OMB No. 0990-0115

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.

<table>
<tr><td colspan="4">Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.</td></tr>
<tr><td>RFP Number:

NIH-NIAID-DAIT-02-16</td><td>Just In Time:

[ ] Yes
[X] No</td><td>Small Bus. Set-Aside [ ]Yes [X]No
8(a) Set-Aside [ ]Yes [X]No
NAICS Code: 54171
Size Standard: 500 employees</td><td>Level of Effort:
[ ] Yes [X] No
Total Effort:
[N/A]</td></tr>
<tr><td colspan="4">TITLE: Bioinformatics Integration Support Contract (BISC)</td></tr>
<tr><td colspan="2">Issue Date: November 20, 2001</td><td colspan="2">Due Date: February 15, 2001
Time: 3:00 PM, EST</td><td>Technical Proposal Page Limits:
[X] Yes (see “How to Prepare and Submit Electronic Proposals”)
[ ] No</td></tr>
<tr><td colspan="2" rowspan="2">ISSUED BY:
Barbara Shadrick, Sr. Contracting Officer
Contract Management Branch, DEA
NIH, NIAID
6700-B Rockledge Drive
Room 2230, MSC 7612
Bethesda, MD 20892-7612</td><td colspan="3">[X] We reserve the right to make awards without discussion.</td></tr>
<tr><td>NO. OF AWARDS:

Phase I: Multiple Awards
Phase II: One (1) Award</td><td colspan="2">PERIOD OF PERFORMANCE:

Phase I: 18 mos. beginning September 30, 2002
Phase II: 6 yrs. Beginning March 31, 2004</td></tr>
<tr><td colspan="4">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)</td></tr>
<tr><td colspan="4">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.</td></tr>
<tr><td colspan="4">POINT OF CONTACT -- Cynthia Cotter --COLLECT CALLS WILL NOT BE ACCEPTED--

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Updated thru FAC 2001-01 (10/22/01)

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INTRODUCTION/BACKGROUND

Bioinformatics Integration Support Contract (BISC)
DAIT-02-16

INTRODUCTION

To address the present and future needs of the Government, the Division of Allergy, Immunology and Transplantation (DAIT), National Institute of Allergy and Infectious Diseases (NIAID), National Institutes of Health (NIH), is seeking a contractor to establish and manage a Bioinformatics Integration Support Contract (BISC). This system will provide scientific data handling support and technical assistance to programs that (a) conduct basic scientific research into the genetic correlates of immune disease; (b) design and conduct clinical trials to evaluate the safety, toxicity, and efficacy of immune diseases; and (c) design and conduct studies of the underlying mechanisms of therapeutic agents that are investigated in DAIT clinical trials.

The purpose of this project is to provide advanced information technology support in the production, analysis, archiving, and exchange of scientific data for a diverse community of life science researchers by: (1) conducting a requirements assessment of bioinformatics needs in a diverse community of basic and clinical researchers, (2) prototyping a system for the collection, storage, and query of data; (3) designing, implementing and maintaining a data warehouse of genomic, proteomic and all other related data relevant to the research of these programs; (4) developing or selecting specialized applications and providing technical assistance to participating centers in the capture, storage, management, query, and analysis of these data, and, (5) measuring performance and benefits resulting from these technical support activities and planning for their appropriate development and use in the future.

THIS PROJECT WILL OCCUR IN TWO PHASES.

PHASE I will include the completion of a systems analysis and requirements assessment and will result in a working prototype of a system for distributed scientific data management.
PHASE II will involve the full-scale implementation and operation of the bioinformatics integration support system conceived and approved under the PHASE I contract.

This RFP contains a separate Work Statement, Deliverables, and Evaluation Criteria for both PHASE I and PHASE II so that offerors understand the entire requirement.

PHASE I: Only proposals in response to PHASE I are required at this time.

PHASE I -- BUSINESS PROPOSAL – UNIFORM TOTAL COST OF PROPOSAL: ALL OFFERORS ARE REQUIRED TO LIMIT THE TOTAL COST OF THEIR BUSINESS PROPOSAL FOR PHASE I TO AN AMOUNT OF $1,415,000.

- **May result in up to 3 awards.**
- **18-month period of performance.**
- **Each contractor will deliver a requirements assessment, working prototype, system implementation plan, PHASE II technical and business plan.**
- **Each contractor will provide an oral presentation for the purpose of evaluating the success of PHASE I and determining if an award will be made for PHASE II.**
- **This information will be evaluated by the NIH Special Emphasis Panel (SEP) to select the offeror to move forward to PHASE II.**
- **PHASE I proposals will be evaluated using the PHASE I Evaluation Criteria contained in this RFP.**

PHASE II: Proposals will be prepared and submitted in accordance with the requirements for PHASE I deliverables.

- **It is anticipated that only one (1) PHASE II contract will be awarded for a period of six (6) years but the Government reserves the right to make multiple awards if funds are available.**
- **Will consist of a base period of two (2) years and an Option period of four (4) years to ensure that the project is fully implemented and demonstrating measurable results.**
- **PHASE II proposals will be evaluated using the PHASE II Evaluation Criteria contained in the RFP.**

As a mission-critical initiative, this project will be closely monitored for its entire duration. The initial 42 months will be critical to design and implementation. It is expected that the project should be fully implemented and demonstrate measurable results within this time period. The NIAID has made a long-term commitment to the work and services described in this RFP, however, various unforeseen changes could necessitate a change in direction for this project. The NIAID reserves the right to continue or discontinue this project based on the NIAID's own assessment of what best serves the interests of its research community. In formulating continuation decisions, the NIAID will evaluate the performance of the Contractor based on negotiated milestones incorporated into the contract. In addition, the NIAID will look for measurable indicators of success in serving the research needs of the research community. The Phase II option will be initiated only when and if: (1) funds are available, (2) the Government determines that negotiated milestones have been met; and (3) the Government exercises the option.

This is a scientific and operational support contract that requires a unique blend of expertise in biology, chemistry, and medicine, as well as the computational requirements of life sciences research. Additionally, in order to qualify to conduct the work specified here, successful offerors must be active participants in the community of researchers working on immune-mediated diseases with advanced genomic and proteomic technologies. While offerors need not have an already established relationship with any of the DAIT programs, they will be evaluated on their ability to gain access to all relevant datasets and develop a working prototype of a system on large multi-dimensional datasets that challenge the limits of the computer system to be developed here. Given the breadth and specialization required by the Work Statements, and in order to assemble the strongest proposal possible, the Contractor is encouraged to establish collaborations (when appropriate) with other organizations as necessary, in order to fulfill the work statement requirements in an expeditious and cost-effective manner.

Subcontracts: It is expected that the complete requirements of this contract may be addressed by a consortium of collaborating firms and institutions, given the high service-level expectations and multidisciplinary nature of the needed scientific support. In this case, it is anticipated that the entity primarily responsible for performance of the stated work will be the prime Contractor and other members of the consortium will function as subcontractors or consultants. While not required to do so, the primary contractor may choose to team with one or more specialized organization in order to acquire special knowledge or practices that strengthens their competitiveness for this contract. Due to the availability of highly experienced Small Business and Small Disadvantaged Business organizations, emphasis should be placed on collaborations with these types of organizations. This consortium should demonstrate a track record of working cooperatively together on complex systems integration assignments. In addition, the proposed technology must be relevant to the fulfillment of this contract requirement. The following websites are provided for offerors to assist in forming collaborations:

- SBA's Pro-Net -- http://pro-net.sba.gov/index7.html
- SBA's Sub-Net --http://web.sba.gov/subnet/
- NIH Small Business Office's ePortals In Commerce (ePIC) Bulletin Board -- http://epic.od.nih.gov/

BACKGROUND

As biomedical research moves into the post-genomic era, advanced technologies are profoundly altering the study of immunology and infectious diseases. These advances offer new approaches to understanding immune activation and regulation; uncovering the genetic bases of disease susceptibility; and the development of new diagnostic, treatment, and intervention strategies. Yet, in order to take full advantage of technological advances, researchers must be able to extract meaningful information from the vast amounts of data that these technologies now generate.

Computers and networked systems of computers are critical to this task. Because they process large volumes of data quickly, computer software and systems can greatly accelerate selected parts of the discovery process. They can increase the accessibility and comparability of certain types of data and relieve bench scientists of mundane archival and analytical tasks. When fueled with reliable data and programmed with the proper algorithms, computers can enable scientists to identify relevant patterns far beyond what is possible through manual approaches. Simply by providing communities of researchers with access to comparable sequence, expression, and polymorphism data, for example, the analysis of diagnostics markers can be greatly accelerated.

Thus, computational support for scientific data management and analysis is an essential component of modern biomedical research. Increasingly this means assembling research data from numerous, diverse places and points in time. It means delivering those data to multidisciplinary teams of experts where they can be fashioned into knowledge. Only if these issues are addressed can we expect to bridge the gap from bench to bedside.

Together with genomics, proteomics, and various other advanced technologies, bioinformatics is enabling life science researchers to greatly deepen our understanding of the immune response. This work promises tremendous insights into the underlying mechanisms and clinical aspects of immune-mediated diseases. If the scientific community continues at the current or a greater rate of productivity, we will soon come to better understand such matters as: (a) genetic and protein pathways in inflammatory responses as determined by cytokines and chemokines; (b) mechanisms of antigen processing and presentation (e.g., proteases, transport molecules, molecules involved in peptide loading, lysosome/endosome function); (c) basic pathways in the maintenance or disruption of immune tolerance (e.g., T-cell activation factors involved in TCR and co-stimulatory molecule signaling pathways); as well as the role of effector T cells in generation of Th1/Th2 phenotypes, cytotoxic T cell function, function/activation of regulatory T cell subsets, and memory T cell generation. In the future even more than in the past, this work of discovery will depend upon advanced computer support for the collection, integration, storage, and analysis of data.

The need for data integration is broad-based and growing in the life sciences research community. David Roos (Science, February 16, 2001: 1260-1261) observed recently that scientists are awash in a sea of data where they "depend absolutely on accessing data from diverse sources, and being able to integrate, transform, reproduce these data in new formats." The constituent parts of the data integration requirement have been succinctly documented by Spengler (Science, August 17, 2000: 1221-1222) as the following needs: (a) to control the quality of scientific data inputs, (b) to overcome limitations in computer processing capacity for certain complex analytical tasks, (c) to develop quick easy ways to transfer vast amounts of data, and (d) to better automate the search, analysis and normalization of scientific data. Spengler also notes that issues of standards, intellectual property, and long-term sustainability of databases require the attention of scientists, managers, and policy makers.

Activity is underway on many fronts to address these issues. First, recognizing that sequencing efforts to date have provided a "genetics 'parts list" which is not yet sufficient to understand essential aspects of biological function, Brasma, et al (Nature, 17 February 2000: 403, 699-700) propose the expansion of publicly-supported repositories. They also call for the scientific community to jointly develop (a) essential minimum information sets for experimental records, i.e. microarray, (b) shared definitions of ontologies and structured vocabularies, and (c) new tools for searching and executing sophisticated queries of databases containing experimental documents. Second, having anticipated some of the emerging data integration requirements, some labs and clinics have piloted data integration projects. Yet, despite some impressive results on a small scale, there is no certainty that these solutions will be widely adopted or that they will scale to meet the needs of larger, more diverse research communities over greatly extended time periods. In depicting salient trends regarding data exchange standards, finally, Achard, Vaysseiz, and Barillot (Bioinformatics, v. 17, no. 2, 2001, p. 115-125) have noted the partial diffusion of emerging standards in the life science research community. In addition, important software standards are now becoming available to the life sciences research community for such applications as middleware, security, fault tolerance, and the specification of domain-specific data models, objects, metadata, and components. Now and even more so in the future, these standards will be fundamental to meeting the data storage and exchange requirements of the life sciences research community.

THE SYSTEM

The Division of Allergy, Immunology, and Transplantation (DAIT) of the NIAID requires a computer-based system for the management of scientific information in a widely distributed, heterogeneous community of researchers. The solicitation guidelines provided herein are motivated by recognition that certain kinds of scientific progress are only possible if we ensure the integrity, usability, survivability, and interoperability of life science data now being collected. This solicitation is further motivated by a recognition that recent technological advances in information technology offer unprecedented opportunities for data integration which can greatly benefit life science discovery. Such a system has the potential to deliver measurable benefits to end users in terms of enhancements to scientific discovery and productivity, improvements in safety and efficacy testing for new therapeutics, and value-creating deployment and management of tangible and intangible scientific assets.

User community. This project aims to facilitate the diffusion of practices, methods, and tools to serve the computational needs of the basic and clinical research communities working on immune-mediated diseases. Although it will be prototyped on a smaller scale in the first phase of this project, ultimately the system will serve the scientific data handling requirements of as many as 150 clinical and basic research scientists distributed across as many as 115 individual laboratories located in the continental United States.

Functionality. A partial list of specific types of computer-based services that are needed would include the following: (a) central data archiving – where databases are centralized, an actively curated repository is required to support both clinical and basic researchers; (b) custom graphical user interfaces and instrumentation interfaces that enable remote and networked submission of data under special constraints; (c) data exchange -- researchers need to share data easily and frequently on a peer-to-peer basis; (d) tools for data acquisition, normalization, and management; and (e) tools that reliably support the storage and retrieval of high-quality data. End users also require technical assistance so the envisioned system will include technical support services and newly developed applications that permit both hypothesis-driven and open-ended hypothesis-generating research. The system must provide for the creation and distribution of tailored data sets in order to advance hypothesis-driven research and clinical decision-making by generating integrated datasets that broaden the observational and temporal usefulness of these scientific data. These services must integrate computers into research so as to facilitate the adoption of high-throughput research methods in proteomics and genomics.

Level of integration versus innovation. Addressing these needs will require the contractor to apply the latest available information technology solutions for the collection, representation, storage, and retrieval of scientific information. While some applications are already available, some new application development will be required, especially in application scaling and data exchange. Satisfying the present need will require the contractor to introduce creative approaches in project management and workflow, perhaps adjusting best practice in other sectors to the needs of scientists. Finally, addressing these needs will require the introduction of emerging industry standards in bioinformatics, computational biology, and the software engineering of life sciences discovery.

Data Inputs. The data inputs to the system should include but not be limited to (a) elispot, (b) tetramer, (c) microarray, (d) flow cytometry analysis, and (e) various textual documents, comprising research notes and clinical records. Genomic data to be handled by the system will include: sequence data, expression data, single nucleotide polymorphism data, protein structure, and pathway data. Proteomic data will include molecular-level records on all biologically active substances – amino acid, peptide, and protein structure -- as generated by numerous experimental methods. This system will integrate data from both public and proprietary sites. Where feasible, it must handle and provide access to annotations and multiple versions of experimental record. In all situations, where access to certain data is restricted for reasons of intellectual property, human subjects, or privacy, the system must enable acquisition and viewing of data in a manner consistent with the institutional policies of participating institutions.

Data complexities. Special challenge arise with the integration of genomic and proteomic data. Genomic data to be handled by the system will include: sequence data, expression data, single nucleotide polymorphism data, protein structure, and pathway data. Proteomic data will include molecular-level records on all biologically active substances – amino acid, peptide, and protein structure -- as generated by numerous experimental methods. This system will integrate data from both public and proprietary sites. Where feasible, it must handle and provide access to annotations and multiple versions of experimental record. In all situations, where access to certain data is restricted for reasons of intellectual property, human subjects, or privacy, the Contractor must derive unique ways to enable the acquisition and viewing of data in a manner consistent with the institutional policies of participating institutions.

PHASE I - REQUIREMENTS ASSESSMENT

- STATEMENT OF WORK
- ADDITIONAL INFORMATION ON THE SCOPE AND REQUIREMENTS OF THE SOLICITATION
- DELIVERABLES, REPORTING REQUIREMENTS AND MILESTONES

PHASE I – Requirements Assessment
Statement of Work

The purpose of Phase I of this project is to determine the requirements and prototype a system for distributed scientific data management. This shall require completion of the following tasks: (a) conduct systems analysis and planning to evaluate and quantify the data requirements of participating research programs; (b) demonstrate the feasibility on a preliminary basis of solutions appropriate to the informatics needs of participating centers; and (c) plan for full implementation and operation of the envisioned support service. These initial steps are necessary in order to prepare for the full-scale implementation and operation of the envisioned bioinformatics support contract in Phase II of the project.

This phase of the project cannot be conducted without extensive experience and contemporary understanding of basic and clinical life sciences (especially immunology), as well as computer science, systems integration and engineering. In pursuing this work statement, the Contractor shall work to satisfy the specific scientific challenges that NAID is seeking to address, as well as to fill the service and capacity requirements that NIAID is seeking to fill. The Contractor must be fully informed about the complex and ever-evolving nature of research methods and instrumentation in biological research, as well as the complexities of basic and clinical biomedical research data.

The Contractor shall apply extensive biological knowledge to the integration of information from various instruments, including elispot, tetramer, microarray, flow cytometry, and mass spectroscopy. Each of these instruments plays a critical role in discovery. Each represents broad-based platforms for research that are themselves evolving with the discovery process. In order to anticipate the data handling requirements of the scientist end-users, the Contractor shall know the current state of the craft in the technology and methods of use, as well as the course of innovation in each technology platform .

STATEMENT OF WORK, PHASE I

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

TASK 1. Conduct a complete systems requirements assessment.

In performing this assessment, the Contractor shall conduct and report on an assessment of the bioinformatics requirements of those laboratories and research centers identified in the Contractor's proposal. They will include understanding the analytical requirements for using various types of scientific data from disparate sources to understand such matters as: (a) human leukocyte gene (HLA) complex, especially as related to matching transplant donors with recipients, (b) immune tolerance as related to the evaluation of new therapies in kidney transplantation, type I diabetes islet transplantation, autoimmune disease, asthma and allergy, (c) hematopoietic stem cell transplantation, and (d) both clinical trials and mechanistic studies of a variety of promising allergen-specific and non-specific immune-based therapies. The requirements to be determined shall pertain to a distributed, multidisciplinary community of basic and clinical researchers. The Contractor shall conduct a requirements specification that includes completion of and reporting on at least the following:

(a) at the initiation of the Phase I award, provide and submit for approval of the Project Officer, a Project Management Plan that defines the critical path for the Phase I statement of work, including: key objectives; technical approach; proposed time schedule of major activities; decision-making criteria; and specific project strategy. The Plan shall include well-described, quantifiable, and feasible criteria for completion of this Phase of the project, as well as a means of monitoring and reporting performance on all parts of the work statement;

(b) the determination and characterization of the novel conditions for work and information management in and between participating centers, based on a detailed understanding of domain-specific knowledge and workflow in the biological sciences, both basic and clinical;

(c) the determination and documentation of the predominant business rules and processes associated with research and treatment in this community and as reflected in (a) specific system roles, goals, bounds and functional limits, (b) various configurations of instruments, (c) legal and policy matters pertaining to biomedical research, and (d) critical human operator activities, such as data curation (or stewardship), documentation, maintenance and support;

(d) the depiction and characterization of basic data forms and common methods of data acquisition, management, and access, focusing particularly on those data forms and methods that determine representations of biological and chemical data in the genomics and proteomics of immunology;

(e) the determination of local conditions relevant to designing, testing, prototyping, and implementing software applications and information technology systems, such as (a) instrument type description, sensors or detection methods, calibration and measurement systems, (b) instrumented and manual methods of sample quantitation and data normalization, (c) instrument on-line identification protocols and configuration, as well as standard methods of data conversion and exchange; (d) instrument-based and manual methods of sample processing and reprocessing;

(f) the determination of local conditions that must be addressed in gaining acceptance of the system to be developed among end users;

(g) a projected utilization level, including such parameters as the (i) number of queries and other substantive transactions, (ii) level of analytical processing to be required of the system; and (iii) amount of data to be kept on-line and archived over a specific period of time;

(h) a set of working assumptions about legacy data, the validity of which is explained in terms of relevant case material or by the Contractor's direct experience in comparable contexts; and

(i) a determination of what functionality is most needed by individual participants, and for developing a build and implementation program that maintains end-user participation and avoids redundancy of tools and services.

TASK 2. Design an information technology system to meet requirements and implement a working prototype of that system.

Consistent with the aims of this project, the Contractor shall propose and prototype a system involving multiple instruments and collection points, where data of varied types are gathered and exchanged with reliable integrity and comparability. For all instruments used in participating laboratories – including, but not limited to elispot, tetramer, microarray, flow cytometry, and mass spectroscopy – the Contractor shall seek to enhance extant methods of sample generation, sample distribution, work scheduling, data verification, normalization, and correction, as well as the generation, storage, and retrieval of all experimental results and records. In designing a system to meet the data handling requirements of this community specifically with respect to genomics and proteomics, the Contractor shall devise means to develop and diffuse (a) common methods of data normalization and curation that can dramatically improve the utility, usability, portability, and survivability of electronic records, (b) expedite the determination of protein structure via X-ray crystallography, NMR, and various sequencing methods, and (c) advance new methods for the analysis of mRNA expression and transcription. While they must enhance the discovery process, these means shall not constrain or disrupt the discovery process. The Contractor shall be sufficiently experienced in the conduct of biomedical research to gather information, as well as propose and implement solutions in a manner that is understood by and agreeable to end users. This shall be achieved via the following tasks:

(a) Drawing upon the information and findings of the requirements assessment, the Contractor shall design, prototype and demonstrate a working prototype of software applications and systems that meet the bioinformatics requirements of participating centers. The requirements assessment shall have determined the following which provide the basis for this systems design and prototyping: (i) the types of applications and algorithms presently used by researchers in participating centers, (ii) the functionality that is needed and desired, as well as features and functionality that may be lacking; (iii) the backgrounds of people using these systems and applications; (iv) the needs for porting data that may pose certain technical challenges due to the data type or restrictions on its use; and (v) institutional objectives and policies that influence the needs for collection, dissemination, and selection or restriction of data.

(b) Based on this information from the requirements assessment , the contractor shall produce a high-level system architecture, including but not limited to: (i) characterization of the end-user populations and their novel requirements; (ii) mapping of core scientific processes that must be supported by this service; (iii) description of the connectivity and functionality requirements at all key productivity and transaction points in each of these core scientific processes; and (v) identification of possible parameters which if properly addressed could improve the discovery process in ways acceptable to participating scientists.

(c) The contractor shall design a system that meets the functional requirements of users. This system shall be comprised of the full array of hardware and software elements determined to be required, including but not limited to: (i) relational databases for data archiving, (ii) servers dedicated to specific tasks, such as web-based communications or on-line data submission, (iii) special stored records, such as personal identifiers, structured vocabularies, or ontologies, (iv) interfaces for machine-machine or human-machine data interchange, and (v) operating systems, middleware, algorithms, and programming languages to be used.

(d) The contractor shall provide for bioinformatics technical support and training to assist participating centers with data collection, storage and analysis. This shall include detailed specifications of the applications, databases, interfaces, inter-connectivity, and data modeling, a detailed description of the specific data collection and analysis methods that will be used in the needs assessment to flesh out and determine the validity of the hypothetical system architecture.

(e) The contractor shall build a working prototype of an information technology system that meets at least some of the most important functional requirements of participating scientists. This system prototype shall also be compatible with end user preferences. It shall demonstrate the feasibility of measurable gains in life science discovery to be realized by scientists through its use. In the event that resource limitations require that only a portion of end-user requirements are addressed with the prototype, the NIAID project officer will decide which requirements are addressed.

TASK 3. Develop an implementation plan for the bioinformatics integration support system.

In order to support the needs of the NIAID's research community, the Contractor shall: (a) establish a data repository, linking lab and clinical data (where feasible), (b) construct, document, and maintain shared data-models, as well as necessary vocabularies and ontologies to make the archive useable by a diverse research community, (c) integrate data and applications from existing archives and data resources, (d) provide access to researchers and other end-users according to precisely-defined protocols, (e) develop and disseminate strictly enforced provisions for the protection of human subjects and/or intellectual property; and (f) develop and disseminate standards and tools that allow scientific data sharing in ways consistent with the interests of participating researchers and their institutions. The Contractor shall be sufficiently experienced in the conduct of biomedical research to implement solutions in a manner that is understood by and agreeable to end-user scientists. Thus, neither the system itself nor its implementation shall impose undue constraints on the scientific enterprise.

The Contractor shall:

(a) provide a detailed plan for implementing a system that meets the assessed requirements and is consistent with the architecture and prototype offered in Task 2 above;

(b) identify and characterize additional bioinformatics needs of the participating laboratories; (i) identify, measure and explain barriers and benefits already achieved by the work contractor; (ii) propose new functionality and services to be developed to serve the needs of the participating community; (iii) consider feedback from end-users and the NIH representatives as well as their designated advisors;

(c) furnish detailed hardware and software descriptions, as well as plans for their acquisition and deployment. As part of this Task, the contractor should provide a proven method for making "build versus buy" decisions and an estimate of the projected portion of the work that can be accomplished with COTS (commercial off-the-shelf) applications; furnish a proven method of software development management, including, but not limited to, life cycle or maturity models, iterative or "waterfall" development techniques, and approaches to address factors of importance to this project, including but not limited to scalability, reliability, interoperability, and portability, and

(d) furnish a proposed set of critical success measures to be considered by project participants, as well as proposed methods for their use and future refinement, remaining cognizant of (a) the ways in which hypotheses are generated and tested in a biological research setting; (b) the way in which protocols are developed, pre-tested and deployed in clinical research setting; (c) the ways in which high-throughput and combinatorial methods can enhance research processes; and (d) the ways in which these processes may be regularized or improved to the benefit of end-user scientists with the skillful introduction of advanced technologies and methods.

TASK 4. Not later than the eleventh (11th) month of the project, the Contractor shall present the results of all Tasks performed under Phase I, as a written proposal and as an oral presentation to the NIAID Project Officer and the NIH's Special Emphasis Panel (SEP). This reporting shall include: (a) the requirements assessment; (b) the envisioned future system; (c) a demonstration of the working prototype of the system; and (d) a plan for implementing and maintaining the system (including a complete technical and business plan for Phase II).

TASK 5. Following the NIH Special Emphasis Panel (SEP) review of deliverables under Phase I, the Contractor shall be advised to either implement Phase II of this project or to close the project. The project closeout shall include an orderly and timely transfer of all data, information and contract-related materials to the Government.

PHASE I - Requirements Assessment
Additional Information on the Scope and Requirements of the Solicitation

THE FOLLOWING INFORMATION IS SPECIFIC FOR PURPOSES OF RESPONDING TO PHASE I OF THIS RFP. ALL OFFERORS SHOULD PROVIDE SPECIFIC DOCUMENTAION IN THEIR PROPOSALS WITH REGARD TO THIS INFORMATION TO MAXIMIZE EVALUATION RESULTS.

BUSINESS PROPOSAL – UNIFORM TOTAL COST OF PROPOSAL: ALL OFFERORS ARE REQUIRED TO LIMIT THE TOTAL COST OF THEIR BUSINESS PROPOSAL FOR PHASE I TO AN AMOUNT OF $1,415,000.

1) **Offerors must submit a technical and business proposal that addresses only Phase I of this RFP. This discussion pertains only to Phase I.**

2) **Proposal contents.** In addition to all other information requested of offerors by this solicitation, the **technical proposal** must include a detailed plan for what will occur in Phase I only. In addition to a complete project management plan, offerors must include detailed hypothetical examples of each of the following: (a) requirements assessment, explaining methods to be used and positing possible findings; (b) a high-level systems architecture; (c) a technical assistance service plan; (d) descriptions of applications likely to be developed during the project; and (e) a training plan, including sample curriculum and discussing the means by which it will be delivered to end users. Offerors will be rigorously evaluated for the completeness and domain-specific knowledge revealed in this section of their proposals.

3) **Need for innovation.** A novel system, custom data architectures, and direct technical assistance will be required to meet the needs of this research community. Specialized interdisciplinary support will be required to develop and maintain the needed data repositories. New data models, middleware, and data exchange or query tools will be needed to access critical research information across various existing platforms. This support should include technical assistance to researchers in characterizing the phenotypic data, as well as their study subjects for data archiving purposes.

   To overcome the challenges associated with central data archiving in fast-moving research fields, this contract should also provide advanced technology solutions to enable local data collection, as well as creative data sharing approaches. A guiding principle of this contract is that direct technical support to participating labs with data acquisition, analysis and curation is equally important as the creation of a central data archive. Advances in information technology in other domains have yielded many options for sharing, parsing, or integrating data that have yet to be tried in the life science research domain. These advances need to be delivered to the NIAID-funded researchers. Novel approaches are needed to deliver these solutions to a widely distributed community, as well as to address other barriers to data integration, such as human subjects and intellectual property concerns.

4) **Aim of providing bioinformatics support.** The services to be provided should accelerate basic and applied discovery, as well as the clinical validation of various therapies by ensuring data quality, timeliness and integrity, as well as by extending the usability of these data sets to larger, evermore-heterogeneous user communities. This requires the development of a common, secure platform for the collection, storage, analysis, and dissemination of numerous heterogeneous sets of basic and clinical research data. As part of the requirement to enhance research, the envisioned system should demonstrate that information technology could deliver measurable benefits that enhance scientific productivity. A special sort of support is needed in order to yield measurable benefits without constraining science. This work is inspired by the recognition that this dual purpose can be achieved through the skillful deployment of recent advances in databases, knowledge representation, object-oriented programming, and data exchange protocols to existing laboratories. Support procured under this contract should provide appropriate information technology solutions, delivered according to a clearly stated and approved project management plan.

5) **System vision.** The envisioned system must store and disseminate information in a flexible manner, so the data models must evolve with the varied and changing needs of the research community. Offerors are expected to introduce their expert knowledge in every aspect of this distributed, N-tiered system. With this in mind, the current vision of the data base system includes the following components:

a) **top level** will be a frame-based representation system that supports an object-oriented organization of data with slots, facets, multiple-inheritance, and features an application programmer's interface (API) that is network accessible;
b) **middle layer** will be a translation layer that converts the knowledge representation into the underlying persistent storage mechanism in a relational database; and
c) **bottom layer** will be a relational database system that is tuned to support a high level of transactions, secure access and backup in an N-tiered computational environment.

The NIAID fully expects that a Contractor suitable to perform under this contract will suggest novel and advanced computer-based solutions that embellish or even alter this framework in fundamental ways, but without compromising the program objectives.

6) **Data model.** Data models are critical to all aspects of this project. The envisioned system must allow users to access, store and disseminate information in a flexible manner; so the data models must be closely tailored to the context of their research. The data model for structuring storage in this resource will contain data relating genomic and proteomic information, laboratory phenotype information and clinical information. Due to the sensitivity of much of its contents, methods for guaranteeing the security of patient clinical information are essential. Thus the Contractor will be expected to demonstrate special knowledge, experience, and a creative approach to securing data while achieving the main goal of this project which is to present the most complete data set possible to the scientific public, limited only by the necessary ethical constraints, in as rapid a manner as possible. This expertise is essential to managing the conceptualization and evolution of data models.

7) **Programs to be served by this contract.** Initially, the Contractor will be expected to identify and plan to assess requirements for a distributed, multidisciplinary community of basic and clinical researchers. In Phase I, the contractor will then assess the requirements of this community and design a system to meet its requirements. In selecting the target community, the offeror should focus on research activities of direct interest to the Division of Allergy, Immunology, & Transplantation (DAIT) of the National Institute of Allergy & Infectious Diseases, NIAID at URL: http://www.niaid.nih.gov/research/dait.htm.) Although offerors will not be expected to have an established relationship with any particular researchers or programs, some of the relevant programs currently supported by DAIT include, but are not limited to those listed below. The Contractor may consider these laboratories to be representative of those that will participate in Phase II of this project.

International Histocompatibility Working Group (IHWG, established FY 2000)
The NIAID led several other ICs and the Juvenile Diabetes Research Foundation International in supporting the International Histocompatibility Working Group (IHWG), an international network of more than 200 laboratories that are collecting and sharing data on the genes of the human leukocyte antigen (HLA) gene complex; one project of the IHWG will establish an international bone marrow registry that will facilitate more accurate matching of transplant donors to recipients. (Background information is available at http://www.ihwg.org/).

Immune Tolerance Network (ITN, established FY 1999)
Established to evaluate promising tolerance induction approaches in 4 clinical areas: kidney transplantation, islet transplantation for type 1 diabetes, autoimmune diseases, and asthma and allergic diseases. The ITN's scientific leadership is composed of more than 70 investigators from more than 40 institutions in 9 countries. (Background information is available at http://128.218.179.235/frameset.html)

Autoimmune Centers of Excellence (ACEs, established FY 1999)
Established to conduct pilot clinical trials of tolerogenic and immunomodulatory therapies for multiple autoimmune diseases, including type 1 diabetes. These Centers support a cooperative research program of integrated basic, pre-clinical and clinical research, and conduct single and multi-site cooperative clinical trials for new immunomodulatory interventions and studies of mechanisms of action of tolerance induction. The clinical component allows the piloting of novel immune therapies for autoimmune diseases.

Cooperative Clinical Trials in Pediatric Renal Transplantation Program (CCTPT, established FY 1999)
The NIAID initiated support of pediatric kidney transplantation clinical trials, focused on increasing the long-term survival and improving quality of life, with the establishment of the CCTPT in 1991. This multicenter clinical trial

group consists of 52 pediatric transplant centers, which register and follow greater than 80% of children receiving renal allografts in the U.S. The CCTPT has successfully conducted seven (7) protocols of new treatment regimens that have changed the standard of care for children receiving kidney transplants.

Clinical Trials of Stem Cell Transplantation for the Treatment of Autoimmune Disease (SCT/TAD, established FY 2000) The NIAID is sponsoring clinical trials to assess the efficacy of hematopoietic stem cell transplantation for treating severe autoimmune diseases. Mechanistic studies are being performed along with the clinical trials.

Inner-City Asthma Consortium (ICAC, established FY 2002)
A new clinical research program will be established to evaluate the safety and efficacy of promising new strategies for the treatment of asthma among minority inner-city children. This new consortium of basic scientists and clinical investigators conducts clinical trials and integrated mechanistic studies of a variety of promising allergen-specific and non-specific immune-based therapies, targeting the major indoor allergens that have been identified as critical risk factors in this population. (Background information is available at http://www.niaid.nih.gov/ncn/concepts/c-ait10-0.htm).

8) **Estimate of Effort**

To assist in proposal preparation, the Government estimates the Phase I **total** level of effort to be approximately 3.05 FTE's. This estimate is furnished for the offeror(s) information only and is not considered restrictive for proposal purposes. As further assistance, it is estimated that the above total labor effort is constituted as follows:

Personnel Required	Phase I Total Percent Effort
PI/Co-PI	55%
Staff Scientist/Project Manager	75%
Research Specialist	75%
Computer Scientist/Engineer	75%
Clerical/Support	25%
TOTAL	305%

Note: Base year = 2,080 hours

9) **Budget Assumptions:**

For **cost estimating purposes** in preparing a proposal, the offeror should assume the following.

a) Participating programs ultimately to be supported under this contract comprise approximately 150 life scientists, engaged in clinical and basic immunology research at approximately 115 laboratories. The vast majority of these labs are located in the continental United States and no travel outside that area will be required of the Contractor.

b) In addition to the work of individual principal investigators, many participating centers act as repositories. These data intermediaries receive, archive, and analyze clinical records, tissue samples, and other clinically relevant data from other sites. In such cases, however, these intermediary centers will tend to address matters of data acquisition, formatting, and quality control at the local level, before submitting data to a central archive.

c) Travel

(1) The Contractor will need to visit research sites to (a) understand their capabilities and needs and (b) collect data for archival purposes.

(2) The PI and Co-PI will need to travel to Bethesda, MD (include airfare, per diem and hotel expenses) for ten 2-day project meetings during Phase I.

d) All work under this contract is to be performed in the English language. No non-English requirements are anticipated either in the day-to-day conduct of work or in any work products.

10) **Intellectual Property/Patents**

a) It is the right of the contractor or subcontractor to elect title to and patent new intellectual property arising from contract-supported research, as described in FAR 52.227-11, Patent Rights -- Retention by the Contractor. See http://www.arnet.gov/far/loadmain52.html. This clause will be included in the resultant contract and any resultant subcontracts.

b) Regarding intellectual property that may be developed in Phase I of this project, the Contractor shall not disclose any intellectual property or claim any such rights that may require negotiation during Phase I of this project. The NIAID cannot permit delays in activating Phase II of this project due to reasons of intellectual property. This will be included in an Advance Understanding in the resultant contract for Phase I

11) Section 508 of the Rehabilitation Act Amendments of 1998 shall apply to this acquisition, where applicable. Please refer to the following website for more information about Section 508: www.section508.gov

12) The information required by the Government will be obtained through the required reports supplied to the Project Officer. FAR 52.227-14 and FAR 227-14 ALT III, Rights in Data General, and FAR 52.227-17, Rights in Data -- Special Works, will be incorporated by reference in any resultant contract.

13) An Advance Understanding will be included in the resulting contracts that states the following: "The Contractor (and any subcontractor) shall not use any data that are archived, curated, or otherwise obtained under this contract for their own purposes. In particular, the contractor and its subcontractor(s) are precluded from using these data to support their own discovery of medical therapeutics.

PHASE I
Deliverables, Reporting Requirements and Milestones

During the contract period of performance, the Contractor shall submit an original and three (3) copies of each of the items listed below. The schedule for delivery for these items (approximated here) is subject to change based on agreement by the NIAID Project Officer and the Contractor. The completeness and acceptability of all deliverables will be determined by the NIAID Project Officer at his or her sole discretion and in consultation with representatives of participating centers.

(a) Phase I Project Management Plan as specified in Task 1 of the Phase I Statement of Work (due date: end of project month 1);

(b) Systems requirements assessment as specified in Task 1 of the Phase I Statement of Work (due date: end of project months 6/11 interim/final);

(c) Information technology system design as specified in Task 2 of the Phase I Statement of Work (due date: end of project months 6/11 interim/final). The Contractor shall: (a) specify solutions to be built and metrics for determining when requirements are met; (b) determine the costs and benefits of the project; and (c) propose a plan for the future development of this resource, as well as the maintenance of its data and applications. Specific performance shall be derived from knowledge of best practice in information technology performance measurement; an in-depth understanding of the critical challenges of laboratory and clinical medicine; and close communication with the NIAID Project Officer and participating laboratories. All monitoring and planning shall be done through close communication with the NIAID Project Officer and the leadership of participating centers.

(d) Working system prototype as specified in Task 2 of the Phase I Statement of Work (due date: end of project months 9/11 interim/final); Working prototypes of all data models, middleware, tools, and interfaces necessary for the collection, normalization, exchange, analysis, and archiving of data. These prototypes must be accompanied by sufficient documentation to enable use of the system by naive users. They must clearly demonstrate the functionality/value of the system to end-users;

(e) System implementation plan as specified in Task 3 of the Phase I Statement of Work (due date: end of project months 9/11 interim/final). This shall be a modification of the plan presented in the original proposal based on information gathered through the requirements assessment. The build-out plan shall include a detailed work breakdown structure and staffing plan. It shall also include detailed plans for (a) providing bioinformatics support to participating centers, (b) training participating scientists, (c) assessing Contractor performance according to the needs and expectations of end-users and (d) Phase II Project Management Plan (see Task 4). This implementation plan shall identify specific work packages that are in modular form with each estimating necessary costs, skill and capacity requirements, as well as the levels of effort associated with each.

(f) Final Report (due date: on/before completion date of Phase I contract). This should provide (a) a chronological account of all activities pursued in the context of the Phase I project: (b) records and data files for all original research conducted for the requirements assessment; (c) final versions (as well as indexes and support documentation) for all reports and computer applications delivered during this project phase; (d) detailed managerial and organizational recommendations relevant to the future implementation and operation of BISC. In addition, this Final Report shall include the annual Automated Information System Security Report, which includes the Automated Information System (AIS) Security Profile, which at a minimum shall include: the Systems' Security Plan (SSP); the Risk Analysis (RA); and the Continuity of Operations Plan (COOP) (also known as the Contingency Plan). Notwithstanding the fact that no proprietary software development is expected in this Phase, any algorithms or computer applications that may be newly developed shall be delivered as shall working copies of any operating systems, middleware, and applications upon which they depend for their use and proper functioning.

PHASE II - IMPLEMENTATION AND OPERATION

- STATEMENT OF WORK (BASIC AND OPTION)
- ADDITIONAL INFORMATION ON THE SCOPE AND REQUIREMENTS OF THE SOLICITATION
- DELIVERABLES, REPORTING REQUIREMENTS AND MILESTONES (BASIC AND OPTION)

PHASE II – Implementation and Operation Statement of Work

The purpose of Phase II is to build and operate the approved version of what was conceived and evaluated in Phase I of this project. In this Phase, the Contractor shall implement and maintain a data repository of genomic, proteomic, and related data from diverse sources. This system shall be comprised of the full array of hardware and software elements determined to be required by participating centers, including but not limited to: (i) databases for data archiving, (ii) servers dedicated to specific tasks, such as web-based communications or on-line data submission, (iii) special stored records, such as personal identifiers, structured vocabularies, or ontologies, (iv) interfaces for machine-machine or human-machine data interchange, and (v) operating systems, middleware, algorithms, and programming languages to be used. In addition, the contractor shall provide bioinformatics technical support and training to assist participating centers with data collection, storage and analysis.

In all material respects this system shall (a) satisfy the scientific data handling needs of basic and clinical immunologists, (b) provide adequate processing and storage capacity for all relevant data sets, (c) furnish data support that accommodates the latest in biomedical research instruments, while permitting the use of advanced methods; and (d) anticipates the complexities of representing biological information. This Phase of the project cannot be conducted without extensive experience and contemporary understanding of basic and clinical life sciences (especially immunology), as well as computer science, systems integration and engineering. This system shall be implemented and maintained by personnel at all levels who are sufficiently experienced in the conduct of biomedical research to conceive and implement solutions in a manner that is understood by and agreeable to biological scientists and clinicians, the end-users of this system.

STATEMENT OF WORK, PHASE II (BASE PERIOD OF TWO (2) YEARS)

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

Specifically, the Contractor shall:

TASK 1. Within thirty (30) days after the initiation of the Phase II award, provide and submit for approval of the Project Officer, a revised Project Management Plan that defines the critical path for the Phase II statement of work, including: key objectives; technical approach; proposed time schedule of major activities; decision-making criteria; and specific project strategy.

The Plan shall include well-described, quantifiable, and feasible criteria for completion of this Phase of the project, as well as a means of monitoring and reporting performance on all parts of the work statement.

TASK 2. Establish a system for the collection, storage and exchange of new and existing clinical and laboratory data from multiple sources and make this accessible to participating end users.

This system will support the analytical requirements of as many as 150 scientists in approximately 115 labs all of whom are using various types of scientific data from disparate sources to understand such matters as: (a) human leukocyte gene (HLA) complex, especially as related to matching transplant donors with recipients, (b) immune tolerance as related to the evaluation of new therapies in kidney transplantation, type I diabetes islet transplantation, autoimmune disease, asthma and allergy, (c) hematopoietic stem cell transplantation, and (d) both clinical trials and mechanistic studies of a variety of promising allergen-specific and non-specific immune-based therapies. The system will serve a distributed, multidisciplinary community of basic and clinical researchers.

This shall include, but not be limited to:

(a) Designing and implementing the architecture for a widely distributed networked system for biomedical scientific data collection, storage and exchange;
(b) Developing, implementing, and/or disseminating software applications to make these data accessible to end users according to their needs and constraints;

(c) Facilitating community consensus on phenotypic data to be collected, archived, analyzed and otherwise used at all participating centers or labs;
(d) Modeling data structures, biochemical processes, and disease states relevant to the genomics and proteomics of immune-mediated diseases;
(e) Allowing for the integration of legacy data and patient records from relevant sources (both public and private), the future acquisition of high-quality data, and the computer-based analysis of those data;
(f) Developing and disseminating protocols for the collection, archiving, and exchange of these biomedical data;
(g) Providing technical assistance in the collection, submission, exchange and analysis of data; and,
(h) Designing and implementing a reliable system of quality control applied to all data and media.

In achieving the above items, the Contractor shall complete the following: (i) evaluate, adopt, and extend some existing data models in this research domain of genome- and proteome-focused informatics; (ii) test and extend existing interfaces and protocols for the acquisition and exchange of genomic and related data; (iii) create new data models and interfaces for the exchange of data between instruments and computers and between humans and computers; and, (iv) create new applications for the exchange, management and quality control of data to be shared, archived and curated.

Successful completion of the above shall require the Contractor to: (i) design, implement and maintain a scaleable architecture for representing, acquiring, and storing data of many types, including but not limited to, genetic, cellular, molecular, and clinical; (ii) rapidly disseminate software for the capture, analysis, query, and storage of genomic and related data; (iii) link to other relevant existing data sources and support of the integration and analysis of those data sets; (iv) enable researchers to share data and analytical tools more readily through a variety of methods ranging from the dissemination of software standards to the redesign of selected standard operating procedures or business processes; and (v) creatively use client-server, peer-to-peer, and/or computer-mediated architectures to adjust the system to end-user needs and constraints.

TASK 3. Lead system and data integration for diverse sets of genomic, proteomic, clinical, and other data that shall include but not be limited to the following:

(a) Designing and implementing a widely distributed on-line scientific data query system (specifically allowing query of legacy, genomic, and proteomic data in accordance with end-user needs);
(b) Developing machine-usable knowledge representations of research and disease phenotype;
(c) Developing and implementing a plan to ensure the usability, interoperability, survivability, and portability of all data sets (including but not limited to elispot, tetramer, microarray, flow cytometry, and mass spectroscopy data from various sources);
(d) Developing a data base translation system and tools to integrate and query across several archives;
(e) Developing interfaces and procedures for lab data entry by machine or human users (e.g. Laboratory Information Management System (LIMS)); and,
(f) Disseminating information and training participating labs on the system and its use procedures.

In conducting this work, the contractor shall:

(a) Devise and introduce new methods. The contractor shall draw upon current information technology developments in the clinical informatics and computational biology communities, where new interfaces, curation tools, and middleware are being developed to serve the special needs of life scientists for advanced data basing and computational analysis of genomic, proteomic and related data. The contractor shall select and extent the best and most appropriate solutions from these domains to better serve the immunology community.

(b) Employ the latest technologies and methods. The Contractor shall make extensive use of the latest technologies for representing, archiving, and analyzing biological and chemical data in order to define, implement, and maintain a database that models essential aspects of the immune phenomena of interest to participating researchers. In particular, the Contractor shall apply extensive biological knowledge to integrate elispot, tetramer, microarray, flow cytometry, and mass spectroscopy data because each of these instruments plays a critical role in genome- and proteome-based discovery.

(c) Anticipate the special needs of scientists in this domain. The Contractor shall anticipate the special challenges arising with the integration of genomic and proteomic data. Genomic data to be handled by the system will include but not be limited to: sequence data, expression data, single nucleotide polymorphism data, protein structure, and pathway data. Proteomic data will include but not be limited to molecular-level records on all biologically active substances – amino acid, peptide, and protein structure -- as generated by numerous experimental methods.

TASK 4. Provide ongoing technical assistance to each of the participating labs with the local analysis and curation of their data. This shall involve the following:

(a) Providing ongoing technical assistance in the collection, submission, and accessing of data relevant to the common research interests of participating labs. This technical assistance shall extend to methodological assistance in biostatistics and research design only where it is critical to the quality and utility of data used in this network;
(b) Advising on the selection and use of software and hardware for data collection and analysis;
(c) Providing information and software to assist laboratories in the collection and normalization of data;
(d) Providing assistance in technology selection to see that tools adopted locally for data capture and analysis are of the best quality;
(e) Providing assistance with phenotype development to see that the local nomenclature and data representations are coordinated with those used centrally; and
(f) Training bioinformatics professionals at participating labs in order to ensure that all applications and services are fully understood at the local labs.

In providing the needed technical assistance, the Contractor (including all its staff and representatives) shall possess and demonstrate a thorough understanding of scientific process in basic and clinical biomedical research. This understanding shall be reflected in any staffing assignments, as well as training and communications programs. In order to provide the proper bioinformatics support, all persons assigned to this effort shall be proficient in both biology and engineering based on the belief that only such professionals are able to apply in-depth biomedical knowledge to the development of novel informatics solutions.

TASK 5. When necessary and agreed by the Project Officer, develop new algorithms and software applications to support capture, analysis, and curation of biomedical data that shall include but not be limited to the following:

(a) Developing new and novel metadata and middleware;
(b) Developing custom applications for data analysis and exchange;
(c) Developing secure archival applications in clinical trials informatics;
(d) Developing special applications for data collection and management; and,
(e) Developing special data collection applications for machine and human interfaces.

The Contractor shall develop and disseminate applications that enable scientists working independently in participating programs to generate, normalize, archive, and exchange data of all types easily and without risk of corruption. The Contractor shall draw on the latest advances in software engineering and computer sciences and translate those advances into practical tools that are easily used by the target users in this project. The software development to be conducted under this task shall integrate rather than displace existing applications. In order to properly conduct this work, the Contractor shall demonstrate a thorough understanding of scientific workflow in the biological sciences, both basic and clinical. Solutions must be conceived and built with only limited inputs from end-user scientists. In order to provide the proper bioinformatics support, all persons assigned to this effort shall be proficient in both biology and engineering because only such professionals are able to apply in-depth biomedical knowledge to the development of novel informatics solutions. The Contractor shall develop, acquire, and disseminate applications as appropriate that address what NIAID has determined to be the most pressing needs of participating centers, which include but are not limited to: (i) improved processes and interfaces (human-machine and machine-machine) for data submission and exchange, (ii) common standards of knowledge representation to enable cross-platform portability of research data, (iii) translation middleware to extend the usability of large legacy data sets, (iv) linking software, as applied to navigation, annotation, or document version accessing, and (v) controlled access and data sharing protocols to protect records under complex human subjects or intellectual property constraints.

TASK 6. Manage and maintain a system of data collection and archiving that shall include but not be limited to the following:

(a) Developing uniform, intelligent web-based interfaces for remote data entry by human users.
(b) Assisting participating labs with submission of normalized, high quality data.
(c) Receiving data from participating centers and insuring the quality and integrity of those data. The exact nature of the data shall be determined in the requirements assessment under Phase I, but are expected to include but not be limited to genotype data, DNA marker names, allele sizes in base pairs and corresponding frequencies, and relative map distances for each marker. In addition, the Contractor shall obtain from all participating laboratories results from sequence and mutation analyses and any other genetic analyses that may become available.

(d) Creating an electronic database containing all available scientific data for each subject, including but not limited to, clinical, diagnostic and pedigree information in those areas specified by end users. Genomic data to be archived or accessed by the system shall include: sequence data, expression data, single nucleotide polymorphism data, protein structure, and pathway data. Proteomic data will include molecular-level records on all biologically active substances – amino acid, peptide, and protein structure -- as generated by numerous experimental methods.. All such data shall be maintained in electronic databases in a format that permits rapid and efficient production of files for distribution. The Contractor shall carefully verify all data in collaboration with the participating laboratories on the grants or contracts under which the data were collected.
(e) Specifying and disseminating data standards for future data collection and analysis.
(f) Integrating system and operational changes according to user needs and technological advances.
(g) Developing/implementing a long-range plan for the long-term maintenance and survival of the data.

The Contractor shall distribute electronic files of clinical, diagnostic, genotypic, and pedigree structure data only with the prior written approval of the NIAID Project Officer, and in accordance with current state or federal laboratory procedures assuring appropriate usage of genetic material.

With regard to the data intended for central archiving, the Contractor shall not use data for any purpose, other than that specified in the contract, without prior written approval of the NIAID Project Officer.

TASK 7. Develop and implement a system for monitoring security and system performance with the aim of maintaining data security and integrity, as well as high levels of service to end users.

(a) Develop a program and needed applications for monitoring use of the system;
(b) Develop and implement a plan to protect data derived from human subjects in compliance with, and keeping up with current regulations;
(c) Test the system according to best and standard practices in computer and engineering services to ensure that it is performing according to requirements;
(d) Report on and repair any potential problems with the system;
(e) Inform and train users in the security procedures of the system; and,
(f) Develop, implement, and maintain security requirements, including:

1) An Automated Information System (AIS) Security Profile, which at a minimum shall include: the System's Security Plan (SSP); the Risk Analysis (RA); and, the Continuity of Operations Plan (COOP)(also known as the Contingency Plan);

2) A log or record of the results from testing the COOP, any existing plans and progress reports for implementing additional security safeguards and controls; and the system access authorization list. The profile shall be kept up-to-date for review and potential inspection upon demand by NIH/DHHS authorized agents. Upon request, copies of specified profile documents shall be presented to NIH/DHHS for its own system's security reporting purposes;

3) The preparation and submission, for Project Officer approval, of an RA following the guidance given in DHHS AISSP Handbook (http://irm.cit.nih.gov/policy/aissp.html). The RA is to be maintained and updated every three years, or in advance of implementing major system modifications or enhancements;

4) The preparation and submission of an annual SSP, following the instruction in OMB Bulletin 90-08, for review and approval by the Project Officer and the NIH SSO (http://irm.cit.nih.gov/itmra/omb90-08.html);

5) The development and maintenance of an up-to-date COOP following the guidance in DHHS AISSP Handbook (http://irm.cit.nih.gov/policy/aissp.html). At a minimum, the COOP shall cover emergency operations, backup operations, and recovery plans to assure continuous operations of the system's facility. COOP testing shall be conducted and the results recorded at least every six months;

6) Plans, procedures, and a recommended schedule and budget for implementation of security safeguards required to satisfy the anticipated conditions of acquiring data from clinical and mechanistic study sites. This includes data integrity and security during electronic transmission, or during transit from the sites to the BISC if non-electronic data transmission is used. All patient identifiable data is subject to the Privacy Act and DHHS regulations; and

7) Provision for the appropriate labeling, storage, handling, and disposal of sensitive or controlled data, media, and output.

TASK 8. Communicate regularly with the NIAID Project Officer and the leadership of participating centers throughout the contract period of performance.

(a) Develop a detailed communications strategy that demonstrates a thorough understanding of scientific process in basic and clinical biomedical research and includes at least the following functionality:

1) captures the scientific inputs of participating scientists relevant to system and software design;
2) establishes mechanisms for ongoing input into subsequent versions of the system;
3) allows for rapid dissemination of new methods and tools developed under this contract (including training);
4) links participating scientists to additional coaching, guidance, and instruction relevant to all aspects of scientific support in genomics and proteomics of immunology and,
5) establishes a way for end-user feedback to be readily integrated into Contractor activities so that the overall performance of the system is continually improved.

(b) Collaborate with the NIAID Project Officer and the leadership of participating labs to address key information policy issues relevant to the performance of this contract including, but not limited to, (1) data access and release; (2) standard nomenclature; (3) data submission and dissemination formats; (4) data security policy; and, (5) intellectual property.

(c) Conduct individual and group working meetings with the leadership of participating labs, BISC staff, and NIAID program staff as necessary for the satisfactory completion of this contract. Group meetings with the leadership of participating labs shall occur no less frequently than one meeting per year.

(d) Provide support to the regular meetings and communication activities of the NIAID Project Officer, the leadership of participating labs, and their technical advisors. This support shall include, but not be limited to, arranging meetings; providing all necessary background material relevant to the decisions of the group; and communicating with members to convene and record the major decisions of meetings. The Contractor may advise the NIAID on issues to be addressed by advisors and lab leadership by communicating directly with the NIAID Project Officer, but the Contractor shall not set the agenda for these meetings.

TASK 9. Report progress according to the Reporting Requirements and Milestones (refer to the "Deliverables, Reporting Requirements and Milestones" in this contract).

TASK 10. At the beginning of the eighteenth (18^{th}) month of the Base Period provide and submit, for review by the Project Officer, a Revised Project Management Plan that defines the critical path for the option's statement of work, including: key objectives; technical approach; proposed time schedule of major activities; decision-making criteria; and specific development tasks. The Plan shall include well-described, quantifiable, feasibility criteria with a discussion of the implications of successful completion of these criteria during performance of the statement of work.

TASK 11. Following an assessment of progress 18 months after the start of the Phase II, either the Government will exercise the option or the Contractor shall close-out the project. The project closeout shall include an orderly and timely transfer of all data, information and contract-related materials to a successor contractor or the Government.

STATEMENT OF WORK - PHASE II, OPTION (4 YEARS)

TASK 1. Within thirty (30) days after the initiation of the option, provide and submit for approval of the Project Officer a Revised Project Management Plan that defines the critical path for the option's statement of work, including: key objectives; technical approach; proposed time schedule of major activities; decision-making criteria; and specific development tasks. The Plan shall include well-described, quantifiable, feasibility criteria with a discussion of the implications of successful completion of these criteria during performance of the statement of work.

TASK 2. Perform TASKS 2. - 9. of the Phase II (Base Period), Statement of Work, above.

TASK 3. Ensure an orderly and timely transfer of all data, information, and contract-related materials to a successor contractor or the Government. Six months prior to the contract completion date, a transition plan shall be submitted to the Project Officer for approval.

PHASE II -- Implementation and Operation
Additional Information on the Scope and Requirements of the Solicitation

THE FOLLOWING INFORMATION IS SPECIFIC FOR PURPOSES OF RESPONDING TO PHASE II OF THIS RFP. ALL OFFERORS SHOULD PROVIDE SPECIFIC DOCUMENTAION IN THEIR PROPOSALS WITH REGARD TO THIS INFORMATION TO MAXIMIZE EVALUATION RESULTS.

1) At the end of PHASE I, each contractor shall deliver a requirements assessment, working prototype, system implementation plan, Phase II technical and business plan, and present an oral presentation for the purpose of evaluating the success of PHASE I and determining if an award will be made for PHASE II. This information will be evaluated by the NIH Special Emphasis Panel (SEP).

2) It is anticipated that only one (1) PHASE II contract will be awarded for a period of six (6) years but the Government reserves the right to make multiple awards if funds are available. The PHASE II contract(s) will consist of a base period of two (2) years and an Option period of four (4) years to ensure that the project is fully implemented and demonstrating measurable results.

3) **Contractor's Role in Service and Support.** Service delivered by the Contractor will be regarded as supplementary, albeit much needed support to participating centers. It will complement bioinformatics activities that are already underway in each of the participating labs. It is expected that all participating labs will have staff who possess graduate level training in the engineering and natural sciences relevant to bioinformatics. It is also expected that each of the participating labs will conduct and equip its own original research. The Contractor will be required to develop and/or deploy specific software applications to participating labs. The Contractor will also advise and train participants in the selection, use, and development of advanced bioinformatics hardware and software. The Contractor will concentrate on fulfilling the aim of (a) exposing participants to best practices in bioinformatics software, and (b) enabling the exchange, portability and interoperability of data and applications.

   Not all of the specific projects to be supported under this contract can be predicted at this time. These projects will vary in size, complexity and duration; they range from long-term projects of several months to special studies. These include development and maintenance of multi-institutional collaborative screening or clinical trials, biostatistical studies on various aspects of immune disease using one or more data files, development of statistical and epidemiological methodology for carrying out such research projects, pilot or feasibility screening and/or prevention trials, and the conduct of epidemiological and biostatistical studies of immune disease screening and prevention. Some projects require computer science expertise in information retrieval and data analysis of existing databases which can only be carried out by the design and development of specialized software; others require the application of general purpose or existing software for data organization, maintenance and analysis. Some projects require data collection expertise in a variety of medical research settings that will necessitate the development of test instruments and coding instruction manuals, and the timely editing of data using rigorous quality control procedures; other projects require the utilization of existing data collection methods and procedures. In the majority of circumstances a high level of professional and technical expertise is required since turn-around time should be rapid, complex situations must be quickly assimilated, and accurate solutions produced using state-of-the-art technology.

   The Contractor will not develop or interpret information policy, data access and security policy, or intellectual property policy for participating institutions. It is expected that each of the participating labs would establish and disseminate policies and procedures that (a) ensure reliable data completeness and quality, as well as thoroughness in data annotation; (b) address data access and security; and (c) address the ownership of all scientific data, in both raw and interpreted forms. The Contractor will provide technology solutions that are consistent with and reinforcing of these policies. The Contractor will be expected to develop software and systems that enable participants to adhere to these policies.

   These points notwithstanding, the offeror must note and should remain cognizant that not all policies concerning the archiving and exchange of these records and/or their personal identifier have been worked out. The successful offeror under this contract should demonstrate superior knowledge of institutional policy relating to intellectual property management and the protection of human subjects. The Contractor will be required to support program staff in developing consensus-based policies on these matters and translating those policies into practical organizational practices and information technology solutions

4) **Novel development versus integration.** While some new front-end application development will be necessary to serve users under this contract, this project is primarily intended to provide support for the acquisition and integration of best existing applications and practices. It should also provide a broadly useful infrastructure of servers and networks upon which best practices and applications in bioinformatics will be disseminated. During contract performance, the contractor:

- may expect that the participating laboratories are familiar with existing tools in this domain and that more tools will be introduced through future NIH-sponsored procurements;
- will be encouraged to integrate existing applications throughout their system and to take special care in forecasting and justifying where new applications will be required;
- in pursuing their technical approaches, will be required to be creative and informed about the latest technological advances, especially in solving the unique challenges of this community, such as real-time data sharing, data security, protection of intellectual property, and data access restrictions due to human subject constraints;
- in all aspects of the system developed here, will be expected to use formats for data representation and storage that enhance data integrity, survivability, and portability;
- should draw on the recent work of various standards-setting bodies, for example, those groups now working to establish standards for the production, maintenance, and exchange of genomic data; and
- will be encouraged to facilitate the rapid diffusion of emerging standards and to explain to the participating scientific leadership how this serves the interests of the community.

5) **Estimate of Effort**

To assist in proposal preparation, the Government estimates the Phase II annual level of effort to be approximately 11 FTE's, for a total of 66 FTE's over the six year period. This estimate is furnished for the Offeror's information only and is not considered restrictive for proposal purposes. As further assistance, it is estimated that the above total labor effort is constituted as follows:

Personnel Required	Phase II Annual Percent Effort
PI/Co-PI/Project Manager	200%
Staff/Research Scientist	200%
Computer Scientist/Programmer	500%
Communications Spec./Webmaster	100%
Clerical/Support/Other	100%
TOTAL	1,100%

Note: Base year = 2,080 hours

6) **Hardware/Software**

Offerors are expected to purchase or provide hardware and software sufficient for the construction and operation of the data basing system, as well as all novel applications and interfaces under this contract. This equipment may be purchased under the contract. Separate interfaces are required for each of the six participating groups, yet they will provide access to shared and complementary datasets (formatted and archived for data sharing to the greatest extent possible.) The Contractor shall assist participating programs in their own technology adoption, but shall not furnish equipment and supplies locally, except where necessary to fulfill the data integration objectives of this project. The participating centers will be responsible for purchasing their own software and hardware. Offerers are encouraged to propose novel methods of developing and disseminating bioinformatics solutions to participating centers and to document the benefits of their approach.

No hardware or software are explicitly specified in this RFP because there are several technology infrastructures that may adequately meet the needs of this community. Offerors are encouraged to remain mindful of the fact that (a) the computer-based analytical requirements of the clinical and basic research community are rapidly growing and becoming more sophisticated and (b) software standards are emerging at several critical points to facilitate high-quality data capture and exchange. Proposals should demonstrate a recognition of the unique application areas in biology to which computers must be applied, as well as an understanding and the ability to adopt best practices and emerging standards in this domain.

7) **Budget Assumptions**

For **cost estimating purposes** in preparing a proposal, the offeror should assume the following.

- The programs to eventually be supported under this contract comprise approximately 150 life scientists, engaged in clinical and basic immunology research at approximately 115 laboratories. These labs are located in the continental United States and no travel outside that area will be required of the Contractor.

- In addition to the work of individual principal investigators, many participating centers act as repositories. These data intermediaries receive, archive, and analyze clinical records, tissue samples, and other clinically relevant data from other sites. In such cases, however, these intermediary centers will tend to address matters of data acquisition, formatting, and quality control at the local level, before submitting data to a central archive.

- During this contract, the Contractor shall be required to support regular meetings and communications between the NIAID Project Officer, the leadership of participating labs and NIAID's technical advisors on this project. This support shall include arranging working meetings; providing all necessary background material relevant to the decisions of the group; and communicating with members to convene and record the major decisions of meetings. This will be a practical working group. No complex reports or studies will be generated. Technical advisors include experienced scientists and engineers from industry and academia, reporting directly to the NIAID Project Officer. Advisors will be selected and appointed by the NIAID. The Contractor may advise the NIAID on issues to be addressed by advisors and lab leadership by communicating directly with the NIAID Project Officer, but the Contractor will not set the agenda for communications or meetings with the NIAID technical advisors.

- Assume the following annual meeting schedule:

	# of Attendees
Annual meeting of participating centers	75-100
Quarterly working meetings	15-25

- The Contractor shall be responsible for arranging and facilitating these meetings. It is anticipated that these meetings will held at hotels in the Washington DC area. The Contractor shall include travel costs for its own employees/subcontractors to attend these meetings. In addition, include travel expenses for lab leadership to attend two (2) of these meetings per year in years one and two and one (1) meeting per year thereafter. Other attendees will not be reimbursed through this contract.

- The Contractor will need to visit participating sites to (a) understand their capabilities and needs and (b) collect data for archival purposes.

- Include a budget for the PI and Co-PI to travel to Bethesda, MD (include airfare, per diem and hotel expenses) for ten 2-day project meetings per year. In addition, budget travel for two investigators to each attend one scientific meeting per year.

- All work under this contract is to be performed in the English language. No non-English requirements are anticipated either in the day-to-day conduct of work or in any work products.

8) **Proprietary Data**

This project aims to provide a robust and broadly useful platform for data integration and exchange. This may involve innovation in database design, data modeling, and various "middleware" that enable interoperability at the operating system and application levels. All newly developed source code related to interoperability and portability of data and applications will remain the property of the U.S. Government to be maintained in the public domain. It is fully expected, however, that the Contractor and other parties will develop proprietary data handling and analysis software on top of this infrastructure. In all instances, however, the current laws governing Contractors or grant recipients with respect to intellectual property rights in the conduct of government-funded contracting and research will apply. This will be included as an Advance Understanding in the resultant contract for Phase II.

9) **Intellectual Property/Patents**

a) It is the right of the contractor or subcontractor to elect title to and patent new intellectual property arising from contract-supported research, as described in FAR 52.227-11, Patent Rights -- Retention by the Contractor. See http://www.arnet.gov/far/loadmain52.html . This clause will be included in the resultant contract and any resultant subcontracts.

b) Regarding intellectual property related to biology-based discovery, however, the Contractor/subcontractor shall not use any data that are archived, curated, or otherwise obtained under this contract for their own purposes. In particular, the Contractor and its subcontractors are precluded from using these data to support their own discovery of medical therapeutics. This will be included an Advance Understanding in the resultant contract for Phase II.

10) Section 508 of the Rehabilitation Act Amendments of 1998 shall apply to this acquisition, where applicable. Please refer to the following website for more information about Section 508: www.section508.gov

11) The information required by the Government will be obtained through the required reports supplied to the Project Officer. FAR 52.227-14 and FAR 227-14 ALT III, Rights in Data General, and FAR 52.227-17, Rights in Data -- Special Works, will be incorporated by reference in any resultant contract.

PHASE II - Implementation and Operation
Deliverables, Reporting Requirements and Milestones

For the entire duration of Phase II (regardless of whether the Phase II Option is exercised), the Contractor shall submit an original and three (3) copies of each of the items listed below. The schedule for delivery for these items (approximated here) is subject to change based on agreement by the NIAID Project Officer and the Contractor. The completeness and acceptability of all deliverables will be determined by the NIAID Project Officer at his or her sole discretion and in consultation with representatives of participating NIAID research centers.

(a) Phase II Project Management Plan as specified in Task 1 of the Phase II Statement of Work (approximate due date: end of project month 1(updates will be submitted at 12-month intervals thereafter for the duration of the project);

(b) Demonstration of a fully operable system of databases including interfaces for data collection, data models, and ontologies or structured vocabularies, as well as initial documentation for all hardware and software. (approximate due date: end of project month 18). The contractor shall regularly update and refine these deliverables in accordance with end-user requirements. These modifications and appropriate measures of their impact shall be reported at least annually to management;

(c) Proof of a fully operational bioinformatics support service including a reckoning of the level and types of service utilization. (approximate due date: end of project month 18) The contractor shall regularly update and refine these deliverables in accordance with end-user requirements. These modifications and appropriate measures of their impact shall be reported at least annually to management;

(d) Demonstration of tested schemes and applications for (i) data submission at all community-agreed interfaces; (ii) data normalization; (iii) data curation; (iv) data exchange and/or sharing; and (v) data comparison (approximate due date: end of project month 18) the contractor will regularly update and refine these deliverables in accordance with end-user requirements. These modifications and appropriate measures of their impact will be reported at least annually to management;

(e) Report on all meetings of end-users, detailing specifically but not exclusively what support levels and functionality they require (approximate due date: end of project month 18) ;

(f) Annual report and requirements update (both due annually beginning month 24). These reports shall provide proof that all feasible aspects of the work plan produced in Phase I have been executed or that reasonable alternative approaches to the execution of this plan have been carried out. Requirements updates shall address all issues that may arise due to modified or newly discovered requirements; they shall also address software lifecycle issues. This report shall explain benefits delivered by the system of databases and technical support work, discuss any barriers to implementation and how they have been addressed, discuss the current and needed functions of the platform based on a thorough understanding of end-user requirements, and include the annual Automated Information System Security Report;

(g) All newly developed source code related to interoperability and portability of data and applications shall remain the property of the U.S. Government, to be maintained in the public domain;

(h) A Final Report shall be submitted by the Contractor on or before the completion date of the contract.

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

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

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

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

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

BECAUSE THIS IS A STREAMLINED RFP, ARTICLES I.2. AND I.3., WHICH IDENTIFY ANY AUTHORIZED ADDITIONS, SUBSTITUTIONS AND/OR MODIFICATIONS TO THE GENERAL CLAUSES, WILL BE BASED ON THE TYPE OF CONTRACT/CONTRACTOR AND WILL BE DETERMINED DURING NEGOTIATIONS.

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

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

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

FAR Clause No.	Date	Title
52.202-1	Oct 1995	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 (Over $100,000)	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
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	Mar 2000	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	Oct 2001	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	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	Feb 2000	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 $100,000)	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over
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	May 2001	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 Contract)	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour
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

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

[END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT – Rev. 05/2001]

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

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

- **PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)**
- **HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)**
- **PROPOSAL INTENT RESPONSE SHEET *Submit on/before: January 4, 2002* (Attached to this listing)**
  [NOTE: Your attention is directed to the "Proposal Intent Response Sheet". If you intend to submit a proposal, you must complete this form and return it to this office via fax or e-mail on or before the date identified above. The receipt of this form is critical as it contains information essential for CMB's coordination of the electronic submission and review of proposals.]

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

To Become Contract Attachments and Reports Required During Contract Performance (as applicable):

- **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)**
- **Privacy Act System of Records #09-25-0200**
- **Report of Government Owned, Contractor Held Property**
- **Disclosure of Lobbying Activities, OMB Form LLL**

PACKAGING AND DELIVERY OF PROPOSALS

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 paper and electronic versions 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-DAIT-02-16
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
Cyndie Cotter Contracting Officer Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Cyndie Cotter Contracting Officer Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

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

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 PHSAR 352.215-10, Late Proposals, Modifications of Proposals and Withdrawals of Proposals (NOV 1986).

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

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

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

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

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

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

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- Keep graphics embedded in documents as simple as possible. Complex graphics require longer periods for the computers used in the evaluation system to draw, and redraw these figures and scrolling through the document is slowed significantly.
- Type density and size must be 10 to 12 points. If constant spacing is used, there should be no more than 15 cpi, whereas proportional spacing should provide an average of no more than 15 cpi. There must be no more than six lines of text within a vertical inch. Margins must be set to 1 inch around.
- 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: https://apps.niaid.nih.gov/ecms/cmsproposal/
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-DAIT-02-16
RFP Title: Bioinformatics Integration Support Contract (BISC)

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **January 4, 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: Cyndie Cotter
RFP-NIH-NIAID-DAIT-02-16
FAX# (301) 402-0972
Email : mailto:cc41w@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 sub line 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 post award debriefings to other offerors:

(i) The overall evaluated cost or price and technical rating of the successful offeror;
(ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
(iii) A summary of the rationale for award; and
(iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

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

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

b. NAICS CODE AND SIZE STANDARD

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

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

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

c. NOTICE OF PRICE EVALUATION ADJUSTMENT FOR SMALL DISADVANTAGED BUSINESS CONCERNS

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 10 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

A small disadvantaged business concern may elect to waive the adjustment, in which case the factor will be added to its offer for evaluation purposes. The agreements in paragraph (d) of FAR Clause 52.219-23 do not apply to offerors that waive the adjustment.

AN OFFEROR WHO ELECTS TO WAIVE THIS EVALUATION ADJUSTMENT MUST SPECIFICALLY INDICATE WITH A STATEMENT TO THIS EFFECT ON THE COVER PAGE OF ITS BUSINESS PROPOSAL.

d. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that MULTIPLE AWARDS will be made under Phase I of this solicitation and that ONE AWARD will be made under Phase II. The Phase I awards will be made on or about September 30, 2002 and the Phase II award will be made on or about March 31, 2004.

It is anticipated that the Phase I awards resulting from this solicitation will each be a cost reimbursement, completion type contract with a period of performance of 18 months. It is anticipated that the Phase II award will be a multiple-year, cost reimbursement, completion type contract with a period of performance of six (6) years. 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 Phase I total 18-month effort to be approximately 6,344 labor hours and the Phase II total 6-year effort to be approximately 137,280 labor hours (22,880 per year). 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. PREPARATION COSTS

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

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

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

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

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

(End of Provision)

l. 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)

m. AVAILABILITY OF THE "FEDERAL ADP AND TELECOMMUNICATIONS STANDARDS INDEX."

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

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

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

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

2. INSTRUCTIONS TO OFFERORS

a. GENERAL INSTRUCTIONS

INTRODUCTION

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

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

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

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

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

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

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

The proposal must be prepared in two parts: a "Technical Proposal" and a "Business Proposal." Each of the parts shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. The technical proposal must include direct cost and resources information, such as labor-hours and categories and applicable rates, materials, subcontracts, travel, etc., and associated costs so that the offeror's understanding of the project may be evaluated (See Attachment entitled, TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS). However, the technical proposal should **not** include pricing data relating to individual salary information, indirect cost rates or amounts, fee amounts (if any), and total costs. The technical proposal should disclose your technical approach in as much detail as possible, including, but not limited to, the requirements of the technical proposal instructions.

(5) **Alternate Proposals**

You may, at your discretion, submit alternate proposals, or proposals that 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 NIAID's policy to conduct discussions with all offerors in the competitive range, NIAID reserves the right, in special circumstances, to limit the number of proposals included in the competitive range to the greatest number that will permit an efficient competition. All aspects of the proposals are subject to discussions, including cost, technical approach, past performance, and contractual terms and conditions. At the conclusion of discussions, each offeror still in the competitive range shall be given an opportunity to submit a written Final Proposal Revision (FPR) with the reservation of the right to conduct finalization of details with the selected 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 NIAID reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet NIAID requirements. Synopses of awards exceeding $25,000 will be published in the Commerce Business Daily.

(12) **Small Business Subcontracting Plan**

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

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

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

(c) The offeror understands that:

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

(2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for small business concerns and small business concerns owned and controlled by socially and economically disadvantaged persons to participate in the performance of the contract.

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

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

(5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to small business concerns, small business concerns owned and controlled by socially and economically disadvantaged individuals, and women-owned small business concerns and that each such aspect of the offeror's plan will be judged independent of the other.

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

(d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small disadvantaged, women-owned, and HUBZone small business concerns as subcontractors.

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

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to small, small disadvantaged, women-owned, and/or HUBZone small business concerns.

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

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

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with small, small disadvantaged, women-owned, and HUBZone small business concerns.

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

(8) A description of the efforts the offeror will make to assure that small, small disadvantaged, women-owned, and HUBZone small business concerns have an equitable chance to compete for subcontracts.

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

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

(11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate small, small disadvantaged, women-owned, and HUBZone small business concerns and award subcontracts to them.

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

(13) **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.

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

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

The factor entitled “Extent of Small Disadvantaged Business Participation” as set forth under the Evaluation Criteria in Section M shall be used for evaluation purposes. Credit under this evaluation factor is not available to SDB concerns that receive a Price Evaluation Adjustment (PEA) under FAR 19.11. Therefore, an SDB will be evaluated on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

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

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

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

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

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

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

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

(15) **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.

(16) **Salary Rate Limitation in Fiscal Year 2002 ****

Offerors are advised that pursuant to P.L.___*___, no NIH 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, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.).

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I*. The salary rate limitation set by P.L. _*__ applies only to Fiscal Year 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. _*__ states in pertinent part:

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

***FY-2002 information is pending passage of legislation. Information regarding the FY02001 rate can be found at: http://www.opm.gov/oca/01tables/execses/html/01execsc.htm.**

(17) **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.

(18) **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.

(19) **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 years and a list of the last FIVE contracts awarded, which are currently in process that are similar in nature to the solicitation work scope. 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 a subcontract that exceeds $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.

(20) **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/ .

(21) **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):

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

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

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 that 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) that 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/omb/circulars/a130/a130trans4.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

a) 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) Cost Elements

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

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

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

3. **Subcontracted Items.** Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with offeror's design, specifications, or direction and that are applicable only to the prime contract. For each subcontract over $500,000, the support should provide a listing by source, item, quantity, price, type of subcontract, degree of competition, and basis for establishing source and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.806.

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

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

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

7. **Indirect Costs**. Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns. Show trends and budgetary data to provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

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

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

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

11. **Royalties**. If royalties exceed $1,500, you must provide the following information on a separate page for each separate royalty or license fee:

    - Name and address of licensor.
    - Date of license agreement.
    - Patent numbers.
    - Patent application serial numbers, or other basis on which the royalty is payable.
    - Brief description (including any part or model numbers of each contract item or component on which the royalty is payable).
    - Percentage or dollar rate of royalty per unit.
    - Unit price of contract item.
    - Number of units.
    - Total dollar amount of royalties.
    - If specifically requested by the Contracting Officer, a copy of the current license agreement and identification of applicable claims of specific patents (see FAR 27.204 and 31.205-37).

12. **Facilities Capital Cost of Money**. When you elect to claim facilities capital cost of money as an allowable cost, you must submit Form CASB-CMF and show the calculation of the proposed amount (see FAR 31.205-10).

(4) **Formats for Submission of Line Item Summaries**

The detailed breakdown shall be in the format as shown on the form **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours** (SECTION J, List of Attachments). For each separate cost estimate, the offeror must furnish a breakdown by cost element as indicated above. In addition, summary total amounts shall be furnished. In the event the RFP cites specific line items, by number, a cost breakdown for each line item must be furnished.

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

(5) **Qualifications of the Offeror**

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

(1) **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.

(2) **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.

(3) **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.

(4) **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.

(5) **Pertinent Grants**

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

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

(6) **Other Administrative Data**

a) **Property**

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

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

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

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

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

b) **Royalties**

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

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

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

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

d) **Financial Capacity**

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

e) **Incremental Funding**

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

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

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

(a) Facilities capital cost of money [(see FAR 15.408(h)] will be an allowable cost under the contemplated contract, if the criteria for allowability in subparagraph 31.205-10(a)(2) of the Federal Acquisition Regulation are met. One of the allowability criteria requires the prospective Contractor to propose facilities capital cost of money in its offer.

(b) If the prospective Contractor does not propose this cost, the resulting contract will include the clause Waiver of Facilities Capital Cost of Money.

(End of Provision)

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

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

[ ] The prospective Contractor has not specifically identified or proposed facilities capital cost of money in its proposal and elects not to claim it as an allowable cost under the contract.

(7) **Subcontractors**

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

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

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

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

d) Information on their cognizant field audit offices.

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

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

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

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

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

(9) **Representations and Certifications**

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

(10) **Travel Costs/Travel Policy**

a) Travel Costs - Commercial

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

b) Travel Policy

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

PART IV

SECTION M - EVALUATION CRITERIA

PHASE I - REQUIREMENTS ASSESSMENT

- TECHNICAL EVALUATION FACTORS FOR AWARD

PHASE I
TECHNICAL 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, Past Performance, and Small Business and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, cost/price, past performance, and Small Business and SDB participation are also important to the overall contract award decision. In any case, the Government reserves the right to make an award to that offeror whose proposal provides the best overall value to the Government.

Offerors must submit a technical proposal that addresses only Phase I of this project. The following discussion of technical evaluation factors pertains to Phase I only.

The evaluation will be based on the demonstrated capabilities of the prospective Contractor(s) 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. EVALUATION OF TARGETS FOR EXTENT OF SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS PARTICIPATION

Evaluation of this component will not be conducted by the NIH Special Emphasis Panel (SEP). The extent of the Offeror's Small Business and Small Disadvantaged Business Participation Targets will be evaluated prior to any communications with offerors leading to establishment of the competitive range. However, this evaluation will not be conducted on any offeror whose proposal will not be admitted to the competitive range on the basis of the results of the evaluation of factors other than SDB. In this phase of the project, the assessment of Small Business and Small Disadvantaged Business Participation will only be used to support the judgment by the Government as it considers all information relevant to the selection decision. The following criteria will apply:

SDB CRITERIA	WEIGHT
1. The extent of participation of Small Business concerns in terms of the value of the total acquisition taking into consideration the complexity and variety of the work Small Business concerns are to perform. Greater emphasis will be given for arrangements where the Small Business shall be performing work appropriate to the scientific objectives expressed in the statement of work.	**10 (Max. for SB)**
2. The extent of participation of SDB concerns in terms of the value of the total acquisition taking into consideration the complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.	**20 (Max. for SDB)**
PLEASE NOTE: In accordance with the above criteria, the participation of capable Small Business concerns qualifies for a maximum of 10 points; the participation of capable Small Disadvantaged Business concerns qualifies for a maximum of 20 points.	

3. PAST PERFORMANCE FACTOR

Evaluation of this component will <u>not</u> be conducted by the NIH Special Emphasis Panel (SEP).

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

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

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

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

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

The offeror is encouraged to provide inclusive narrative accounts and references on relevant past performance, especially on work that is comparable to that procured here. 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 relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the offeror.

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 PHASE I "ADDITIONAL INFORMATION ON THE SCOPE AND REQUIREMENTS OF THE SOLICITATION" SECTION OF THIS SOLICITATION PACKAGE 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 evaluated based on the following factors:

	CRITERIA	WEIGHT
A.	**TECHNICAL APPROACH**	**50**
	The technical approach will be evaluated based on the suitability of the proposed approach to perform the Phase I Statement of Work in its entirety, including the following:	
	1) Conduct a complete systems requirement assessment (the essential contents of which are provided in the Statement of Work - Phase I)	
	2) Design, prototype, and provide a plan for implementation of a system to serve the data analysis and management requirements of a large, heterogeneous, and widely distributed research community; including the demonstrated ability to communicate findings, methods, outcomes, and performance metrics with participating labs and program staff;	
	3) Prototype, establish and maintain a curation service for new and legacy laboratory and clinical data and develop a system to serve the data analysis and management requirements of a large, heterogeneous, and widely distributed research community; including the demonstrated ability to communicate findings, methods, outcomes, and performance metrics with participating labs and program staff; and,	
	4) Lead large-scale projects for systems design and data integration in a life sciences research and clinical setting; including the demonstrated ability to gain consensus for a scientific rationale or an engineering approach relevant to the work statement. This will also include the ability to consistently work in a coordinated and efficient manner with subcontractors and participating centers over the life of the project.	
B.	**PERSONNEL**	**30**
	The suitability of proposed staff with respect to documented relevant training, qualifications, expertise, experience, education, competence, and availability to perform the requirements of the work statement, including:	
	1. Basic and Clinical Life Sciences Research a) documented knowledge and advanced credentials in clinical and basic biomedical research and documented ability to translate that knowledge into information systems which improve life science data acquisition, analysis and dissemination; and, b) documented knowledge and advanced credentials in bioinformatics, biostatistics, chem-informatics, and laboratory automation, including knowledge of laboratory information management systems (LIMS) and all other computer-based methods of data collection and management;	
	2. Computer Science, Systems Integration and Engineering a) documented knowledge, experience and advanced credentials in the widest range of computer-based algorithmic approaches to querying and analyzing data; and, b) documented knowledge, experience and advanced credentials in systems integration, software engineering and project management methods.	
	3. Leadership ability and level of effort a) documented availability and documented related experience of the Principal Investigator/Project Director and the surrounding leadership of the organization to successfully plan and manage the project. b) documented related experience and leadership capacity of lead staff with demonstrated capability of thought leadership in both computer sciences and life sciences relevant to this project and scientific interests of DAIT c) demonstrated involvement in the scientific communities that are currently conducting clinical and basic research in allergy, immunology, and transplantation.	

C.	FACILITIES	20
	The suitability of facilities described with respect to: 1) the availability, accessibility and adequacy of proposed facilities consistent with all project requirements described in the work statement that will enable the offeror to efficiently serve a scientific community based in the continental United States;	
	2) Access to all equipment and other resources necessary for performance of the contract including but not limited to special resources essential to the development and testing of software and systems that address project requirements; test beds, selected software development environments, and engineering methods consistent with best practices or emerging standards;	
	3) Capacity for material and data distribution, including but not limited to telecommunications infrastructure and server capacity, established methods for avoiding data loss and corruption, as well as tracking errors in handling of all materials, communications planning and capacity, and the ability to facilitate scientific communication and collaboration through advanced network-based technology; and,	
	4) Standard operating procedures and business practices, as well as a physical plant appropriate to handle data for scientific and clinical investigation where valuable, sensitive, and proprietary data are routinely generated, used, and exchanged. This would be evidenced by documented and tested information policies governing privacy, human subjects protection, and data access, as well as the exchange, disclosure, and ownership of scientific data.	
	TOTAL POINTS	**100**

PHASE II - IMPLEMENTATION AND OPERATION

- TECHNICAL EVALUATION FACTORS FOR AWARD

PHASE II
TECHNICAL EVALUATION FACTORS FOR AWARD

THIS SECTION PERTAINS TO THE EVALUATION OF THE PHASE II – IMPLEMENTATION AND OPERATION, PORTION OF THIS PROJECT. THE BELOW EVALUATION CRITERIA WILL BE UTILIZED TO EVALUATE THE PHASE I DELIVERABLES, WHICH INCLUDE: THE REQUIREMENTS ASSESSMENT, THE ENVISIONED FUTURE SYSTEM, A DEMONSTRATION OF THE WORKING PROTOTYPE OF THE SYSTEM, AND A PLAN FOR IMPLEMENTING AND MAINTAINING THE SYSTEM (INCLUDING A COMPLETE TECHNICAL AND BUSINESS PLAN FOR PHASE II).

1. GENERAL

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

The following technical evaluation factors pertain to the entire Phase II Statement of Work.

The evaluation will be based on the demonstrated capabilities of the prospective Contractor(s) 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. 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 17.206(b) not to be in the Government's best interest. Evaluation of the options will not obligate the Government to exercise the options.

3. EVALUATION OF TARGETS FOR EXTENT OF SMALL BUSINESS AND SMALL DISADVANTAGED BUSINESS PARTICIPATION

Evaluation of this component will <u>not</u> be conducted by the NIH Special Emphasis Panel (SEP). The extent of the Offeror's Small Business and Small Disadvantaged Business Participation Targets will be evaluated by the Government after the technical evaluation has been completed, but before determination of the competitive range. Evaluation of SDB participation will be assessed based on consideration of the information presented in the Offeror's proposal.

CRITERIA	WEIGHT
1) The extent of participation of Small Business concerns in terms of the value of the total acquisition taking into consideration the complexity and variety of the work Small Business concerns are to perform. Greater emphasis will be given for arrangements where the Small Business shall be performing work appropriate to the scientific objectives expressed in the statement of work.	**10 (Max. for SB)**
2) The extent of participation of SDB concerns in terms of the value of the total acquisition taking into consideration the complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.	**20 (Max. for SDB)**
PLEASE NOTE: In accordance with the above criteria, the participation of capable Small Business concerns qualifies for a maximum of 10 points; the participation of capable Small Disadvantaged Business concerns qualifies for a maximum of 20 points.	

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**.** 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 PHASE II "ADDITIONAL INFORMATION ON THE SCOPE AND REQUIREMENTS OF THE SOLICITATION" SECTION OF THIS SOLICITATION PACKAGE 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 and deliverables related to these requirements, and the qualifications, availability, and experience of the professional and technical personnel necessary to perform contract requirements. Proposals will be evaluated based on the following factors:

	CRITERIA – PHASE II	WEIGHT
A.1.	**TECHNICAL APPROACH: DELIVERABLES**	**30**
	Suitability to conduct Phase II of this project will be judged by the Offeror's performance on the previous Phase I contract as reflected in the deliverables of that Phase I contract and which include a specification of requirements, a high-level design of the envisioned future system, a working system prototype, and an implementation plan.	
	a) Specification of requirements. As specified in <u>Task 1</u> of the Phase I Statement of Work.	
	b) System design and working prototype. As specified in <u>Task 2</u> of the Phase I Statement of Work.	
	c) Implementation Plan. As specified in <u>Task 3</u> of the Phase I Statement of Work. The merit of this plan will be judged in terms of the project objectives, which are to enhance scientific discovery, to improve the testing of new therapies, and to ensure the responsible management of research assets.	

A.2.	**TECHNICAL APPROACH: CAPABILITY TO IMPLEMENT AND OPERATE**	**40**
	The offerors will be evaluated based on their capability to carry out the implementation plan. Factors applied shall include the following abilities:	
	a) Operate a system to serve the data analysis and management requirements of a large, heterogeneous, and widely distributed research community. This will include the ability to establish and maintain a curation service for new and legacy data and develop a system to serve the data analysis and management requirements of participating centers;	
	b) Lead implementation of large-scale projects for systems design and data integration in a life sciences research and clinical setting. This should include the ability to work in a coordinated and efficient manner with subcontractors and participating centers over the life of the project;	
	c) Provide ongoing technical assistance to a large, heterogeneous research community, including the local analysis and curation of data and the development and dissemination of best practices in software engineering and systems integration, as well as appropriate software standards in life sciences research and development;	
	d) Develop new software applications, especially where the analysis, storage, and exchange of scientific data are concerned; including the demonstrated ability to ensure the usability, interoperability, survivability, and portability of all data sets;	
	e) Implement a system for monitoring system performance, including system security. This includes evaluation of the Offeror's Information Technology (IT) Security Plan; and,	
	f) Implement a plan to communicate regularly on complex biomedical and computer science matters with the NIAID project officer and leadership of participating centers throughout the contract period of performance.	
B.	**PERSONNEL**	**15**
	The suitability of proposed staff with respect to documented relevant training, qualifications, expertise, experience, education, competence, and availability to perform the requirements of the work statement, including:	
	1. Basic and Clinical Life Sciences Research:	
	a) documented knowledge and advanced credentials in clinical and basic biomedical research and documented ability to translate that knowledge into information systems which improve life science data acquisition, analysis and dissemination;	
	b) documented knowledge and advanced credentials in bioinformatics, biostatistics, chem-informatics, and laboratory automation, including knowledge of laboratory information management systems (LIMS) and all other computer-based methods of data collection and management*;*	
	c) documented knowledge and advanced credentials in laboratory automation, including knowledge of laboratory information management systems (LIMS) and all other computer-based methods of data collection and management; and,	
	d) documented knowledge in the policy matters affecting the protection of human subjects in life science research as they pertain both to tissue and information.	
	2. Computer Science, Systems Integration and Engineering	
	a) documented knowledge, experience and advanced credentials in the widest range of computer-based algorithmic approaches to querying and analyzing data;	
	b) documented knowledge, experience and advanced credentials in the laboratory systems support required to generate, analyze, and curate life science research data of all types; and,	
	c) documented knowledge, experience and advanced credentials in systems integration, software engineering and project management methods.	
	3. Leadership ability and level of effort --	
	a) documented availability and documented related experience of the Principal Investigator/Project Director and the surrounding leadership of the organization to successfully plan and manage the project.	
	b) documented related experience and leadership capacity of lead staff with demonstrated capability of thought leadership in both computer sciences and life sciences relevant to this project and scientific interests of DAIT.	
	c) demonstrated involvement in the scientific communities that are currently conducting clinical and basic research in allergy, immunology, and transplantation.	

C.	FACILITIES	15
	The suitability of facilities as described with respect to:	
	1. the availability, accessibility and adequacy of proposed facilities consistent with all project requirements described in the work statement that will enable the offeror to efficiently serve a scientific community based in the continental United States;	
	2. access to all equipment and other resources necessary for performance of the contract including but not limited to special resources essential to the development and testing of software and systems that address project requirements test beds, selected software development environments, and engineering methods consistent with best practices or emerging standards;,	
	3. Capacity for material and data distribution, including but not limited to telecommunications infrastructure and server capacity, established methods for avoiding data loss and corruption, as well as tracking errors in handling of all materials, communications planning and capacity, ability to facilitate scientific communication and collaboration through advanced network-based technology; and,	
	4. Standard operating procedures and business practices, as well as a physical plant appropriate to handle data for scientific and clinical investigation where valuable, sensitive, and proprietary data are routinely generated, used, and exchanged. This would be evidenced by documented and tested information policies governing privacy, human subjects protection, and data access, as well as the exchange, disclosure, and ownership of scientific data. The offeror should also provide assurances that the information policies of any participating individuals, laboratories, and institutions are conducive to the full implementation and operation of the envisioned system.	
	TOTAL POINTS	**100**