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

RFP-NIH-NIAID-DMID-05-22
Tularemia Vaccine Development Team

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

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

3. **Issue Date:**	4. **Due Date:** December 1, 2004 **Time:** 4:00 p.m. EST	5. **Small Bus. Set-Aside:** [ ]Yes [X] No **8(a) Set-Aside:** [ ]Yes [X] No **NAICS #:** 541710 (See Part IV, Section L.)
July 13, 2004		

6. **Just In Time:**	7. **Number of Awards:**	8. **Technical Proposal Page Limits:**
[X] No [ ] Yes (See Part IV, Section L.)	[X] Only 1 Award [ ] Multiple Awards	Number of Copies: 12 Page Limitations: 300 Electronic File Size: 10 mega-bytes

9. **Issued By:**	10. [X] **NIAID reserves the right to make awards without discussion.**	
Elizabeth Osinski Contracting Officer Contract Management Program, DEA NIH, NIAID 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	11. **Options:** **[X] No** **[ ] Yes** (See Part IV, Section L.)	12. **Period of Performance:** 5 years beginning on/about August 1, 2005

13. **Primary Point of Contact:**	14. **Secondary Point of Contact:**	15. **Protest Officer:**
Name : Elizabeth Osinski **Phone:** 301-402-6289 **Fax:** 301-402-0972 **E-Mail:** eosinski@niaid.nih.gov	**Name: Jacqueline Holden** **Phone: 301-496-7119** **Fax: 301-402-0972** **E-Mail: jholden@niaid.nih.gov**	Program Director, CMP Address (see Block 9.)

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

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

18. **DELIVERY ADDRESS INFORMATION**

19. **Hand Delivery or Overnight Service:**	20. **U.S. Postal Service or an Express Delivery Service**
Elizabeth Osinski Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Elizabeth Osinski Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

21. The **Official Point of Receipt** for the purpose of determining timely delivery is the address provided in Block 19, above. The original paper copy with original signatures is the official copy for recording timely receipt. If the original paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.

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Background and Introduction

Background

The National Institute of Allergy and Infectious Diseases (NIAID) is the primary institute at the National Institutes of Health (NIH) for emerging infectious disease research including research on pathogens that can be used as agents of bioterrorism. Bioterrorism is defined as the use of microorganisms or the toxins released from them in order to harm people or to elicit widespread fear or intimidation of society."

Events of recent years have significantly changed the world's perception of the nature and degree of threats posed by the use of infectious agents as weapons of bioterrorism. The risk of using such weapons had appeared to be restricted to military encounters. However, the deliberate exposure of postal workers, other government employees and the American public to *Bacillus anthracis* spores highlighted the need to devise safe and effective measures to protect the U.S. population from the lethal and pathologic effects of biological agents.

Tularemia is a zoonotic disease caused by *Francisella tularensis*, a gram negative, facultative intracellular bacterium. The pathogen is most commonly transmitted to humans by contact with infected animals, insect bites (ticks, deer flies, mosquitoes), or inhalation of aerosolized bacteria. Human-to-human transmission has not been documented. *F. tularensis* is highly infectious in that the inhalation of less than 10 cells is sufficient to cause disease. The typhoidal form of the disease follows inhalational infection and leads to a pneumonia, which can cause 30% mortality if untreated or 3% mortality if treated early and aggressively with antibiotics. A vaccine is needed to protect both at-risk researchers and the general public.

NIAID's *Biodefense Research Agenda for CDC Category A Agent* (http://www.niaid.nih.gov/Biodefense/research/biotresearchagenda.pdf) identifies the need for basic resources to ensure a robust *F. tularensis* research program. In the late 1950s, the U.S. Army developed a live attenuated *F. tularensis* vaccine (the Live Vaccine Strain, or LVS) from a live vaccine strain provided by the former Soviet Union. An extensive experimental database documents the ability of LVS to produce protective immunity in animal models and humans. It is widely believed within the tularemia research community that a live attenuated vaccine for tularemia is the most feasible short-term approach. Efforts to develop a subunit vaccine have been unsuccessful to date.

Recent advances in genomics and proteomics, coupled with new information about pathogenesis and attenuation, should enable the accelerated identification of new candidate vaccines. To support the development and evaluation of these candidates, standard research tools are needed. Such tools include animal models that accurately reflect human disease with associated pathology and immune responses, sensitive and specific assays to measure humoral and cell-mediated immune responses, and combined *in vivo* and *in vitro* approaches to assess surrogate markers and correlates of immunity.

Introduction

The goal of this Request for Proposal (RFP) (NIH-NIAID-DMID-05-22) is to award a contract to support the coordinated development of research tools to identify and evaluate new candidates for a safe, effective, general use tularemia vaccine. The NIAID recognizes that the accomplishment of this goal will require a range of research and development capabilities that may not be readily available in a single institutional entity. Therefore, the contract to be awarded in response to this RFP will support the formation of a collaborative team of diverse researchers, laboratories and other organizations to integrate the necessary expertise, and research and development capabilities into a unified, product-oriented project. The Tularemia Vaccine Development Team will carry out research to:

1. Develop and qualify or validate animal models to support vaccine development
2. Assess the relevant humoral and cellular immune responses of the host when exposed to either natural infection or to vaccination through the use of existing *in vitro* tests or assays or through the development of new immunoassays
3. Conduct investigations to correlate protection in animal models with human immunologic responses to *F. tularensis* infections or vaccination using the animal models and immune assays developed
4. Study mechanisms of pathogenesis and/or attenuation to evaluate new vaccine candidates using newly available genomic and proteomic information

To link the necessary experts, facilities and resources, a combination of foreign and domestic, academic and industrial entities are encouraged to collaborate. Foreign entities are permitted to serve as either the Prime Contractor or as subcontractors. The successful conduct of this research effort requires proven scientific and product development expertise, as well as a comprehensive plan for the entire project with clearly defined timelines, objectives and milestones for the entire project.

The NIAID anticipates making a single award under this solicitation.

Tularemia Vaccine Development Team
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Statement of Work

Independently and not as an agent of the government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the work described below.

Specifically, the Contractor shall:

1. **Animal Models:** Develop, improve, establish and/or maintain, as necessary, and qualify or validate, as feasible, appropriate animal models to support tularemia vaccine development. Multiple animal models may be required to assess the full range of vaccine development parameters, including the history of natural infection, the innate and/or adaptive immune responses, the efficacy with an emphasis on aerosol challenge, markers of protective immunity, product potency and similarity to human disease, pathology and immune responses. During contract performance, the Contractor shall assure and continually assess how amenable these animal model(s) are to demonstrating GLP regulatory compliance and to supporting a licensure strategy that is likely to be dependent on the Animal Rule (21 CFR 601.90). (**See Note to Offerors # 2, 9 and 10)**

2. **Immunoassays**: Develop new and/or utilize existing *in vitro* tests or assays to assess the relevant humoral and cellular immune responses of the host when exposed to either natural infection or vaccination. This may include both adaptive and innate immune responses of importance to achieve protective immunity. **(See Note to Offerors #3)**

3. **Correlates of Protection**: Use the animal models and immune assays developed in tasks 1. and 2. above, to conduct coordinated, multidisciplinary investigations that correlate protection in animal models with human immunologic responses to *F. tularensis* infection or vaccination. These correlates shall be used to identify and evaluate new vaccine candidates and to demonstrate efficacy in accordance with the "Animal Rule." **(See Note to Offerors #4)**

4. **New Vaccine Candidates**: Use newly available genomic and proteomic information to conduct studies of the mechanisms of pathogenesis and/or attenuation, such as microbial factors expressed during *F. tularensis* infection (e.g., protein or gene expression, cell signaling, etc.) in order to identify and evaluate new vaccine candidates. **(See Note to Offerors #5)**

5. **Scientific and administrative leadership:** Design and implement a systematic management and administrative plan for furthering tularemia vaccines research that includes developing the tools necessary for identifying and evaluating safe and effective new candidates. The Contractor shall organize, coordinate and manage the basic research and development activities of the contract and manage and coordinate all contract sites and activities. **(See Notes to Offerors #6 and 7)** When multiple investigators are involved, the roles and responsibilities of the participating organizations and individuals must be coordinated carefully and defined clearly.

   a. **Strategic Work Plan:** The Contractor shall design, implement and submit a Final Contractor's Strategic Work Plan encompassing all contract activities. The Contractor's Strategic Work Plan shall link budget, spread by month, to all activities contained in the work plan timeline. The Contractor shall continually update this strategic plan monthly during contract performance in consultation with the NIAID Project Officer. (**See Note to Offerors #1)** The Strategic Work Plan shall include the following:

   (1) Key research and development objectives; For example, a worthwhile objective might be development of two or more animal models acceptable to the FDA such that vaccine candidate efficacy will be demonstrated using the Animal Rule (21 CFR 601.90)
   (2) A detailed description of each step in the research and development process, timelines and milestones for achieving research and development objectives, preferably using Microsoft Project, and the total costs associated with achieving each milestone;
   (3) Plans for ensuring quality control over the implementation and operation of the contract;

(4) A description of the qualitative and quantitative criteria and the decision-making process that will be used in relation to advancing through each stage of the product development process,;
(5) A plan describing the procedures and processes for allocating and utilizing resources in an efficient manner and for redirecting the focus of research, including the reallocation of funds, to capitalize on new knowledge, changing needs and emerging scientific opportunities; and
(6) Procedures for obtaining patent coverage and for the resolution of potential legal issues that may arise. The Contractor shall provide intellectual property agreements signed by all parties involved, outlining procedures to be used for: (1) obtaining patent coverage and licensing wherever applicable (e.g. methods, models, processes), (2) resolving potential legal issues that may arise, such as intellectual property.

b. **Data sharing, Delivery of Data and Compatibility with NIAID Systems**: The Contractor shall manage the information generated, including transmission, storage, validation and statistical analysis in accordance with NIH data sharing policy; details can be found at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-03-032.html. All data generated under this contract shall be delivered to the Government at the end of the contract. The data system used by the Contractor must be compatible with and transferable to the NIAID system. The Contractor may not use any proprietary data management and analysis systems that, upon completion of the contract, are not in a form that is readily usable by NIAID.

c. **Publications:** The Contractor shall coordinate the preparation of all manuscripts and presentations involving studies performed under this contract. The Contractor shall establish and implement a publication policy for results of all studies supported by this contract. All publications and presentations shall acknowledge NIAID support. The Government, through the NIAID Project Officer, shall have access to all data generated from efforts funded under this contract.

d. **Meetings: The Contractor shall** organize and attend meetings including annual site visits (**See Note to Offerors #8**) for the purposes of future planning, study development and/or evaluation, data discussion between co-investigators and other essential personnel, and meeting with NIAID and FDA staff. These meetings shall be arranged at the request of the NIAID Project Officer and shall include NIAID scientific advisors as deemed necessary by the Project Officer. The Contractor's key personnel and relevant staff shall meet with the NIAID Project Officer and other relevant staff and advisors/consultants at periodic intervals to be determined after contract award.

e. **Transition Plan: The Contractor shall** submit a draft Transition Plan to ensure the orderly transition of the contract data, equipment, animals and other materials to Government designated locations/contractors. The Plan shall be submitted to the Government ninety (90) days prior to contract completion and shall be subject to the revisions by the Government. Upon approval by the NIAID Project Officer, the plan shall be implemented.

[END OF STATEMENT OF WORK]

Notes To Offerors
Tularemia Vaccine Development Team
DMID RFP 05-22

General: For items 1 through 4 in the Statement of Work, the Contractor shall address both the conceptual (near-term) and the applied (down-stream) phases of research. Because successive studies and eventual product development efforts will rely on documented results, all work will require high scientific relevance and rationale for product development. During the conceptual phase of the research, the Contractor shall explore proof-of-concept and establish the concept's technical merit and feasibility. If the Contractor meets the defined proof-of-concept milestones, the project may transition to an extensive, applied developmental and/or validation phase. Because of inherent differences in conceptual research and applied research efforts, the Contractor may choose to involve more than one laboratory or entity for accomplishing single or multiple tasks. When multiple investigators are involved in the technical proposal, as well as during contract performance, the roles and responsibilities of the participating organizations and individuals must be coordinated carefully and defined clearly. Relevant data and publications may be submitted as part of the proposal if the Offeror wishes them to be considered as part of the proposal evaluation. Because the design and development path of this research program cannot be entirely anticipated, the Offeror must describe plans for the integration of new scientific findings into the existing goals and milestones.

Note 1. Draft Strategic Work Plan
a. Technical Proposals shall include a draft Strategic Work Plan. This draft Plan, with changes resulting from final negotiations with NIAID, will be incorporated into any resulting contract as well as the relevant components of the Technical Proposal. A final Strategic Plan will be a deliverable under this contract three (3) months after award. The final Strategic Plan will incorporate any changes made during final negotiations, as well as changes resulting from post-award discussions with NIAID.

b. The Contractor's progress shall be determined by the completion of goals and milestones according to the negotiated schedule included in the resultant contract. Proposed criteria for satisfactory completion of milestones shall be included in the Technical Proposal. The Government expects that the Offeror will identify approximately 30-40 significant milestones (i.e. less than 10 per year) for the full 5-year period of performance.

c. The Contractor after award and with the approval of NIAID staff and the Project Officer may have access to other relevant Institute programs and resources as necessary to accelerate progress. This may include access to bacterial strains, prototype vaccines, antibody preparations and other assay reagents, testing facilities and clinical sites that may be available through established NIAID research resources and programs. Nonetheless, work plans, schedules and task-linked budgets shall be proposed for all activities contained in the proposal. Offerors are to link direct cost estimates to goals, milestones and timelines in the Technical Proposal.

Note 2. Animal Models: Offerors shall identify and describe in detail the preferred animal model for a given purpose, including the scientific rationale and the existing data to support meeting the objectives of the contract. Where feasible, a second choice of animal model shall be proposed for each purpose. The NIAID is most interested in approaches based on existing data rather than theoretical plans. Existing site plans for animal testing facilities, especially for proposed BSL-3 work, may be submitted in support of your proposal. The conceptual and applied phases of the animal model research component of this contract may be divided among laboratories for optimal use of expertise and resources. If this approach is taken, include carefully described coordination and transition plans in the Technical Proposal. For any proposed validation effort, cGLP compliance shall be of paramount importance and evidence attesting to the Offeror's cGLP capabilities should be included in your Technical Proposal. A schedule for developing each proposed model shall be presented (preferably MS Project), with key events (establishing parameters such as challenge material and dose, challenge route, vaccination route, measurement of exposure dose, etc.) clearly identified. Important decision criteria for evaluating the success of the model shall be prospectively defined in the proposal. Potential difficulties shall be noted where possible and alternate strategies presented. Where feasible, include for purposes of proposal evaluation the predicted impacts of alternate strategies on cost, schedule and quality of outcome.

Note 3. Immunoassays: Each proposed assay shall be described with underlying scientific rationale supported with methodology and preliminary data where available. Emphasis shall be placed on selecting assays with optimal sensitivity, reproducibility and robustness of data across a wide range of populations, and ease of adaptation to cGLP compliance. Likewise, similar considerations shall be given to the array of potential antigens (e.g. whole or fractionated cells, chemical extracts, etc.) selected for use in the immunoassays. The Offeror may divide the conceptual and applied phases of this effort among laboratories for optimal use of expertise and resources. With such approaches, include carefully described coordination and transition plans. For immunoassay efforts intended for validation, cGLP compliance will be especially

important. Any documentation attesting to the Offeror's cGLP capabilities shall be included in your proposal. A schedule for developing each proposed assay shall be presented (MS Project preferred), with key parameters (such as accuracy, sensitivity, specificity, and robustness) clearly identified as well as decision criteria for evaluating success prospectively. Potential difficulties shall be noted where possible and alternate strategies presented. Where feasible, include for evaluation the predicted impacts of alternate strategies on cost, schedule and quality of outcome.

Note 4. Correlates of Protection: For purposes of proposal evaluation, the Offeror shall list and discuss multiple immune response mechanisms believed relevant to disease progression and/or protection. The Technical Proposal shall provide a detailed rationale and scientific approach for investigating those immune responses that seem to hold most promise as surrogate markers or correlates of protection to *F. tularensis*. The rationale for the choice of factors and the use of animal models shall directly relate to the ultimate goal of this contract: a safe and effective vaccine against tularemia for use in the general population. The goals of the animal model research, the immunoassay work and this surrogate marker component are interconnected and shall be coordinated to achieve maximum synergy. The Offeror shall present a plan describing how the component laboratories will work together to achieve synergy in these three major areas of research. This may entail a description of distinct, sequential goals, with predefined criteria to judge success before proceeding to the next phase. A timeline (MS Project preferred) showing both the conceptual and the applied phases of the research shall be included in the Technical Proposal.

Note 5. New Vaccine Candidates: For purposes of proposal evaluation, the Offeror shall propose microbial factors for evaluation, prioritized and including the associated rationale and research plan. If factors from species other than *F. tularensis* are proposed, include a rationale that details how these studies relate to the ultimate goal of a safe and effective tularemia vaccine for general use.

Note 6. Project Structure: The Government is aware that no single organization or institution may have the expertise and facilities required to perform all requirements set forth in this work statement. Therefore, it may be necessary for the Contractor to subcontract a significant portion of the work. The Offeror's rationale and selection criteria for adding additional subcontractors during contract performance shall be clearly delineated in the Technical Proposal. The NIAID recognizes that the inherent differences in conceptual research and methods validation may require more than one laboratory to participate in accomplishing any single element in the Statement of Work. Where this is the case, the Technical Proposal shall include a clear explanation of the proposed division of labor of the participating laboratories and a well thought out technology transfer plan that includes all facilities, especially any cGLP validation facilities. Subcontractors identified in the Technical Proposal require the same information required of the Prime Contractor such as technical approach, knowledge, methods, facilities, experience, personnel qualifications and work to be performed. Cost details shall be provided for all subcontractors in the same detail as required for the prime Contractor. (**Refer to Section L. Business Proposal Instructions Item (6) Subcontractors)**

Note 7. Project Organization
The Technical Proposal shall delineate clear lines of authority and organization and include a detailed organization chart that outlines the administrative structure, reporting structure, supervisory roles and interactions among the groups and projects. The Offeror must clearly demonstrate the capacity of individuals proposed to manage/staff the proposed projects for both the prime and the subcontractors.

Note 8. Annual Site Visits
The Contractor shall host an annual site visit review for NIAID contract and program staff and their advisors/consultants, the Principal Investigator and all Co-Investigators. The first site visit shall take place not later than six (6) months after award. The location of the meeting may vary depending on results obtained during the reporting period. Pertinent project staff shall present: (1) an update and summary of results generated on each research component of the contract; (2) summaries of all goals and milestones achieved during the review period; (3) a description of all problems encountered that will affect the achievement of future goals,, milestones and costs; (4) proposed approaches to overcome problems, including redirection of research focus and resources where necessary and appropriate; (5) the goals, milestones, development objectives and projected costs for the coming year; and (6) the policies and procedures for monitoring the direction of specific projects and how these policies and procedures have been applied. If foreign subcontracts are involved as part of the team, this annual site visit also shall report details about approvals for work that may have been obtained from both the U.S. and foreign governments. The Offeror shall use the following guidance for cost estimates: two trips per year for the PI, two Co-PIs and other essential staff to attend a one-day meeting in Bethesda, MD; two trips per year for the PI and relevant staff to attend meetings at alternate sites; one trip per year for all key personnel to attend a meeting at the Prime Contractor's site; and travel for the Prime Contractor for monitoring subcontractor performance.

Note 9. Office of Laboratory Animal Welfare Requirement

Vertebrate animals shall be needed for preclinical studies to satisfy regulatory agency requirements and are likely to be used in other studies required under this Contract. The Technical Proposal shall include provisions for complying with NIH guidelines for the humane care and use of laboratory animals as delineated by the Office of Laboratory Animal Welfare (<OLAW; http://grants.nih.gov/grants/olaw/olaw.htm>). Access to and utilization of animal facilities as defined in Paragraph IV.A.2. of the Public Health Service Policy on Humane Care and Use of Laboratory Animals OFFICE OF LABORATORY ANIMAL WELFARE amended August, 2002, shall be required. This document is found at the OLAW web site.

Note 10. Care of Live Vertebrate Animals and AAALAC Certification

In Section L. of this Request for Proposal, Item 27, Care of Live Vertebrate Animals, is applicable to the RFP. The following is added to paragraph b. of Section L. of this solicitation. Paragraph b. of Section L. specifies the information that is required in an offeror's technical proposal:

The information required in Section L., Item 27, (10) b. shall be provided to the maximum extent possible. Protocol synopses, including rationale and study objectives, which include this information shall be provided for all proposed animal studies. However, due to the uncertainty regarding start, number and design of specific studies, detailed study protocols with statistical justifications and IACUC approval prior to award may not be possible. Unlike OLAW Animal Welfare Assurance which is a requirement for contract award, AAALAC certification is not. Nonetheless, AAALAC certification is highly desirable and a copy of this certification, when available, shall be included in the Offeror's Technical Proposal.

Note 11. Technical Proposal Cost Information

The Technical Proposal shall include Technical Proposal Cost Information for the contract's five-year period of performance so that the Offeror's understanding of the project's cost may be evaluated. Cost information shall list costs associated with activities by milestone and must include **direct** cost and resources information, such as labor hours and categories and materials, subcontracts, travel, etc., and associated costs. The technical cost proposal should disclose the Offeror's technical approach in as much detail as possible. However, the technical cost proposal should not include pricing data relating to individual salary information, indirect cost rates or amount, fee amounts (if any), and total costs.

Note 12. Estimate of Effort and Business Proposals by Milestone and Annual Contract Year

Offerors are directed to Section L., Item 14 for an estimate of the annual effort anticipated for this solicitation. Offerors are also advised that two separate sets of Excel Spreadsheets must be submitted in response to this Request for Proposal. One set of Excel Spreadsheets must be proposed by Contract Milestone. The second set shall be by annual Contract periods. The cost proposal by annual Contract period must be based on milestones or partial milestones that are anticipated to be performed in each annual Contract period.

Note 13. Sharing of Model Organisms for Biomedical Research

In the technical proposal, the Contractor shall include a description of a specific plan for sharing and distributing unique model organism research resources generated using NIH funding so that other researchers can benefit from these resources or state appropriate reasons why such sharing is restricted or not possible.

The Contractor shall refer to the web site listed below for information on preparing this plan. This web site includes the NIH Guide notice which includes the NIH POLICY ON SHARING OF MODEL ORGANISMS FOR BIOMEDICAL RESEARCH.

http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-04-042.html

Reporting Requirements and Deliverables
Tularemia Vaccine Development Team
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The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. These reports are subject to the technical inspection and requests for clarification by the Project Officer. The reports 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) Contractor's Final Strategic Work Plan

The Contractor shall continually update this strategic plan during contract performance. This plan shall be submitted three months after the award of the contract and it shall be updated in the monthly technical reports thereafter. This plan shall include the following:

- Key research and development objectives;

- A detailed description of each step in the research and development process, timelines and milestones for achieving research and development objectives, preferably using Microsoft Project, and the total costs associated with achieving each milestone;
- Plans for ensuring quality control over the implementation and operation of the contract;
- A description of the qualitative and quantitative criteria and the decision making process that will be used in relation to advancing through each stage of the product development process,;
- A plan describing the procedures and processes for allocating and utilizing resources in an efficient manner and for redirecting the focus of research, including the reallocation of funds, to capitalize on new knowledge, changing needs and emerging scientific opportunities; and
- Procedures for obtaining patent coverage and for the resolution of potential legal issues that may arise. The Contractor shall provide intellectual property agreements signed by all parties involved, outlining procedures to be used for: (1) obtaining patent coverage and licensing wherever applicable (e.g., methods, models, processes), (2) resolving potential legal issues that may arise, such as intellectual property.

(2) Monthly Technical Progress Reports – On the fifteenth of each month for the previous calendar month, the Contractor shall submit five (5) copies of a Monthly Technical Progress Report, submitting four (4) copies to the Project Officer and one (1) copy to the Contracting Officer. The format and the requirements listed (see item 3. below) for the semiannual progress report, are the same requirements that should be used for the Monthly Report.

(3) Semiannual Progress Reports – The semi-annual progress report is due on the fifteenth of each month following the end of each six-month period. The number of copies and their distribution and the work requirements are the same for both the monthly and the semiannual reports.

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 – The report shall include a description of the 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 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. In addition, Section II shall contain a description of current technical performance and any problems encountered that may exist along

with proposed corrective action. An explanation of any difference between planned progress and actual progress, including why the differences have occurred, and the corrective steps to be taken shall also be provided. A monthly report shall not be required for the period when the semi-annual or final report is due. Preprints and reprints of papers and abstracts shall be submitted on an annual basis.

d. SECTION III – For the monthly report, this section shall include an anticipated work plan for the upcoming month. For the semi-annual report, the anticipated work plan shall be for the upcoming six months.

e. SECTION IV – Contract Expenditures and Subcontractor Billing

This section shall contain a narrative statement as to whether there is any discrepancy at this time between the % of work completed and the % of cumulative costs incurred to date with regard to planned effort and proposed budget. Section IV of this report shall also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. These shall be listed for each Subcontractor. If the subcontractors were not working or did not incur any costs in the current or the previous month, then a statement to this effect shall be included in the monthly report for those respective subcontractors.

(4) Milestone Reports - A milestone report shall be provided after the completion of each Milestone unless otherwise agreed upon by the Principal Investigator and the Project Officer. Milestone reports and monthly reports may be combined if agreed by the Contracting Officer and the Project Officer.

(5) Final Report – By the completion date of the contract, the Contractor shall submit five (5) copies of a comprehensive Final Report, as above, submitting four (4) copies to the Project Officer and one (1) copy to the Contracting Officer. This final report shall detail, document and summarize the results of the entire contract work for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved. Preprints and reprints not submitted previously shall be submitted.

(6) Summary of Salient Results - With the annual and final reports, the Contractor shall submit a summary (approximately 200 words) of salient results achieved during the performance of the contract.

(7) Research Data – All data developed during the course of this contract shall be delivered to the Government no later than the completion date of this contract. The data must be compatible with the NIAID data systems and transferable to NIAID.

(8) Transition Plan - This draft plan shall be submitted 90 days before the completion date of this contract. This plan shall insure the orderly transition of the contract data, equipment, animals and materials to Government designated locations/contractors.

(9) Intellectual Property Agreements - After award, the Contractor shall be required to provide an agreement, signed by all parties involved, outlining procedures to be used for: (1) obtaining patent coverage and licensing wherever applicable (e.g., methods, models, processes), (2) resolving potential legal issues that may arise, such as intellectual property. The Offeror shall also obtain any necessary patent coverage and/or licensing for the use of all substances and technologies used to execute the Statement of Work.

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.

I.1. General Clauses

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

The following General Clause Listings will be applicable to most contracts resulting from this RFP. However, the organizational structure of the successful offeror(s) will determine the specific General Clause Listing to be contained in the contract(s) awarded from this RFP:

Negotiated Cost-Reimbursement Research and Development Contract

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

ITEM 9: **Alternate II** (OCTOBER 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (OCTOBER 2001) is added.

No additional or supplemental Authorized Substitutions of Clauses are applicable to this solicitation. See **I.2 Authorized Substitutions of Clauses** of SECTION I at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf for the general listing of Authorized Substitutions of Clauses.

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

ITEM 34: FAR Clause **52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns** (JUNE 2003), is applicable to this solicitation as follows:

"(b) Evaluation adjustment. (1) The Contracting Officer will evaluate offers by adding a factor of 10% percent to the price of all offers, except--...".

Offerors will be evaluated by adding a factor of 10% to the price of all offers, except offers from disadvantaged business concerns that have not waived the adjustment.

No additional or supplemental Additional Contract Clauses are applicable to this solicitation. See **I.3 Additional Contract Clauses of** SECTION I at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf for the general listing of Additional Contract Clauses.

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

No additional or supplemental Additional FAR Contract Clauses Included in Full Text are applicable to this solicitation. See **I.4. Additional FAR Contract Clauses Included in Full Text** of SECTION I at http://rcb.cancer.gov/rcb-internet/wkf/sectioni.pdf for the general listing of Additional FAR Contract Clauses Included in Full Text.

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: (http://www.niaid.nih.gov/contract/eproposal.htm#pack)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (http://www.niaid.nih.gov/contract/eproposal.htm#electronic)

PROPOSAL INTENT RESPONSE SHEET SUBMIT ON/BEFORE: October 11, 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 *although not binding* is critical as it contains information essential for CMP'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**
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours**
- **Two separate sets of Excel Spreadsheets, one by Milestone and the other by Annual Contract Year must be submitted (See Note 12)**
- **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**
- **Report of Government Owned, Contractor Held Property**
- **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. On the cover sheet of the business proposal, the offeror 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-05-22
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 twelve (12) unbound copies. Twelve (12) 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
Elizabeth Osinski Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214 Bethesda, Maryland 20817	Elizabeth Osinski Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, Maryland 20892-7612

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

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

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. THIS PAGE LIMIT EXCLUDES PUBLICATIONS. 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 a limit of ten (10) megabytes 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.
- Documents must be converted to a .pdf searchable format.
- 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 RESPONSE 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 via e-mail.
3. Log-in Password: Will be provided by the Contract Specialist via e-mail.

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—05-22
RFP Title: Tularemia Vaccine Development Team

Please review the attached Request for Proposal. Furnish the information requested below and return this page by October 11, 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:
CMP, NIAID, NIH
Room 3214
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Elizabeth Osinski
RFP-NIH-NIAID- DMID-05-22
FAX# (301) 402-0972
Email : eosinski@niaid.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

The following information is specific to this solicitation and is provided to supplement and/or complete the associated ITEMS presented at the SECTION L website at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf

I. GENERAL INFORMATION

ITEM 2: **Alternate I, of FAR Clause 52.215-1, INSTRUCTIONS TO OFFERORS-COMPETITIVE ACQUISITION,** is applicable to this solicitation.

ITEM 9: **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 NAICS Code is 541710.
(2) The small business size standard is 500 employees or less.

ITEM 11: **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.

ITEM 12: **TYPE OF CONTRACT AND NUMBER OF AWARD(S)**

It is anticipated that ONE AWARD will be made from this solicitation and that the award(s) will be made on/about August 1, 2005 .

It is anticipated that the award from this solicitation will be a multiple-year COST REIMBURSEMENT type COMPLETION contract with a PERIOD OF PERFORMANCE OF 5 years and that incremental funding will be used.

ITEM 14: **ESTIMATE OF EFFORT**

It is expected that a Cost Reimbursement Completion type contract will be awarded as a result of this RFP. To assist offerors in the preparation of proposals, the Government considers the effort to be estimated at approximately 66,000 labor hours per year for the 5-year period of performance. The estimated effort above includes the total annual effort for this project, including both prime and subcontractor effort. The prime contractor shall propose the division of labor between the prime and the subcontractors based on its technical approach to this project. The hours listed above are for guidance only for proposal preparation purposes and are not to be considered restrictive. The hours for this project will be negotiated based on the Contractor's proposed effort for the technical milestones proposed in the Contractor's draft strategic work plan. The Contractor's cost estimate will be based on budget linked to milestone activities contained in the work plan and the timeline. The milestone linked budget will be spread by month and by annual contract years.

ITEM 17: 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.

ITEM 21: LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70, is applicable to this solicitation.

II. GENERAL INSTRUCTIONS

ITEM 24: Potential Award Without Discussions, is applicable to this solicitation.

ITEM 27: Care of Live Vertebrate Animals, is applicable to this solicitation.

ITEM 28: Possession, Use and Transfer of Select Biological Agents or Toxins, is applicable to this solicitation.

ITEM 30: Sharing Research Data, is applicable to this solicitation.

ITEM 34: Small Business Subcontracting Plan, is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

The anticipated minimum subcontracting goals for this RFP are as follows:

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

ITEM 36: Extent of Small Disadvantaged Business Participation, is applicable to this solicitation.

ITEM 38: Salary Rate Limitation in Fiscal Year 2004, is applicable to this solicitation.

ITEM 41: Past Performance Information is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

Past Performance information shall be submitted as part of the Business proposal. A list of the last 5 contracts completed during the past three years and the last contracts awarded currently in process that are similar in nature to the solicitation workscope.

ITEM 50: Prohibition on Contractor Involvement with Terrorist Activities, is applicable to this solicitation.

ITEM 51: Solicitation Provisions Incorporated by Reference, FAR 52.252-1 (February 1998), are applicable to this solicitation.

a) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).

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

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

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

III. TECHNICAL PROPOSAL INSTRUCTIONS

ITEM 53: Project Objectives, NIH-1688-1, is applicable to this solicitation.

IV. BUSINESS PROPOSAL INSTRUCTIONS

ITEM 58: Proposal Cover Sheet, is applicable to this solicitation.

ITEM 59: Information Other than Cost or Pricing Data , is applicable to this solicitation.

[X] This information may be submitted in the offeror's own format.
[ ] This information shall be submitted in the following format.

ITEM 60: Level of Detail, is applicable to this solicitation.

ITEM 61: Cost and Pricing Data is applicable to this solicitation.

Subparagraph 3. Formats for Submission of Line Item Summaries:

[X] The format specified in SECTION L at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf is applicable to this solicitation.
[ ] The following format shall be used in lieu of the one specified in SECTION L at http://rcb.cancer.gov/rcb-internet/wkf/sectionl.pdf :*

ITEM 67: Incremental Funding, is applicable to this solicitation.

ITEM 69: Certification of Visa's for Non-U.S. Citizens, is applicable to this solicitation.

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. **EVALUATION OF DATA SHARING PLAN**

The offeror's plan for the sharing of final research data, or, if data sharing is not possible, the offeror's documentation of its inability to share research data, shall be assessed for appropriateness and adequacy.

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.

CRITERIA **WEIGHT**

1. Scientific and Technical Approach

60 Points

a) Scientific and technical appropriateness, adequacy and feasibility of the proposed plans to develop animal models with attributes included in the Statement of Work. (15 Points)

b) Scientific and technical appropriateness, adequacy and feasibility of the proposed immunological assays as described in the Statement of Work. (15 Points)

c) Scientific and technical appropriateness, adequacy and feasibility of the plans to develop correlates of immunity as described in the Statement of Work. (10 Points)

d) Scientific and technical appropriateness, adequacy and feasibility of the proposed plans for developing and evaluating proposed new vaccine candidates. (10 Points)

e) Scientific and technical appropriateness of the Draft Strategic Work Plan. (10 points)

2. Personnel

30 Points

a) Adequacy and appropriateness of the documented experience, education, training and availability of the Team investigators and other personnel proposed to accomplish all tasks identified in the Statement of Work. (15 points)

b) Adequacy and appropriateness of the demonstrated ability of the key personnel to manage complex and diverse medical product research and development projects (15 points)

3. Facilities

10 Points

a) Documented availability of adequate facilities for conducting all phases of the proposed research as specified in the Statement of Work including product development and documentation of capacity for accomplishing the stated tasks (especially for BSL3 aerosol capability), and access to appropriate animal facilities.

Total Score (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 mechanical or mathematical analysis of an offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

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

The 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) Complexity and variety of the work SDB concerns are to perform
(b) Extent of participation of SDB concerns in terms of the value of the total acquisition.