSO TO [EXHIBIT J.4](#), page 46, OF SAMPLE CONTRACT). This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. 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.

g. 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.

h. 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.

i. COMPARATIVE IMPORTANCE OF PROPOSALS

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

j. REFERENCE MATERIALS

A "reading room" providing the Standard Operating Procedure (SOP) manuals currently used under this contract and pertinent to this acquisition is available in Room 2230, 6700-B Rockledge Drive, Rockville, Maryland, from April 1, 2002, Monday through Friday (except Government holidays) through July 1, 2002. Appointments can be scheduled between the hours of 9:00 AM through 2:00 PM. Use of the reading room is by appointment only. Contact Nancy M. Hershey, (301) 496-0193 for arrangements. Failure of offerors to examine the reference materials prior to proposal preparation and submission will be at the offeror's risk.

k. PREPARATION COSTS

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

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

(18)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

(18)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)

m. 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)

o. 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/level of effort)/fixed price] 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) 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>.

(10) Privacy Act (Treatment of Proposal Information)

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

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

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

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

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

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

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

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

(11) Selection of Offerors

- a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-
 - (1) Communications will be held with offerors whose past performance information is the determining factor preventing them from being placed within the competitive range. Such communications shall address adverse past performance information to which an offeror has not had a prior opportunity to respond. Also, communications may be held with any other offerors whose exclusion from, or inclusion in, the competitive range is uncertain.

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

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

While it is 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.

(12) HUBZone Small Business Concerns

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

(13) 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.

(14) Salary Rate Limitation in Fiscal Year 2003 **

Offerors are advised that pursuant to current P.L. 107-116, for Fiscal Year 2002, no Fiscal Year 2002 (October 1, 2001 - September 30, 2002) 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. 107-116 applies only to Fiscal Year 2002 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. 107-116 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."

Information regarding the FY-2002 rate can be found at: <http://www.opm.gov/oca/02tables/ex.pdf>

IT SHOULD BE NOTED THAT SHOULD A SIMILAR PUBLIC LAW BE ENACTED IN FISCAL YEAR 2003, THAT PUBLIC LAW WILL BE INCORPORATED INTO ANY RESULTANT CONTRACT.

(15) 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.

(16) ROTC Access and Federal Military Recruiting on Campus

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

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

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

Include the following information for each contract or subcontract:

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

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as any subcontract exceeding \$500,000.

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

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

(18) 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> .

(19) 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) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

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

(4) Resumes

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

(2) Technical Evaluation

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

(4) 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.

(5) 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.

(6) 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>

(7) Proposer's Annual Financial Report

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

(8) 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.

(9) 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/price and past performance. Although technical factors are of paramount consideration in the award of the contract, cost/price and past performance 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.

Offerors must submit a technical proposal that includes both the basic and option portions of the Work Statement, with each part clearly marked. The following discussion of technical evaluation factors pertains to the entire Statement of Work, including the basic and option portions.

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 carefully evaluated. 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. MANDATORY QUALIFICATION CRITERIA

THE OFFEROR SHALL INCLUDE ALL INFORMATION THAT DOCUMENTS AND/OR SUPPORTS THE MANDATORY QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS PROPOSAL.

THE FOLLOWING MANDATORY QUALIFICATION CRITERIA ESTABLISH CONDITIONS THAT MUST ALL BE MET AT THE TIME OF RECEIPT OF FINAL PROPOSAL REVISIONS (FPRs) IN ORDER TO BE CONSIDERED FOR THE AWARD.

- 1) Proximity to DAIDS (within a 75-100 mile radius of the RAB/DAIDS office located at 6700B Rockledge Drive, Bethesda, Maryland 20817)**

3. EVALUATION OF OPTIONS

It is anticipated that any contract awarded from this solicitation will contain option provisions and periods.

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 171.206(b) not to be in the Government's best interest. Evaluation of the options will not obligate the Government to exercise the options.

4. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. **Proposals will be judged solely on the written material provided by the Offeror and only material within the prescribed page limits will be considered.** 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 THE “NOTES TO OFFERORS” [see page 7] FOR GUIDANCE AND INFORMATION RELATED TO THE PREPARATION AND EVALUATION OF PROPOSALS.

The demonstrated evidence of capability should include current and/or past related work experience, activities for related requirements, and the qualifications, availability, and experience of the professional and technical personnel necessary to perform contract requirements. Proposals will be based on the following factors:

	CRITERIA	SUB-WEIGHT	WEIGHT
A.	TECHNICAL APPROACH The technical approach should be evaluated based on the Offeror’s ability, experience, and proposed approach to perform the work statement in its entirety, including the following:		40
A.1.	Soundness and Practicality of Technical Approach for Providing Support of Regulatory Affairs 1) Support the Investigational New Drug (IND) Application Process 2) Support the Informed Consent Development and Review Process 3) Establish and Maintain the Clinical Protocol Registration System 4) Establish and Maintain the Serious Adverse Experience (SAE) Reporting System Accessing and determining relevancy of scientific information and computerized information systems.	25	
A.2.	Soundness and Practicality of Administrative/Management Framework within which the contract will operate. Suitability of the management and organization plan to accomplish tasks in a timely manner and to maintain quality control over the duration of the contract.	15	
B.	PERSONNEL QUALIFICATIONS The offeror should document relevant training, qualifications, expertise, experience, education, competence, and availability to perform the requirements of the work statement. The Offeror should provide evidence of the quality of the professional team proposed to undertake the work solicited in the work statement. That evidence of ability should include the demonstration of previous experience doing similar complex projects, as evidenced in documentation of relevant assignments, and, when appropriate, publications.		40
B.1.	Senior Management/Technical Staff Documented availability, experience in regulatory affairs, processing and evaluating adverse experiences in regulatory affairs, processing and evaluating adverse experiences related to the use of clinical research products, experience in participating in large-scale multi-center clinical trials programs and experience in preparing plans and reports, monitoring progress, and maintaining budget control for an activity of similar scope and complexity.	20	

	<ul style="list-style-type: none"> a. The Project Manager shall possess a Ph.D., or equivalent, with a minimum of five (5) years in managing a clinical research organization, or in clinical trial management, that involved substantial interaction with the FDA. b. The Health Manager shall possess a M.S. or equivalent. c. Senior IT/Network Specialist d. Senior Programmer Analyst e. Senior Programs Analyst 		
B.2.	<p>Other Personnel/Staff Plan Must have demonstrated qualifications, competence and experience necessary to accomplish tasks as required by the Work Statement. To include the following essential individuals plus necessary support staff:</p> <ul style="list-style-type: none"> a. The Technical Assistant shall possess a B.S. or B.A. b. The Health Coordinator shall possess at a minimum a B.S. and be a Registered Nurse (R.N.). c. The Health Analyst shall at a minimum be a B.S. Registered Nurse (R.N.). d. IT/Network Specialist e. Programmer Analyst f. Systems Analyst g. Paralegal 	20	
C.	CORPORATE EXPERIENCE, FACILITIES AND RESOURCES		20
C.1.	<p>Experience in Serving as an Operational and Regulatory Center Documented successful experience of the Offeror in serving as an operational and regulatory center for similar complex multi-center, multi-protocol clinical research efforts. This shall include, but not be limited to, letters and/or evaluation reports from multi-national or other similar projects.</p>	10	
C.2.	<p>Availability of Adequate Physical Facilities, Etc. Documented availability of adequate physical facilities, ADP equipment, and other resources i.e., staffing, necessary to ensure data integrity, to meet requirements of the project, and future enhancements, including security for both electronic and paper files.</p>	10	
TOTAL WEIGHT:			100

5. PAST PERFORMANCE FACTOR

NOTE: This criteria will not be evaluated by the peer review panel. It will be evaluated following the completion of the initial technical evaluation and be conducted by the Project Officer and Contracting Officer prior to determination of competitive range.

The Government will evaluate the offeror's past performance 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 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 that will not be used to the advantage or the disadvantage of the offeror.

The past performance sub-factors are listed below in order of relative importance. These subfactors will be used to subjectively evaluate the quality of past performance. No weights are assigned.

Past Performance Sub-factors

Record of conforming to specifications and to standards of good workmanship

Record of forecasting and controlling costs under cost-reimbursement contracts

Adherence to contract schedules, including the administrative aspects of performance

Reputation for reasonable and cooperative behavior and commitment to customer satisfaction

Business-like concern for the interest of the Customer