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.

Purchase Authority: Public Law 92-218, as amended. **NOTE: The issuance of this solicitation does not commit the government to an award.**			
RFP Number: NIH-NIAID-DMID-04-21	***Just In Time:*** [ ] Yes [x] No	Small Bus. Set-Aside [ ]Yes [X]No 8(a) Set-Aside [ ]Yes [x]No NAICS Code: None Size Standard: None	***Level of Effort:*** [ ] Yes [x] No ***Total Effort:*** [N/A]
TITLE: **TB Vaccine Testing and Research Materials**			
Issue Date: October 8, 2003	***Due Date:*** ***02/06/2004*** ***Time:*** **4:00 PM, EST**		***Technical Proposal Page Limits:*** [X] Yes *(see "How to Prepare and Submit Electronic Proposals")* [ ] No

ISSUED BY:	[X] ***We reserve the right to make awards without discussion.***	
Jacqueline C. Holden Contracting Officer Contract Management Branch, DEA NIH, NIAID 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, MD 20892-7612	***NO. OF AWARDS:*** [X] Only 1 Award [ ] Multiple Awards	***PERIOD OF PERFORMANCE:*** 7 years beginning on or about 9/30/2004

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

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

POINT OF CONTACT **-- Hank Durand** ***--COLLECT CALLS WILL NOT BE ACCEPTED--***

Telephone: ***Direct*** **301-451-3688** ***Main*** **301-496-0612**	***Fax*** **301-402-0972**	***E-Mail*** **HDurand@niaid.nih.gov**

Updated thru FAC 97-25 (05/02/01)

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BACKGROUND / STATEMENT OF WORK / NOTES TO OFFERORS

Background
TB Vaccine Testing and Research Materials
RFP DMID-04-21

The Division of Microbiology and Infectious Diseases (DMID) of the National Institute of Allergy and Infectious Diseases (NIAID) supports a comprehensive program in all aspects of tuberculosis (TB) research (http://www.niaid.nih.gov/dmid/tuberculosis/), including the biology and physiology of the pathogen, host/pathogen interaction, host response to infection by Mycobacterium tuberculosis (Mtb) animal models of infection and disease, as well as research leading to the development of improved vaccines, drugs and diagnostics.
To advance research in TB and accelerate development of novel vaccines, the NIAID is supporting the Tuberculosis Research Materials and Vaccine Testing Contract, currently awarded to Colorado State University (http://www.cvmbs.colostate.edu/microbiology/tb/top.htm), to provide researchers with standardized reagents and vaccine testing services. This contract has proven to be an essential component of support for national and international TB researchers and the NIAID is now re-competing this contract to maintain such a valuable resource.

Since the resurgence of TB in the US during the early 1990s, NIAID has steadily increased funding through its TB programs to support research needs and provide state of the art resources to the community to keep pace with the rapid advances in the field. During the past 10 years, major milestones have been achieved in TB research, marked by the completion of the genome of *M. tuberculosis* (Mtb), the creation of genetic tools to manipulate the pathogen, insights into the immunology of host responses to infection as well as the physiology of the microbe. These advances have led to a transition from basic research to include applied studies for the development of novel vaccines, the identification of promising drug candidates and the evaluation of novel diagnostic methods. This contract enables and facilitates the participation of researchers, many of whom are without the required BSL3 facilities needed to culture quantities of Mtb or evaluate candidate vaccines and drugs, in basic and clinical research projects that require these resources.

This contract will provide standardized research materials, such as inactivated microorganisms, purified protein, lipid and carbohydrate antigens, culture filtrates, nucleic acid constructs and post-genomic reagents. Furthermore, this contract will fund development of advanced techniques and customized tools for the preparation of mycobacterial reagents and genomic analysis of gene expression in mycobacteria and animal models of TB disease. Data generated by these tools will assist the research community by creating standards for laboratory evaluations of commonly studied mycobacterial strains, and vaccine candidates and adjuvants. Furthermore, the contractor will provide expert guidance in the design, execution, and analysis of targeted experiments for the evaluation of vaccine candidates, adjuvants and immune-modulators.

Statement of Work
TB Vaccine Testing and Research Materials
RFP DMID-04-21

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

[GENERAL NOTE TO OFFEROR]

A. Development, Production and Characterization of Research Reagents and Mycobacterial Strains:

As directed by the Project Officer, the contractor shall:

A1.Systematically characterize virulent clinical strains/isolates and commonly used virulent reference strains of Mtb as well as of *M. bovis* BCG with regard to:

a. Their protein expression profile and antigen composition when grown under a series of identical laboratory conditions.
b. Their virulence in animal models of infection and disease by assessing parameters such as, but not limited to, growth kinetics, organ burden and other relevant measures.
c. Their suitability as challenge strains when used with standardized vaccine constructs under identical test conditions.
d. Any potential difference among strains when used as challenge material in standardized vaccine testing models with reference vaccines.

[NOTE 1 TO OFFEROR]

A2. Develop methods and protocols for the preparation, scale up, purification, characterization and quality control of recombinant and native mycobacterial antigens, proteins, lipids and lipoglycans, monoclonal and polyclonal antibodies, as well as mycobacterial cellular fractions.

a. Using selected and well characterized reference strains of Mtb, develop or utilize optimized techniques and methods for the preparation of non-recombinant mycobacterial antigens, proteins, lipids and lipoglycans, and of cellular fractions and make these methods available to the research community (as publications or upon request).
b. Develop methods to produce recombinant mycobacterial proteins in appropriate hosts. For this, develop or implement molecular techniques to clone and express selected recombinant antigens/proteins. Furthermore, evaluate appropriate bacterial species for their suitability to express active and/or immunogenic mycobacterial proteins, and for their suitability to facilitate large scale production and purification of recombinant mycobacterial proteins.
c. Develop suitable assays to characterize and validated the biological activity of native and recombinant antigens and proteins and lipids from large-scale preparations as well as from selected small scale preparations, where appropriate.
d. Prepare short protocols for protein expression, quality control and suggested purification to be distributed with recombinant clones and plasmids carrying recombinant mycobacterial proteins. This is to facilitate production of these proteins by outside investigators.
e. Develop and validate methods for inactivation of virulent mycobacterial cells harvests that are intended for distribution to outside investigators or that will be used for the preparation of research reagents. Cell inactivation shall be done using methods that will not interfere with the intended use of the preparations. These methods may include, but are not limited to gamma irradiation, heat or chemical inactivation. Quality control procedures for verification of cell death shall also be developed.

[NOTE 2 TO OFFEROR]

A3. Using methods validated in Statement of Work A2, identify and prepare relevant antigens, proteins, lipids, lipoglycans and cellular fractions, as well as monoclonal and polyclonal antibodies potentially useful for, but not limited to, a) the

development of diagnostic tools, b) the identification of surrogate markers of disease progression, and correlates of protective immunity; c) the detection of host immune response to infection; and d) immunological assays to support research in TB:

a. Produce large scale batches of wet cell paste for distribution to outside investigators and for use under Statement of Work A3b. For virulent mycobacterial strains, cell pastes are to be inactivated as listed under Statement of Work A2e before making them available to outside investigators. It is anticipated that approximately 25 liters batches of culture may be grown per week and that approximately 2.5 kg of wet call past may be produced per year.
b. Prepare native mycobacterial antigens, proteins, lipids and lipoglycans using well characterized mycobacterial laboratory or clinical strains. It is anticipated that approximately 10 individual native mycobacterial proteins, and approximately 100 mg of lipids/lipoglycans will be produced per year.
c. Prepare mycobacterial cell fractions including, but not limited to culture filtrates, cell wall and surface fractions, membrane proteins, soluble and cytoplasmic fractions. It is anticipated that approximately 5 g of cellular fractions will be produced per year.
d. Prepare sufficient stock cultures of recombinant bacterial clones, expression hosts or sufficient quantities of plasmids carrying recombinant genes for mycobacterial antigens, developed under Statement of Work A2b., for distribution to outside investigators; It is expected that approximately 10 new bacterial expression constructs will be developed per year and that approximately 10 ug of plasmid will be provided to outside investigators.
e. Prepare sufficient quantities of recombinant proteins, developed under Statement of Work A2b. for distribution to outside investigators; It is expected that approximately 10 mycobacterial proteins will be routinely produced in recombinant bacterial hosts and that approximately 500 mg of recombinant protein may be produced per year.
f. Produce polyclonal sera and, where relevant, also purified monoclonal antibodies and culture supernatants to selected antigens. It is anticipated that monoclonal antibodies for approximately 10 antigens may be produced per year and that quantities of approximately 20 mg per purified antibody or 200ml of culture supernatant will be produced.
g. Provide customized large scale preparations of selected reagents to outside investigators where justified. Justification for the need of large scale preparations shall be solicited from requesting investigator and shall be discussed with the Project Officer.

[NOTE 3 TO OFFEROR]

A4. Provide and distribute well-characterized strains/isolates of Mtb and *M. bovis* BCG, as evaluated under statement of Work A1 to qualified researchers. It is expected that approximately 50 stock vials of each strain will be maintained.

A5. Provide and distribute to qualified investigators purified high molecular weight DNA preparations from mycobacterial species, including virulent Mtb.

A6. Produce purified genomic DNA from selected mycobacterial species, including clinical strains/isolates. It is anticipated that genomic DNA will be prepared from up to 5 strains/isolates and approximately 1.5 mg of genomic DNA will be produced per strain/isolate.

A7.Develop customized postgenomic resources for distribution to the qualified researchers and for use under the contract.

a. Produce customized microarray slides for selected mycobacterial species, including multi-species arrays. It is anticipated that approximately 200 array slides may be produced per year.
b. Develop molecular techniques that will facilitate the execution of relevant sections of the statement of work of this contract, such as the characterization of mycobacterial strains as listed in Statement of Work A1. The development of these techniques is not to exceed 5% of total contract activities.

A8. Initiate research collaborations to facilitate custom support through the contract. As part of research collaborations, the contractor shall:

a. Perform custom culture of selected mutant mycobacterial species or reference strains under conditions developed after consultation with outside investigators.
b. Produce reagents from mycobacterial strains submitted by outside investigators.
c. Utilize specialized methods or approaches for custom preparation of mycobacterial reagents.
d. Produce specialized custom genomic and post-genomic reagents as designed after consultation with outside investigators.

e. Conduct custom studies to characterize selected mycobacterial strains and constructs.

[NOTE 4 TO OFFEROR]

B. Organization, Maintenance and Distribution of Research Reagents:

As directed by the Project Officer, the contractor shall:

B1. Organize well characterized research reagents, produced as described in Statement of Work A., in a research reagent bank.

a. Maintain frozen stocks of characterized mycobacterial strains under controlled laboratory conditions.
b. Develop a computerized database to track and control the inventory of these reagents, document requests and shipment, and maintain electronic records of quality control performance.
c. Develop a contract web page summarizing all reagents, services and collaborations available through the contract, listing contact personnel and offering printable forms and instructions for reagent ordering; This web page is expected to be operational no later than 6 month after contract award and is expected to be updated when new reagents become available.
d. Develop quality control procedures and protocols for the characterization of each batch of antigen, protein, lipid and lipoglycans, cell fraction and genetic and genomic material.
e. Establish quality control procedures and protocols for the maintenance of bacterial stocks, seed stock and culture preparations.
f. Establish quality control data sheets for all reagents produced under this contract. These data sheets are intended to disclose the level of purity and the extent of characterization performed for each reagent.
g. Verify the biological activity in relevant assays for large scale preparation of native or recombinant protein, where possible. Biological activity of small scale preparations shall only be performed where relevant.
h. As part of the validation of alternative expression systems for recombinant proteins, where possible, evaluate the biological activity of recombinant proteins in appropriate biological assays.
i. Provide data sheets and culture instructions for each characterized mycobacterial strain as part of the reagent shipment.
j. Establish quality control data sheets for all reagents produced under this contract. These data sheets are intended to disclose the level of purity and the extent of characterization performed for each reagent.
k. Within 3 months of contract award, develop material transfer agreements to cover distribution of all research reagents listed above.
l. Within 3 month of contract award, establish criteria by which to determine qualifications that have to be met by outside investigators to receive research reagents, including post-genomic reagents, through the contract.
m. Package and ship, according to local and federal regulations covering the shipment of potentially infectious and/or hazardous material, requested research reagents to investigators worldwide. It is expected that shipping costs will be paid by the requestor.

[NOTE 5 TO OFFEROR]

C. Vaccine Testing and Optimization of Animal Models:

As directed by the Project Officer, the contractor shall:

C1. Validate and/or optimize existing small animal models of Mtb infection and TB disease for the purpose of estimating the efficacy of experimental agents. For the purpose of this solicitation, experimental agents shall be vaccines, adjuvants and immunomodulatory agents, and may include novel reagents suitable to produce immune protection against Mtb infection or TB disease or enhance the activity of other vaccines and or adjuvants.

a. Establish suitable testing models in mice, guinea pigs or rabbits, utilizing appropriate methods of infection and challenge to result in reproducible endpoints to estimate immune protection of experimental agents.
b. Evaluate the suitability of using multiple parallel or sequential animal models to obtain maximum information about particular experimental agents.
c. Develop standardized protocols and define performance expectations for each model that shall include quality control agents and data on acceptable experimental variability.
d. Establish baseline data for each model with a series of standard reference vaccines, vaccine/adjuvant combinations and/or immunomodulatory agents which will serve as controls for testing of novel candidate agents.

e. Establish activity ranges by which to demonstrate significant differences between reference agents and experimental agents to estimate efficacy.
f. Establish a series of animal models to be used for the evaluation of experimental agents at advanced stages of development for which more detailed assessment of activity is warranted. These models may include endpoints other than bacterial organ burden and may include or histological and immunological readouts.
g. Periodically develop, with input from the Program Officer and the expert panel of advisors, a limited set of scientific questions that need to be addressed to continuously improve the animal models and make them consistent with current scientific advances and findings.

[NOTE 6 TO OFFEROR]

C2. Implement standardized animal models validated under Statement of Work B1 at the relevant contract site(s) to test experimental agents as a service to the research community. Candidates for testing shall be reviewed together with the Project Officer and after consultation with an expert panel of advisors and shall be approved by the Project Officer.

a. Evaluate approved experimental agents in appropriate standardized animal models to estimate immunoprotective efficacy against challenge with virulent Mtb. While procedures shall be standardized, experimental protocols may be modified to obtain relevant information and maximal information about an experimental agent ant to determine its utility for advanced development and testing. It is estimated that approximately 10 novel experimental agents will be tested in approximately 10-20 experiments per year and that approximately 5 advanced candidates will be evaluated.
b. Evaluate preliminary safety and suitability of live, attenuated vaccine candidates, where appropriate, in animal models prior to initiating challenge studies.
c. Conduct preliminary evaluations, where appropriate, to determine optimal protocols and combinations of experimental agents prior to initiating challenge experiments**.**
d. Utilize standardized infection methods for each model and provide methods but may be modified for each test agent.

[NOTE 7 TO OFFEROR]

C3. Within 6 months of contract award, establish standard operating procedures for receipt, review and acceptance of experimental agents for testing. These shall include:

a. Standardized testing request forms, available through the contract web site to specify a set of minimum information that must be submitted as part of each request for testing.
b. Minimum quality control data/information for each experimental agent that must be provided by each investigator submitting an approved experimental agent for testing. This may include, but is not limited to, purity data for proteins and nucleic acids, restriction maps for nucleic acids, and growth characteristics and safety of attenuated live vaccines in animal models. This process is to assure that only high quality, characterized agents will be submitted for testing and that reproducible data will be obtained. The responsibility for producing these data lies with the submitting investigator. The contractor may wish to verify the identity of an experimental agent using these data as a guide.
c. Development of procedures for interaction with outside investigators to assure confidentiality for data obtained through evaluation of experimental agents in animal models.

[NOTE 8 TO OFFEROR]

D. Contract Administration and Performance:

D1. Establish a coordinated plan for the integration of contract services and scientific studies. Scientific studies are to be designed so that contract activities can be improved on a continuous basis and that relevant findings from the research community can be translated to benefit contract activities. This plan is also to include coordination between all activities of the contract that require testing in animals. Close integration of all aspects of the contract is highly desirable will be an expectation for contract performance.

D2. Investigator Training and interaction with the research community to enhance contract activities.

a. Key personnel involved in the design and production of research reagents shall attend at least one scientific meeting or training course over the course of the period of the contract on requirements and quality control procedures for the production of biological materials.
b. Key personnel involved in the evaluation of vaccines, adjuvants and immunomodulatory agents are to attend at least one meeting or training course over the course of the period of the contract, on regulatory requirement for vaccines to be considered for clinical trials and/or the use of animal models in product development.
c. Key personnel is to attend periodic scientific meetings to communicate contract activities, solicit input and present scientific findings derived from contract activities to the community.
d. Conduct work in accordance with the CDC and NIH Guidelines for Biosafety in Microbiological and Biomedical Laboratories, and NIH guidelines for animal care and use. A copy of the applicable Biosafety guidelines can be obtained at: http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm . These guidelines will also apply to all animal models that may be used as part of this contract.
e. Together with the Project Officer, establish an expert panel of advisors no later than 3 month after the contract award. This panel is to participate in the review of requests for testing of experimental agents in animal models, is to participate in annual contract meetings and provide advice to the contractor and the Project Officer on selected topics.
f. Schedule yearly meetings with the Project officer and the expert panel of advisors to discuss contract progress, pending issues and suggestions for improvement.

[NOTE 9 TO OFFEROR]

Notes To Offerors
TB Vaccine Testing and Research Materials
RFP DMID-04-21

NOTES TO OFFEROR

[GENERAL NOTE TO OFFEROR] As part of the Technical Proposal, the offeror is expected to list examples for all approaches, techniques, protocols, models and procedures listed under the Statement of Work, as well as a solid rationale for their selection. Furthermore, the offeror is to demonstrate knowledge in the field of mycobacteriology and relevant animal models by discussing approaches to meet the work outlined in this solicitation. This information shall be in sufficient detail so that the quality of the Technical Proposal can be evaluated. The offeror should also list any shortfalls and alternative approaches that may need to be developed to meet the performance expectations set forth under the Statement of Work. It will be especially critical to address quality control procedures and minimum quality criteria that will be applied to reagents produced under the contract. The offeror is to list these criteria for sample reagents. The procedures and reagents proposed by the offeror may not be the final products produced under this contract. The offeror is to demonstrate expertise in all evaluations that are proposed and shall propose sub-contractors where appropriate. For the development of the Business Proposal, the offeror is to consider quantities and performance expectations listed in the Statement of Work and shall consider flexible production and testing schedules.

[NOTE 1 TO OFFEROR] As part of the Technical Proposal, the offeror shall propose reference strains, provide sample protocols for culture and evaluation of protein profiles of mycobacterial strains and shall provide a justification for their selection. The offeror shall also provide examples of studies to assess virulence and pathogenicity of mycobacterial strains. These evaluations should address whether differences in protein expression exist among reference strains maintained by different laboratories and under different growth conditions and whether these differences may affect results obtained with standardized vaccine candidates in challenge experiments. Clinical strains collected as part of the contract may be drug sensitive or drug resistant. As part of the Business Proposal, assume that a maximum of 10 strains will be characterized each year. These activities are to involve no more than 10% of the overall contract activities.

[NOTE 2 TO OFFEROR] As part of the Technical Proposal, the offeror shall propose a list of research reagents, and a rationale for their selection, that may be produced as part of this contract. The offeror shall furthermore list draft methods and protocols for preparation of selected reagents that may be applicable for work under the contract. This is to include examples for antigens, proteins, lipids and lipoglycans, as well as cell fractions The offeror shall also describe methods and bacterial hosts that may be useful for the production of active and antigenic recombinant proteins from mycobacterial species. The offeror shall furthermore demonstrate that facilities for irradiation of mycobacterial cell cultures, as well as facilities for the large scale production of mycobacterial cultures are available. Reagents provided by the current contract (see http://www.cvmbs.colostate.edu/microbiology/tb/top.htm) may be used as a guide for selection of materials proposed for production. Furthermore, the offeror shall outline quality control procedures that will be implemented for characterization of large scale and small scale protein batches and associated assays for characterization of biological activity, where appropriate, and shall propose methods and quality control procedures for suitable inactivation of virulent Mtb cell harvests.

[NOTE 3 TO OFFEROR] As part of the Technical and Business proposal, the offeror shall outline resources and techniques that may be required to produce research reagents as described in this section of the Statement of Work. The offeror shall also describe what infrastructure and facilities are available to produce these reagents at the extent requested.

[NOTE 4 TO OFFEROR] As part of the Business Proposal, assume that 2-3 active collaborations may be ongoing per year and that these activities will not exceed 5% of contract activities.

[NOTE 5 TO OFFEROR] As part of the Technical Proposal, the offeror shall list examples of web-pages and databases that may be used to meet this section of the Statement of Work and how these electronic tools will be utilized to optimize performance under this contract. The offeror shall furthermore provide examples of data, quality control protocols, quality data sheets and biological assays that may will be provided with individual batches of antigens/protein, as well as provide examples of biological assays that may be useful for the characterization of key or large scale antigens/proteins. The offeror is to provide documentation that space and equipment that will be needed to establish and maintain a reagent bank, and that includes adequate back-up systems, are available. The offeror shall provide examples of Material Transfer Agreements (MTA) as part of the proposal. These MTA shall address confidentiality and shall cover appropriate use of all research materials that may become available through the contract. This is to include prohibited use of research materials for use in humans as part of clinical trials but allow use of research reagents as part of clinical studies when used in laboratory assays with human derived materials. The offeror is to provide examples of criteria that will have to be met by outside investigators to receive reagents through the contract. The offeror is to address specifically using appropriate examples, how post-genomic

reagents will be distributed and what qualifications are expected of outside researchers to receive these reagents through he contract. As part of the Business Proposal, assume that on-line ordering and maintenance of an interactive web-infrastructure will not be part of this contract. Also assume that up to 10 shipments will be made each week.

[NOTE 6 TO OFFEROR] As part of the Technical Proposal, the offeror shall provide protocols describing suitable challenge models in relevant small animal models and shall describe how experimental agents may be characterized in these models. The offeror should propose specific scientific questions that will be addressed and that are geared towards developing a better understanding of the respective animal models and their utility for vaccine testing. This is NOT to include basic research on animal models of infection and disease, but rather how best to design and employ challenge models to estimate vaccine efficacy and potentially, safety.

[NOTE 7 TO OFFEROR] As part of the Technical Proposal, the offeror shall provide examples of how testing of novel experimental, and also more advanced candidates will be conducted as part of the contract. This is to include hypothetical experimental agents and shall address how decisions will be made to move a candidate to different models and/or what performance would be expected from an active agent.

[NOTE 8 TO OFFEROR] As part of the Technical Proposal, the offeror shall provide examples of standard requirements for submitted reagents and a rationale for their selection. The offeror is to propose evaluation criteria for the acceptance of experimental agents and is to proposed decision points to move agents to more advance models.

[NOTE 9 TO OFFEROR] As part of the Technical Proposal, the offeror is to propose plans on how to integrate contract services and contract related research. The Technical Proposal is to include a detailed description of the expertise of the principal investigator and other key personnel or collaborators in working with all aspects of mycobacterial species, particularly virulent Mtb. under BSL-3 conditions, including experience in the design and execution of animal models of Mtb infection and TB disease, and the evaluation of vaccine candidates and related agents in challenge models of tuberculosis, molecular manipulation of mycobacteria, and expression and proteomic technologies and how these individuals will interact to bring their combined expertise to bear on the performance of this contract. The offeror shall also describe expertise utilizing biohazardous and potentially toxic materials, as well as radioisotopes, if the use of the latter is included in the proposal. In addition, procedures for the care of experimental animals shall be discussed. The offeror is to refrain from listing names of past collaborators that may have been involved in contract related activities. The offeror shall propose one overall Principal Investigator for the contract but may propose co-Principal investigators for any of the sub-components of the Statement of Work. The Business Proposal shall include funds for 1-2 key personnel involved in the production of research reagents and 1-2 key personnel involved in vaccine testing to attend the requested courses once during this contract period. The Business Proposal furthermore is to include funds to provide travel costs and per diem (estimates are to be based on government per diem rates) for the expert panel of advisors to attend one contract meeting per year in Bethesda, MD to meet with the Project Officer. Assume that the expert panel will consist of 3-4 scientists, of whom one individual may be from an institution outside the US. It is expected that the PI and Co-PIs will attend this meeting together with 2-3 additional support personnel. The business proposal is also to include funds for one scientific meeting per year for up to 2 key personnel (2 scientific meetings in total per year). One of these meetings may be an international meeting. These meetings are to provide the contractor the opportunity to interact with the research community and provide public updates on contract activities and to communicate important findings.

Reporting Requirements
TB Vaccine Testing and Research Materials
RFP DMID-04-21

Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to technical inspection and requests for clarification by the Project Officer. These shall be brief and factual and prepared in accordance with the following format:

A. Technical Reports:

The Contractor shall prepare and submit the following reports in the manner stated below:

(1) Technical Progress Reports

The Contractor shall submit the semi-annual technical report electronically to the Project Officer and one (1) paper copy to the Contracting Officer at the end of each six month period. Such reports shall include the following specific information:

a. A cover page that lists the contract number and title, the period of performance being reported, the contractor's name and address, the author(s), and the date of submission;

b. SECTION I -An introduction covering the purpose and scope of the contract effort;

c. SECTION II -A description of overall progress plus a separate description for each task or other logical segment of work on which effort was expended during the report period. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project;

d. SECTION III -Substantive performance; a description of current technical or substantive performance and any problems encountered and/or which may exist along with proposed corrective action. An explanation of any difference between planned progress and actual progress, why the differences have
occurred and if behind planned progress what corrective steps are planned;

e. An anticipated work plan for the next six months; and

f. Copies of preprints and published manuscripts shall be submitted along with the report.

Semi-annual Technical Progress Reports are not due for periods in which an annual or final report is due.

(2) Annual Reports

The Contractor shall submit electronically on the anniversary date of the award the Annual Progress Report in addition to one (1) paper copy to the Contracting Officer and the Project Officer one (1) copy on an electronic medium. Such reports shall detail, document, and summarize the results of the entire contract work for the period covered. These report shall be in sufficient detail to explain comprehensively the results achieved. Also to be included in the report is a summary of work proposed for the next reporting period. An annual report will not be required for the period when the final report is due. Preprints and reprints not submitted in the semi-annual report shall be submitted.

(3) Final Report

Thirty (30) days prior to the completion date of the contract, the Contractor shall submit electronically the Final Report as above. These final reports shall detail, document and summarize the results of the entire contract period of performance. These reports shall be in sufficient detail to explain comprehensively the results achieved. Preprints and reprints not included previously shall be submitted.

B. If the Contractor becomes unable to deliver the reports specified hereunder within the period of performance because of unforeseen difficulties, notwithstanding the exercise of good faith and diligent efforts in performance of the work, the Contractor shall give the Contracting Officer immediate written notice of any anticipated delays with reasons, therefore.

C. Technical Progress Report Distribution:

In addition to the electronic submission of each report, paper copy and copies on electronic media of the technical reports shall be submitted as follows:

Copies of the technical reports shall be submitted as follows:

Type of Report	No. Copies	Addressee	Due Dates
Monthly Progress	4	Project Officer (P.O.) DMID/NIAID/NIH 6610 Rockledge Dr., MSC TBD, Room Bethesda, MD 20892-	Specific dates will be listed in the contract document
Monthly Progress	1	Contracting Officer (C.O.) CMB/NIAID/NIH 6700B Rockledge Dr, MSC 7612, Room 2230 Bethesda, MD 20892-7612	Same as above
Milestone Reports	4	Submitted after Milestone completion (3 to Project Officer and 1 to Contracting Officer)	Same as above
Final	4	Submitted with Final Report (3 to Project Officer and 1 to Contracting Officer)	Expiration date
Summary of Salient Results	4	Same as above	Anniversary and expiration dates

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

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

http://rcb.cancer.gov/rcb-internet/wkf/sample-contract.htm

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)

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

52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B., Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays

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

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. 4/2003]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

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

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

FAR 52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns (JANUARY 1999).

"(c) Waiver of evaluation preference.....

[ ] Offeror elects to waive the evaluation preference."

ALTERNATE I (OCTOBER 1998), FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (OCTOBER 1999).

FAR 52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting (OCTOBER 1999).

FAR 52.223-3, Hazardous Material Identification and Material Safety Data (JANUARY 1997), ALTERNATE I (JULY 1995).

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

FAR 52.227-16, Additional Data Requirements (JUNE 1987).

FAR 52.230-3, Disclosure and Consistency of Cost Accounting Practices (APRIL 1998).

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

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

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

HHSAR 352.223-70, Safety and Health (JANUARY 2001) This clause is provided in full text in SECTION J - ATTACHMENTS.

HHSAR 352.270-9, Care of Live Vertebrate Animals (JANUARY 2001).

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

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

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

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

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

This contract incorporates the following clauses in full text.

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

FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS (MAY 2002)

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

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

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

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

(c) (1) The Contractor shall insert the following clauses in subcontracts for commercial items:

(i) 52.219-8, Utilization of Small Business Concerns (OCT 2000) (15 U.S.C. 637(d)(2) and (3)), in all subcontracts that offer further subcontracting opportunities. If the subcontract (except subcontracts to small business concerns) exceeds $500,000 ($1,000,000 for construction of any public facility), the subcontractor must include 52.219-8 in lower tier subcontracts that offer subcontracting opportunities.
(ii) 52.222-26, Equal Opportunity (APR 2002) (E.O. 11246).
(iii) 52.222-35, Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans (DEC 2001) (38 U.S.C. 4212(a)).
(iv) 52.222-36, Affirmative Action for Workers with Disabilities (JUN 1998) (29 U.S.C. 793).
(v) 52.247-64, Preference for Privately Owned U.S.-Flag Commercial Vessels (JUN 2000) (46 U.S.C. Appx 1241) (flowdown not required for subcontracts awarded beginning May 1, 1996).

(2) While not required, the Contractor may flow down to subcontracts for commercial items a minimal number of additional clauses necessary to satisfy its contractual obligations.

(d) The Contractor shall include the terms of this clause, including this paragraph (d), in subcontracts awarded under this contract.

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 6, 2004] (Attached to this listing)

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

RFP FORMS AND ATTACHMENTS:

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

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

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

- **Technical Proposal Cover Sheet**
- **NIH-1688-1, Project Objectives**
- **Technical Proposal Cost Information**
- **Summary of Related Activities**
- **Government Notice for Handling Proposals**

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

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

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Disclosure of Lobbying Activities, OMB Form LLL**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

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

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

ELECTRONIC SUBMISSION: In addition to the paper submission, you are requested to submit your proposal electronically through the CRON (Contracts Review Online) in accordance with the instructions provided below. If you experience difficulty or are unable to transmit, you should submit your proposal on a CD-Rom or ZipDisk by an express delivery service. We can then upload your proposal into the electronic system. You must certify that both the original paper and electronic versions of the proposal are identical. The electronic submission is solely for the benefit of the Agency. Such submission is still in a "test" stage, and the electronic submissions may or may not be utilized, at the sole discretion of the Agency.

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-DMID-04-21
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
Hank Durand Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Hank Durand Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

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

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

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 300 PAGES. PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES. [THIS PAGE LIMIT INCLUDES: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

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

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

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

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

Formatting Requirements:

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

SUBMISSION OF "PROPOSAL INTENT TO RESPOND SHEET":

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

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

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

LOG-IN / TRANSMISSION INSTRUCTIONS:

1. Log-in Site: Will be provided by the Contract Specialist after receipt of the "Proposal Intent Response Sheet"
2. Log-in Name: Will be provided by the Contract Specialist.
3. Log-in Password: Will be provided by the Contract Specialist.

4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.

- You must have Explorer 3.1 or higher.
- It is essential that you use antiviral software to scan all documents.
- Click on "Sign On" and enter your log-in name and password.
- Click on "Browse" to locate your saved files on your computer.
- Click on "Upload Proposal" after you have located the correct file.
- After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
- If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
- If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

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

PROPOSAL INTENT RESPONSE SHEET

RFP No.: NIH-NIAID-DMID-04-21
RFP Title: TB Vaccine Testing and Research Materials

Please review the attached Request for Proposal. Furnish the information requested below and return this page by **January 6, 2004**. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will also 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: Hank Durand
RFP-NIH-NIAID-DMID-04-21
FAX# (301) 402-0972
Email : hd43g@nih.gov

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

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

1. REPRESENTATIONS AND CERTIFICATIONS

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

http://rcb.cancer.gov/rcb-internet/forms/rcneg.pdf

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

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE AND SUBMIT ONE ORIGINAL OF THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT IT AS PART OF YOUR ORIGINAL BUSINESS PROPOSAL. ADDITIONALLY, A COMPLETED ORIGINAL MUST BE SUBMITTED FOR ANY PROPOSED SUBCONTRACTORS.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(3) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.

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

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

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

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

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

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

(11) The Government may disclose the following information in postaward debriefings to other offerors:

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

(End of Provision)

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

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

b. **NAICS CODE AND SIZE STANDARD**

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

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

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

c. **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 ONE AWARD will be made from this solicitation and that the award will be made on/about September 30, 2004 .

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

e. **COMMITMENT OF PUBLIC FUNDS**

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

f. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

g. **RELEASE OF INFORMATION**

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

h. **COMPARATIVE IMPORTANCE OF PROPOSALS**

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

i. **PREPARATION COSTS**

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

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

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

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

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

(End of Provision)

k. **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.

a. Project Objectives, NIH-1688-1

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

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

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

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

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

(5) **Alternate Proposals**

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

(6) **Evaluation of Proposals**

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

(7) **Potential Award Without Discussions**

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

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

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

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

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

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

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

(9) **Care of Live Vertebrate Animals**

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

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

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

b. The following information must be included in the offeror’s technical proposal:

- identification of the species and approximate number of animals to be used;
- rationale for involving animals, and for the appropriateness of the species and numbers used;
- a complete description of the proposed use of the animals;
- a description ofprocedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
- a description of any euthanasia method to be used.

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

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

(10) **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.

(11) **Sharing Research Data**

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

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

**Note to Offeror: If this RFP is for a Multi-Center Clinical Trial or Epidemiological Study, the following paragraph will also apply.*

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

(12) **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.

(13) **Selection of Offerors**

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

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

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

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

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

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

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

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

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

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

(14) **Small Business Subcontracting Plan**

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

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

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

c) The offeror understands that:

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

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

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

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

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

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

d) Each plan must contain the following:

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(15) **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 refernce in ARTICLE I.3. of this solicitation. Qualified HUBZone firms are identified in the Small Business Administration website at http:/www.sba.gov/hubzone.

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

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed $500,000 ($1,000,000 for construction) subject to certain

limitations (see FAR 19.1202-1 and 19.1202-2(b). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

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

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

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

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

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

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	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.

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

NOTE: This award is intended to be made in Fiscal Year 2004. The current Fiscal Year 2003 Salary Rate Limitations should be adhered to in the preparation of your proposal. All costs associated with any resultant award

will be required to be in compliance with the current Fiscal Year 2003 limitations and will be subject to change based on Fiscal Year 2004 Salary Rate limitations.

Offerors are advised that pursuant to P.L. 108-7, no NIH Fiscal Year 2003 (October 1, 2002 - September 30, 2003) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, 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. 108-7 applies only to Fiscal Year 2003 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-7 states in pertinent part:

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

Link to Executive Schedule Salaries: http://www.opm.gov/oca/PAYRATES/index.htm
(click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll down to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years).

(18) **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.

(19) **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.

(20) **Past Performance Information**

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

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

Include the following information for each contract or subcontract:

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

The offeror shall submit comparable information on all subcontractors that the offeror proposes to perform a major subcontract under this effort. For the purpose of this solicitation, a "major subcontract" is defined as exceeding $5000,000.

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.

(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):

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

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

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

(22) **Prohibition on Contractor Involvement with Terrorist Activities**

The Offeror/Contractor acknowledges that U. S. Executive Orders and Laws, including but not limited to E.O. 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the contractor to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under any resultant contract(s).

(23) **Office of Health and Safety – Laboratory Registration / Select Agent Transfer Program**

The awardee is responsible for ensuring that all work under this grant, cooperative agreement, or contract complies with all Federal requirements related to select agents including CDC's that can be found at http://www.cdc.gov/od/ohs/lrsat.htm and NIH's OBA that can be found at http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-02-052.html .

b. **TECHNICAL PROPOSAL INSTRUCTIONS**

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

(1) **Technical Discussions**

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

a) **Statement of Work**

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

b) **Personnel**

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

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

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

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

(4) Resumes

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

(2) **Technical Evaluation**

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

(3) **Additional Technical Proposal Information**

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

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

(4) **Other Considerations**

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

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

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

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

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

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

c. **BUSINESS PROPOSAL INSTRUCTIONS**

(1) Basic Cost/Price Information

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

(2) Proposal Cover Sheet

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

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

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

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

(a) Exceptions from cost or pricing data.

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

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

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

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

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

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

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

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

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

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

(End of provision)

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

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

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

(4) Qualifications of the Offeror

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

a) **General Experience**

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

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

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

c) **Performance History**

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

d) **Pertinent Contracts**

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

e) **Pertinent Grants**

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

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

(5) Other Administrative Data

a) **Property**

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

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

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

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

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

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

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

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

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

c) **Financial Capacity**

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

d) **Incremental Funding**

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

HHSAR 352.232-75, Incremental Funding (January 2001)

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

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

(End of provision)

(6) Subcontractors

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

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

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

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

d) Information on their cognizant field audit offices.

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

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

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

(7) Proposer's Annual Financial Report

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

(8) Representations and Certifications

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

(9) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

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

b) **Travel Policy**

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

(10) Certification of Visa's for Non-U.S. Citizens

Proposed personnel under research projects are not required to be citizens of the United States. However, if non-U.S. citizens are proposed under a contract to be performed in the United States and its territories, then the offeror must indicate in the proposal that these individuals have the required visas.

(11) Guidance Regarding Federal Government Collaborations

In keeping with FAR 3.6 and recent legal decisions involving conflict of interest issues, it is the policy of the NIAID that any proposal either submitted by a Federal agency or submitted by an offeror that includes the collaboration of a Federal agency or Federal employee must include a letter describing the role and effort being provided by that government agency and/or employee and stating that: (1) no actual or potential conflict of interest exists with the proposed effort; and (2) the collaborator's supervisor is aware of and approves of the effort. This letter **must** be signed by **both** the agency's ethics official and the head of the agency (or his/her designate). The NIAID reserves the right to reject a proposal that includes effort by Federal government employees in order to avoid any actual or apparent conflict of interest.

SECTION M - EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: technical, cost, past performance and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, past performance, cost/price and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost/price, when combined, are significantly more important than cost or price. The trade-off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award to other than the lowest priced or highest technically rated offeror. In any event, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

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

2. MANDATORY QUALIFICATION CRITERIA

OFFERORS MUST INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS PROPOSAL INCLUDING AN INDEX WITHIN ITS PROPOSAL WHICH DIRECTS THE REVIEWERS TO THE SPECIFIC AREA OF THE PROPOSAL THAT ADDRESS THE PARTICULAR MANDATORY QUALIFICATION CRITERIA.

THE FOLLOWING MANDATORY QUALIFICATION CRITERIA ESTABLISHES CONDITIONS THAT MUST BE MET AT THE TIME OF SOURCE SELECTION IN ORDER FOR PROPOSALS TO BE CONSIDERED FOR AWARD:

The offeror must have available all facilities that are required to conduct all aspects of the statement of work. This is to include BSL-3 laboratory and animal facilities, equipment to perform aerosol infection and to produce, evaluate and store research reagents, as well as non-BSL-3 laboratories and animal holding space. These facilities and equipment are to be large enough to accommodate the tasks required under this statement of work. The offeror is required to provide adequate documentation as to the availability of these resources as part of the proposal.

PROPOSALS THAT DO NOT MEET THE MANDATORY QUALIFICATION CRITERIA AT THE TIME OF SOURCE SELECTION WILL NOT BE CONSIDERED FOR AWARD.

3. TECHNICAL EVALUATION CRITERIA

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

CRITERA	**WEIGHT**
A. **Technical approach**	**Total 65 Points**

a. SCIENTIFIC MERIT AND TECHNICAL APPROACH FOR THE DEVELOPMENT AND PRODUCTION OF RESEARCH REAGENTS (25 POINTS)
Scientific merit, utilization of current techniques and feasibility of the technical approach are of critical importance. Sample protocols and approaches provided by the Offeror are intended to illustrate feasibility and are intended to provide a framework by which to judge the quality of the proposed technical approach.

The Offeror needs to demonstrate, at a minimum:

- Clear understanding of criteria that need to be assessed as part of the characterization of mycobacterial strains for virulence and for protein expression profiles.
- Suitability of the proposed strategies to select appropriate hosts and strategies to produce recombinant mycobacterial proteins and recombinant plasmids, and suitability of the proposed strategies to produce native mycobacterial proteins.
- Suitability of proposed strategies to produce lipids and lipoglycans, genomic DNA, post-genomic reagents, and intact, killed cells as well as cell fractions and antibodies.
- Suitability of assays proposed for the verification of biological function of selected research reagents.
- Level of integration and suitability of proposed scientific studies to develop improved methods and techniques to better perform the statement of work.
- Clearly described expected outcomes from proposed strategies and clearly defined quality control procedures
- Suitability of examples to outline qualifications that have to be met by outside investigators to receive reagents, including post-genomic reagents, through the contract.
- Presentation of alternative approaches

b. SCIENTIFIC MERIT AND TECHNICAL APPROACH FOR VACCINE TESTING (25 POINTS)
Scientific merit, utilization of validated models and appropriateness of strategies for optimization of existing models are of critical importance. Sample protocols and approaches provided by the Offeror are intended to illustrate feasibility and are intended to provide a framework by which to judge the quality of the proposed technical approach.

The Offeror needs to demonstrate, at a minimum:

- Suitability of performance criteria for each model.
- Relevance of proposed scientific questions to be answered to allow continuous improvement of the models.
- Suitability of the proposed models for the evaluation of potential product candidates.
- Inclusion of appropriate controls and definition of appropriate performance criteria.
- Appropriateness of evaluation criteria for the acceptance of experimental agents and any proposed decision points to move agents to more advance models.

c. SUITABILITY AND FEASIBILITY OF PLANS FOR ADMINISTRATION, MANAGEMENT AND QUALITY CONTROL PROCEDURES (15 POINTS)

The Offeror need to demonstrate, at a minimum:

- Establishment of an appropriate administrative framework and integration of contract services and scientific studies, showing clear lines of authority, and how staff resources will be adjusted to accommodate model and technology development, as well as providing resources and services to the research community.
- Suitable draft quality control procedures and criteria.
- Assessment of how web-sites and proposed databases will facilitate interaction with the research community and will facilitate maintenance and distribution of research reagent, as well as facilitate testing experimental agents at the contract sites.
- Assessment of the applicability of these procedures and criteria to the overall goal of the contract, which is to provide high quality well characterized research reagents and vaccine testing services to the community.

B. **Personnel Qualifications** **Total 25 Points**

The Offeror will be evaluated, at a minimum, on the basis of:

- Documented training, experience and qualifications of the proposed personnel in working with mycobacteria, infectious diseases, and animal models of mycobacterial infection will be evaluated.
- Experience and current participation of personnel in programs similar to that described in the Work Statement.
- The documented qualifications of the overall research team, which may include sub-contractors. This team shall, as a whole, provide all necessary expertise to perform work under this contract.

a) PRINCIPAL INVESTIGATOR(s) (10 POINTS)

The Offeror will be evaluated on the appropriateness of the academic training and experience of the principal investigator(s) to conduct this contract.

The Offeror need to demonstrate for the Principal Investigator, at a minimum:

- Relevance and quality of recent work in the area of mycobacteriology and/or mycobacterial infections.
- Expertise in mycobacterial biology, genetics, biochemistry, molecular biology, vaccine development, immunology and animal models of Mtb infection and tuberculosis.
- Documented ability to manage the proposed project in relation to other commitments.

b) OTHER PERSONNEL/STAFFING PLAN (15 POINTS)

The Offeror need to demonstrate for Other Personnel, at a minimum:

- Relevant experience and documented skills of other professional and technical staff, including sub-contractors, in mycobacterial biology, genetics, general molecular biological techniques, biochemistry and animal modeling with Mtb.
- Adequacy of the staffing plan, including provisions to conduct this model as a service to the community.
- Plans to accommodate fluctuations in workload

C. Facilities and Resources **Total 10 Points**

The Offeror need to demonstrate, at a minimum:

- Suitability, availability and accessibility of laboratory and animal housing space, major equipment and physical facilities required to conduct the proposed studies in a timely and efficient manner.
- Availability of sufficient laboratory and animal space under appropriate (BSL2/3) biosafety containment for the proposed experiments.
- Adequate equipment and computing infrastructure available to produce genomic and post-genomic resources, including microarrays.

Total 100 Points

4. **PAST PERFORMANCE FACTOR**

An evaluation of offeror's past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any offeror whose proposal would not be selected for award based on the results of the evaluation of factors other than past performance.

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

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

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

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

behavior and commitment to customer satisfaction; and generally, the offeror's business-like concern for the interest of the customer.

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

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

5. **EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION**

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

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

Offers will be evaluated on the following sub-factors:

(a) Extent to which SDB concerns are specifically identified
(b) Extent of commitment to use SDB concerns
(c) Complexity and variety of the work SDB concerns are to perform
(d) Realism of the proposal
(e) Past performance of offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
(f) Extent of participation of SDB concerns in terms of the value of the total acquisition.