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

RFP-NIH-NIAID-DAIT-BAA-05-10
Modeling Immunity for BioDefense

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**

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.

1. Issue Date:	2. Due Date: November 23, 2004 **Time:** 4:00 PM	**3. Small Bus. Set-Aside:** [ ]Yes [X] No 8(a) Set-Aside: [ ]Yes [X] No NAICS #: 541710 (See Part IV, Section L.)
August 20, 2004		

4. Just In Time:	5. Number of Awards:	6. Technical Proposal Page Limits:
[X] No [ ] Yes (See Part IV, Section L.)	[ ] Only 1 Award [X] Multiple Awards	Number of Copies: See SECTION J Page Limitations: 100 Electronic File Size: 5 mega-bytes

7. Issued By:	8.	
Carl A. Newman Contracting Officer Contract Management Program, DEA NIH, NIAID, DHHS 6700-B Rockledge Drive Room 3214, MSC 7612 Bethesda, MD 20892-7612	[X] NIAID reserves the right to make awards without discussion.	
	9. Options: **[X] No** [ ] Yes (See Part IV, Section L.)	10. Period of Performance: Five (5) years beginning on or about July 29, 2005

11. Primary Point of Contact:	12. Secondary Point of Contact:	13. Protest Officer:
Name : Robert J. Singman Phone: 301-451-2607 Fax: 301-480-4675 **E-Mail:** rsingman@niaid.nih.gov	Name: Carl A. Newman Phone: 301-496-8371 Fax: 301-480-4675 **E-Mail: cnewman@niaid.nih.gov**	Program Director, CMP Address (see block 7.)

14. COLLECT CALLS WILL NOT BE ACCEPTED. FACSIMILE SUBMISSIONS ARE NOT ACCEPTABLE.

15. 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)

16. DELIVERY ADDRESS INFORMATION

17. Hand Delivery or Overnight Service:	**18. U.S. Postal Service or an Express Delivery Service**
Robert J. Singman Contract Management Program, DEA NIAID, NIH, DHHS 6700-B Rockledge Drive, Room 3214 Bethesda, MD 20817	Robert J. Singman Contract Management Program, DEA NIAID, NIH, DHHS 6700-B Rockledge Drive, Room 3214, MSC 7612 Bethesda, MD 20892-7612

19. 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.

Updated thru FAC 2001-23 (5/05/2004)

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BROAD AGENCY ANNOUNCEMENT DESCRIPTION

You are invited to submit a proposal in accordance with the requirements of this BROAD AGENCY ANNOUNCEMENT (BAA) (NIH-NIAID-DAIT-BAA-05-10) entitled "Modeling Immunity for BioDefense." The Broad Agency Announcement is authorized by FAR 6.102 and further described in FAR 35.106 as well as the NIH Manual Issuance 6035, Broad Agency Announcements. A BAA is a general announcement of an agency's research interest and constitutes a solicitation. The intent of a BAA is to encourage the submission of creative and innovative approaches to specific research areas identified by the Government.

A proposal submitted in response to this BAA must present a detailed technical and cost proposal designed to meet the Research and Technical Objectives described in this announcement. The proposal must be signed by an official authorized to contractually commit the submitting organization.

The Statement of Work, including the specific work requirements and performance specifications, is developed and defined by the Offeror, not the Government. The Statement of Work should not exceed ten (10) single spaced-pages in length within the technical proposal, which is limited to one hundred (100) pages total.

Proposals are not evaluated against a specific Government need, as in the case of a conventional Request for Proposal (RFP), since they are not submitted in accordance with a common Statement of Work issued by the Government. Instead, Research and Technical Objectives are provided in the BAA that describe the research areas in which the Government is interested. Proposals received as a result of the BAA are evaluated by a Scientific Review Group (SRG) in accordance with the Evaluation Criteria specified in the BAA.

There is no Source Selection Determination utilized under the BAA process. All the competing proposals are ranked on the basis of their respective relevance and scientific merit. The score assigned by the SRG is considered the final score. An Order of Merit Ranking is established by the Contracting Officer in lieu of a Competitive Range.

Negotiations are conducted with those Offerors in the Order of Merit Ranking whose proposals would comprise the best group of contractors to fill the NIAID's needs for this project based on technical merit, available funds, scientific priority, and programmatic balance. During negotiations, there is an opportunity to refine the proposed Statement of Work in consultation with the Project Officer, including the incorporation of the comments of the SRG, as appropriate. At the conclusion of negotiations with the Offerors selected from the Order of Merit Ranking, those Offerors are allowed the opportunity to submit a Final Proposal Revision (FPR) to address weaknesses in the proposal, based on issues identified by the SRG and to revise costs as may be appropriate.

It is anticipated that multiple awards will result from this announcement and these awards will be multi-year, cost-reimbursement, and completion type contracts. The NIAID anticipates awarding up to three (3) contracts based on technical merit, available funds, scientific priority, and programmatic balance. Awards are expected to be made on or about July 29, 2005. The NIAID estimates that the average annual total cost (direct and indirect cost combined) for these contracts is $1 million to $2 million per contract. However, it is anticipated that the total cost for each award may vary substantially depending upon the scope of the project and the technical objectives of the award. The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. The maximum period of performance is five (5) years.

The award document will be tailored to the final negotiations with the selected Offeror(s) and modified as appropriate for the type of contractor organization, cost and/or fee arrangements, and other elements as negotiated prior to award.

RESEARCH AND TECHNICAL OBJECTIVES

This section presents the technical objectives that the Government seeks to achieve through this BAA. Proposals should explain how the Offeror will contribute to these overall objectives. In contracts awarded as a result of this BAA, the Statement of Work will be the Statement of Work proposed by the Offeror and negotiated and accepted by the Government.

When preparing proposals in response to this BAA, offerors must review the "Technical Proposal Instructions for Broad Agency Announcements" included in Section L, Part III and the "Evaluation Factors for Award" included in Section M of this RFP for additional information.

INTRODUCTION

The National Institute of Allergy and Infectious Diseases (NIAID) of the National Institutes of Health (NIH) supports research related to basic understanding of microbiology and immunology leading to the development of vaccines and novel therapeutic agents for the prevention and treatment of infectious and immune-mediated diseases, and improvements in public health. As part of its research program to improve defense against potential agents of bioterrorism, the NIAID seeks to establish Immune Modeling Centers (hereinafter referred to as Centers). These multi-disciplinary Centers will develop novel or improved highly predictive mathematical models to define host immune responses to infection, as well as vaccination and other therapeutic interventions used to protect against NIAID Category A, B and C Priority Pathogens (**http://www.niaid.nih.gov/biodefense/bandc_priority.htm**). In some cases, immunological mechanisms relevant to biodefense are broadly applicable for many pathogens and may be most efficiently studied using model systems. Inclusion of immunological research that is not directed specifically at NIAID Category A, B and C Priority Pathogens or their products is responsive to this solicitation if it directly addresses a practical approach to developing mathematical models to define host immune responses to infection, as well as vaccination and other therapeutic interventions against NIAID Category A, B, or C pathogens. This correlation should be described very clearly in the proposal. Knowledge gained from these studies will advance our understanding of the delicate balance required to induce protective immunity and guide laboratory experiments of host immune responses against infectious agents. Results obtained from these programs will sharpen our assessments of vaccine efficacy and responses to other prophylactic and therapeutic treatments and will advance development of novel or improved vaccines, prophylactics, and immunotherapeutics against NIAID Category A, B and C Priority Pathogens.

The NIAID expects to award up to 3 contracts for Centers under this Broad Agency Announcement (BAA). Offerors may propose a maximum project period of five (5) years; however, the length of time for which funding is requested should be consistent with the nature and complexity of the proposed research. In addition, it is anticipated that individual awards will vary depending on the scope of the project; average total annual costs are anticipated to be in the range of $1 million to $2 million per award.

This BAA is open to all domestic and foreign sources; subcontracts to domestic and foreign institutions are acceptable.

Award documents will be tailored to the final negotiations with the selected offeror(s) and modified, as necessary, for the type of organization, cost or price arrangements, and other elements as negotiated prior to award.

BACKGROUND

As a part of its biodefense research mission, the NIAID announces a program to support the development of innovative and functional mathematical models of immunity. This BAA will establish multi-disciplinary Centers focused on developing mathematical modeling packages that provide tools for high (whole organism or system), intermediate (tissue or organ), or fine (single cell) resolution modeling of host immune responses to infection and vaccines with a focus on NIAID Category A, B and C pathogens (**http://www.niaid.nih.gov/biodefense/bandc_priority.htm**). In some cases, immunological mechanisms are broadly applicable to many pathogens and may be efficiently studied using model systems. Inclusion of immunological research that is not directed specifically at NIAID Category A, B and C Priority Pathogens or their products is responsive to this solicitation if it addresses a practical approach to inducing, controlling or improving the effectiveness of innate or adaptive immune responses to infection by these pathogens or vaccines to prevent infection. Offerors may also include basic immunological mechanisms when understanding those mechanisms is necessary for the development of protective approaches for biodefense. Offerors not specifically addressing NIAID Category A, B and C Priority Pathogens or their products should justify clearly how the proposed studies are applicable to immune responses against the listed agents.

Under this program, the Centers shall conduct basic and applied research to develop new mathematical models or improve existing models of immune responses to NIAID Category A, B and C Priority Pathogens or vaccines and immune-based therapies against these pathogens. The models shall be validated through appropriate immunological experimentation. The multi-disciplinary research team shall consist of immunologists, physicists or engineers, mathematicians, computer scientists, and infectious disease experts. Centers may be “virtual;” however, frequent interactions and communication are key elements to the program’s success. Each Center shall focus on a specific immunological area, such as various aspects of innate or adaptive immunity, or the interface between innate and adaptive immune responses that are critical for protection against pathogens. Each Center will have strong bioinformatics and education components: (i) the bioinformatics component will develop methods and standards for data sharing and communication among the Centers, using open-source protocols, and shall also facilitate the development and distribution of “user-friendly” immune modeling tools to the broader research community; and (ii) the Center-localized education component shall be directed at graduate students, post-doctoral fellows, and visiting scientists within the Centers that provide trainees with an understanding of the power of applying mathematical principles to biological phenomena in immunology.. Drawing from other fields to develop the education programs, such as population genetics, ecology, and epidemiology is encouraged.

In the field of immunology, researchers have used mathematical models to advance the understanding of the dynamics of adaptive immunity, such as antibody generation and specificity, development of CD4+ T cell responses that include parameters for Th1 and Th2 differentiation, generation and maintenance of immunological memory, and predictions of host-pathogen interactions. This BAA will support research to improve the predictive qualities of immune-focused mathematical models, which may be used to extract knowledge from complex data sets and to suggest new experiments; predict vaccine efficacy and responses to other prophylactic and therapeutic treatments; and facilitate the development of novel or improved vaccines, prophylactics, and therapeutics against potential agents of bioterrorism by translating *in vitro* and *in vivo* animal study data into predictions of human immune responses. This program will benefit from current expertise and recent advances in immunology, infectious disease, mathematics, and computational biology.

NIAID Expert Panel: On June 10-11, 2003, the NIAID convened an expert panel of immunologists and mathematical modelers to advise on the state of the art and the scientific needs and opportunities for the development of mathematical models capable of simulating immune responses, directing novel experimentation, and generating a greater understanding of the immune system in infection, vaccination, and immune homeostasis. This panel concluded that mathematical modeling has great potential to deepen our understanding of immunological principles that will drive the development of improved vaccines and immunotherapeutics against infectious agents, as well as provide predictive models of disease outcome, and of the safety and efficacy of candidate vaccines. Development of these mathematical models requires multi-disciplinary teams that combine expertise in computer science, engineering, mathematics, and immunological processes, as well as the technical aptitude to collect the quantitative information necessary for effective simulation. These teams should develop modeling tools that are validated and perfected through iterative rounds of simulation and laboratory experimentation, after which the tools will be made available to the broader research community.

The panel also defined areas that are important for the development of predictive mathematical models. A partial list of these areas includes:

- defining the minimum set of immunological parameters required to develop useful models. Modeling efforts need to be based on systems that are quantifiable and well documented. In addition, standards are needed for the generation and collection of quantifiable data from immunological studies. The types of data collected, and thus the utility of the model, are dependent upon well-defined questions. Comparisons of data from various laboratories are of limited utility when data collection or reporting is not consistent. Technologies and methods for standardization of data collection need to be accessible to the broader researcher community.

- facilitating multi-disciplinary efforts that are critical for developing, improving, and validating mathematical models, and requiring medium to large teams composed of diverse groups working in close proximity, with frequent interactions, and in a goal-oriented manner.

- developing innovative methods to extrapolate from animal studies to humans.

- developing user-friendly modeling/simulation tools that: i) permit experimentalists to conduct computer simulations based on data-derived hypotheses without requiring direct input from outside mathematicians; and ii) guide further experimentation to refine the model. Efforts should be made to integrate or modify existing tools and systems which are commercially or publicly available to the field of immunology.

- developing an education program to foster an understanding of the power of mathematical modeling to immunological phenomena.

- developing and enhancing bioinformatics and computational tools for construction of a publicly accessible database of immunologic data. This resource is critical for development of robust models because it provides access to large data sets for model generation and validation.

RESEARCH AND TECHNICAL OBJECTIVES

This section presents the Technical Objectives that the Government seeks to achieve through this BAA. Proposals should explain how the offeror will contribute to these overall objectives. In contracts awarded as a result of this BAA, the Statements of Work contained therein shall be those proposed and written by the offeror and negotiated and accepted by the Government.

When preparing proposals in response to this BAA, offerors must follow the "Technical Proposal Instructions for Broad Agency Announcements" included in Section L, Part III and are encouraged to review the "Evaluation Factors for Award" included in Section M of this BAA for additional information.

TECHNICAL OBJECTIVES

The NIAID seeks proposals to establish Immune Modeling Centers of highly interactive, multi-disciplinary teams to develop innovative mathematical models of immunity to vaccines/therapeutics or infection, with a focus on NIAID Category A, B and C Priority Pathogens. The list of eligible agents is available at **http://www.niaid.nih.gov/biodefense/bandc_priority.htm**. The ultimate goal of the Centers is to develop "user-friendly" mathematical modeling tools for high (whole organism or system), intermediate (tissue or organ), or fine (single cell) resolution modeling of host immune responses to infection and vaccines/therapeutics against NIAID Category A-C priority pathogens. Immunological research that is not directed specifically at NIAID Category A, B and C Priority Pathogens or their products is responsive if it addresses a practical approach to inducing, controlling or improving the effectiveness of innate or adaptive immune responses to infection by those pathogens or vaccines to prevent infection. Offerors not specifically addressing NIAID Category A, B, or C Priority Pathogens or their products should provide solid justification for how the proposed studies are applicable to immune responses against the listed agents.

Under this program, the Centers shall conduct basic research for new mathematical model development or the improvement of existing models, accompanied by validation and model refinement through laboratory experimentation. Therefore, each Center shall include, at a minimum, immunologists, bioinformaticians, and scientists with expertise in mathematical modeling (physicists, engineers, mathematicians). Additional expertise/disciplines, such as statistics, infectious disease, epidemiology, and microbiology, shall be included as dictated by the scope of the proposed project. It is expected that *in vitro* studies and *in vivo* animal models will be used as part of the model validation methods and the inclusion of data from human samples is encouraged. The team shall use the results from experimental data to refine the modeling tools, such that each model is validated and perfected through iterative rounds of simulation and laboratory experimentation. While this solicitation will support clinical studies (e.g., use of human tissue and blood samples), clinical trials will not be supported under this BAA (see definitions of clinical research verses clinical trials at **http://grants1.nih.gov/grants/funding/phs398/section_3.html**).

The Centers shall develop models that focus on a particular aspect of immunology. Specific examples of responsive research include, but are not limited to:

- characterization of innate immune responses as a first line of defense against pathogens, for example, elucidation of pathways and network for functions of toll-like receptors (TLR's) and other signaling molecules;
- elucidation of mechanisms of expression and activation of anti-microbial peptides and other natural anti-microbial molecules;
- characterization of the role of innate immunity in orchestrating adaptive immune responses;
- mechanisms of T cell activation (effector function) and maintenance (memory) in response to infection, vaccination, or therapeutic interventions;
- mechanisms of B cell activation including antibody production and class switching, plasma cell differentiation, and generation of memory;
- antigen processing and presentation events, such as antigen presenting cell (APC) maturation, differentiation, and function during infection with pathogenic organisms, or following vaccination or immunotherapeutic interventions against these pathogens; and
- immune evasion strategies of pathogens and the effects on development of protective immunity against the original pathogen or secondary infections with different pathogens or vaccination against NIAID Category A, B and C Priority Pathogens.

Areas of research which are not responsive to this solicitation are:

- characterization of mechanisms of immune-mediated diseases, including graft rejection in solid organ, cell or tissue transplantation, autoimmune diseases, allergic reactions, and asthma;
- characterization of fundamental immune responses to infectious agents not considered NIAID Category A, B and C Priority Pathogens without a clear justification of how the proposed studies are applicable to immune responses against these priority pathogens;
- development of mathematical models with a focus on transmission, growth, survival, or pathogenesis of NIAID Category A, B, or C Priority Pathogens, that do not focus on immunity to these pathogens;

- analysis of host immune responses to NIAID Category A, B or C Priority Pathogens without development of mathematical models of immunity; and
- clinical trials - see definition of clinical research verses clinical trials at **http://grants1.nih.gov/grants/funding/phs398/section_3.html**.

Immune Modeling Center Requirements:

1. Multi-Disciplinary Teams: Each Immune Modeling Center shall establish multi-disciplinary, interactive teams of investigators with appropriate expertise to enhance and apply existing models or to develop novel mathematical models of host immune responses to infection, vaccination, or therapeutic intervention. The models shall enhance current assessments of vaccine efficacy and responses to other prophylactic and therapeutic treatments and advance development of novel or improved vaccines, prophylactics, and immunotherapeutics against NIAID Category A, B and C Priority Pathogens. At a minimum, each Center shall include immunologists, bioinformaticians, and scientists with expertise in mathematical modeling (physicists, engineers, mathematicians). Additional expertise/disciplines, such as infectious disease, microbiology, epidemiology, and statistics, shall be included as dictated by the scope of the project.

2. Immunological Focus: Each Center shall focus on development of robust and functional mathematical models of host immunity in response to immunotherapeutics, vaccination, or infection with NIAID Category A, B or C Priority pathogens. The Center may choose to develop mathematical modeling tools for high (whole organism or system), intermediate (tissue or organ), or fine (single cell) resolution modeling of host immune responses to infection and vaccines/therapeutics against NIAID Category A, B and C Priority Pathogens. Some Centers may choose to develop modeling tools that can simulate more than one area of resolution (single cell, tissue/organ, whole organism). In this case, each parameter of the model shall be well described and validated through laboratory experimentation.

3. Immunological Laboratory Experiments: Since the goal of the program is to produce truly functional models, immunological laboratory experiments shall be included in the program to test, refine, and validate the mathematical models. Offerors may adapt existing mathematical models or develop novel models that simulate and predict host immune function. The offeror shall clearly describe how experimentation shall be used to refine the models and how the computer models shall be applied to guide future experimentations and make predictions about host immune functions in response to vaccination, immunotherapeutic strategies, or infection with NIAID Category A, B, and C Priority Pathogens. It is expected that progress on computer model development shall result from iterative rounds of simulation and laboratory experimentation. The Centers shall validate and refine the models by *in vitro* and *in vivo* experimentation in animal models, as appropriate, and inclusion of *in vitro* studies with human samples or use of data from previous or ongoing clinical trials is strongly encouraged, though not required. Results from animal model studies are expected to guide development of models that can predict human immune responses to infection or vaccination. Therefore, the offeror shall describe how the animal studies, and associated mathematical models, will provide valuable insights into human immune responses.

4. Scientific/Technical Plan and Project Milestones and Timelines: The offeror shall develop a detailed plan describing the rationale for experimental and computational approaches; the iterative process for computer model building that includes use of experimentation to refine the models; experimental methods; and alternatives if these methods do not achieve the defined goals. The offeror shall also identify proposed milestones, with associated timelines, for the tasks required to develop novel or improved highly predictive mathematical models that simulate immune function. The milestones and timelines shall be presented with sufficient detail to allow clear assessment of program progress by the NIAID Project Officer.

5. Education Program: Each Center shall develop an education program for graduate students, post-doctoral fellows, and interested visiting scientists working at or affiliated with the Center. These programs shall provide the participants with an understanding of the power of applying mathematical principles to biological phenomena in immunology. The main goal of the education program will be to foster the next generation of researchers with multi-disciplinary expertise in mathematical modeling and immunology. The offeror shall provide a plan for the development and implementation of the education program including the number of participants expected per year, the types of disciplines to be covered, the methods that shall be used to provide participants with an understanding of the power of applying mathematical principles to immunology, and how the success of the education program will be measured.

The education program shall propose to fund at least one of the following activities that focus on application of mathematical modeling to immunological principles: support of a lecture series or symposia; development of teaching tools based on simulations of immune function; and/or short-term (one to two week) training programs. The offeror shall make the education opportunities available to staff (students, post-doctoral fellows, and visiting scientists) at the Center, and may include interested scientists from non-Center laboratories. Funds may be used to cover travel (housing and per diem) for

domestic non-Center, non-government scientists for a period of up to two weeks to attend the training programs (if applicable). Up to five scientists from other domestic institutions may be supported per year. For graduate students and postdoctoral fellows education programs funded under this initiative should be a component of their education, but is not intended to serve as the basis of an entire degree program or multiyear postdoctoral training experience. The latter are more appropriately funded through NIH training grant mechanisms. In addition, education funds may not be used to support salaries or stipends of the trainees.

6. Bioinformatics Component: Each Center shall include a local bioinformatics component for data management and model development within the Center. The bioinformatics component shall develop methods and standards for data sharing and communication among the Centers, using open-source protocols. The offeror shall prepare a draft plan for the development of methods and standards for data sharing and communication among the Centers, as well as with the broader research community. In order to coordinate development of these methods and standards, the NIAID will establish a Data Advisory Board comprised of representatives from each of the participating Contractors, the NIAID Project Officer or his/her representative, and additional members, if deemed necessary by the NIAID Project Officer. The Data Advisory Board will set standards and policies for data sharing, including data collection, controlled vocabularies, and data handling, to be used by all participating Contractors so that data and the computational models will be consistent and interpretable across sites. The Data Advisory Board will meet at the NIH twice during the first year of funding and annually thereafter. The draft data sharing plans submitted with the final contract proposal, will be provided to the Data Advisory Board at the first meeting as a starting point for development of a single plan for the Modeling Immunity to Emerging/Re-emerging Infectious Diseases Program.

The bioinformatics component shall also facilitate the development "user-friendly" immune modeling tools that will be made available to the broader research community. Each offeror shall prepare a clear description of the procedures for the development and distribution of the immune modeling tools to the broader research community including methods for training the research community to use the tools. The training may include demonstrations at national scientific meetings and web-based training approaches shall be included to ensure long-term technical support of the tools through availability of online, automated help for users.

7. Animal Welfare: Each offeror shall include all of the proper documentation for animal welfare as required by NIH guidelines (**http://grants1.nih.gov/grants/funding/phs398/section_1.html#f_vertebrate_animals**).

8. Human Subjects: Those offerors using human tissue samples or blood shall comply with all NIH guidelines for human subjects' inclusion (**http://grants1.nih.gov/grants/funding/phs398/section_1.html#e_humansubs**).

9. Clinical Studies: Although clinical trials will not be supported under this program, the IRB-approved protocol and the investigators brochure for any parent or core clinical trial that is a source for data or human materials for the proposed studies shall be included with the proposal as part of the human subjects section. Informed consent form(s) shall also be included as part of this section. While drafts of the consent forms at participating sites are not required, it would be useful to include them if they are available. NIH will treat as confidential any scientific, preclinical, clinical, or formulation data and information that the sponsor deems to be proprietary and confidential. In order to ensure coordination between the proposed studies and any parent or core clinical trial, the Offeror and the sponsor of the parent or core clinical trial shall provide written agreement for the conduct of the studies as presented in this proposal. Prior to award, the Offeror shall provide to NIAID a memorandum of understanding signed by the Offeror, an appropriate representative of the applicant institution, the principal investigator of the parent or core clinical trial, and an appropriate representative of the sponsor of the parent or core clinical trial. This memorandum shall indicate agreement and shall outline the specifics of the agreement for the following areas:

- nature of the biological specimens and the manner of access;
- data from the proposed studies, including ownership, analysis, access, and release;
- timing and manner of access to the data from the parent or core clinical trial needed to analyze the proposed studies, including procedures to prevent unblinding of the parent trial;
- documentation of quality assurance procedures for both the parent trial and the proposed studies;
- documentation of data and safety monitoring procedures for the parent trial, especially for efficacy trials;
- ownership of intellectual property developed during the proposed studies; and
- publication of the results of the proposed studies.

10. Program Meetings: In addition to participation in the Data Advisory Board, each Center shall participate in programmatic meetings organized by the NIAID Project Officer. The purpose of the programmatic meetings is to foster collaborations and exchange of ideas among the Centers. Two programmatic meetings shall be held in the first year of the

contract and one meeting per year thereafter, unless otherwise determined by the NIAID Project Officer. Attendees at the programmatic meeting shall include: the Principal Investigators of each Immune Modeling Center; three (3) additional staff members from each Center, with prior approval by the NIAID Project Officer; and Government officials, including Project Officers, Contracting Officers, and other relevant government staff.

NOTES TO THE OFFEROR

NOTE 1
Subcontracting agreements are allowable and encouraged to accomplish the work outlined in this solicitation. For each proposed subcontract, the technical proposal must provide a detailed description of the subcontract research plan and contribution to the overall proposal, a complete description of the facilities, the professional backgrounds of proposed personnel, and associated costs.

NOTE 2
Disclosures of any and all patents and copyrights or patent and copyright applications of mathematical modeling tools, database design, data analysis tools, or procedures filed in or outside the U.S. by the Offerors and/or listed personnel or collaborators must be made at the time of proposal submission and updated in progress reports. Individual and institutional intellectual property rights and rights to inventorship under United States patent law will not be affected by participation in this BAA. The involvement of the NIH in the performance of this contract will not affect ownership rights of the participating parties beyond U.S. Government rights under any funding agreement as specific under 35 U.S.C. #202.

It is expected that the Offeror will administer their patent rights in a manner that will not conflict with the central goal of this BAA, which is to make the project-generated mathematical models, experimental methods, and standardized immunological data widely available to the research community.

All licensing agreements entered into by the Contractor and required for completion of the research listed in this BAA and proposed by the Contractor in their Statement of Work, as well as any licenses required for or for utilization of the deliverables shall be transferable to the Government.

NOTE 3
For budget estimating purposes, assume the following:

The programmatic meeting and the Data Advisory Board meeting cost estimates should include travel costs (transportation, meals, hotel, etc.) for contract participants, including the Principal Investigator, and an additional three (3) staff members per meeting, with prior approval by the NIAID Project Officer. Each Offeror also shall budget for travel and per diem costs for 2 additional personnel (e.g., outside advisors) to be determined by the Project Officer to attend the meetings. All cost estimates should be based on Government rates for per diem, hotel, and transportation (coach class). Assume the meetings will be held in Bethesda, MD, for 1.5 days per meeting.

The Offeror shall budget travel for 2-3 key personnel to attend two scientific meetings per year, not including the annual workshops. All cost estimates should be based on Government rates for per diem, hotel and transportation (coach class).

REPORTING REQUIREMENTS AND DELIVERABLES

As part of the work to be performed under this BAA, the Contractor shall prepare and deliver the following reports throughout the contract period. The exact submission schedule will be negotiated and established in the contract document.

I. Semi-Annual Reports

The Contractor shall submit two (2) copies on the 15th of the month following the end of each 6 months (180 calendar days) of the performance period. The original shall be submitted to the Project Officer, with one copy submitted to the Contracting Officer. Each Semi-Annual report shall include the following:

- Face page to include contract number, contract title, performance period covered, Contractor's name and address, telephone, fax and E-mail address and submission date.
- An executive summary, to include but not limited to:
- An overview of the status of the Immune Modeling Centers including personnel and model development activities and application to the chosen immunological question;
- A brief overview of the work completed during the current reporting period, obstacles to completing part or all of the proposed work, justification for failure to complete intended work or performance on unintended work, and any Key Personnel changes since the previous reporting period;
- A brief overview of the activities that occurred during the current reporting period and any problems (technical or financial) that occurred during the current reporting period; and
- The fulfillment of production goals and of the specific aims set forth in the proposal.

A full description of:

- The work performed during the reporting period including progress on immune model development and implementation, results of accompanying validation studies *in vivo* or *in vitro*;
- The relation between the accomplishments and the goals and objectives of the contract; and
- A full disclosure of the results and their relevance, explanations of any differences between planned and actual progress, and, if necessary, what corrective steps are planned or have been implemented.

Copies of manuscripts (published or unpublished) derived from research performed under the contract and copies of all abstracts, manuscripts, preprints, and publications that resulted from work conducted or any protocol or method developed specifically under this contract during the performance period.

A full disclosure of intent to file patent applications or copyrights within or outside of the U.S. on procedures utilized, derived, or established by the work supported under this contract; full disclosure of patent applications or copyrights filed, as well as copies of patent or copyright applications.

Semi-Annual Progress Reports are not required for period in which the Final Report is due.

II. Final Report

The Contractor shall submit two (2) copies (as specified above) of the Final Report that document and summarize the results of the entire contract period of performance. This report shall be submitted on or before the completion date of the contract. The report shall conform to the following format:

- Face page to include contract number, contract title, performance period covered, Contract's name and address, telephone, fax numbers and E-mail address and submission date.

- Introduction covering the purpose and scope of the contract effort including a summary of salient results. The Contractor shall submit a summary, not to exceed 200 words, of salient results achieved during performance of the contract;

- An executive summary, to include fulfillment of production goals and of the specific aims set forth in the contract; and

- A detailed description of the work performed (as described for the Semi-Annual Reports), the results obtained, and discussion of the relevance of the results, their relation to work being conducted in the area by other groups, and impact on the scientific community based on annual meetings, training sessions, and community feedback.

Deliverable Reports	No. of Copies	Addressee/Distribution	Due Dates
Semi-Annual Reports	2	Contracting Officer NIAID 6700-B Rockledge Drive Bethesda, MD 20892 Project Officer NIAID 6610 Rockledge Drive Bethesda, MD 20892	The 15th of the month following the end of each semi-annual reporting period
Final Report	2	Contracting Officer NIAID 6700-B Rockledge Drive Bethesda, MD 20892 Project Officer NIAID 6610 Rockledge Drive Bethesda, MD 20892	On or before the completion date of the contract

Other Deliverables

As directed by the Project Officer or the Contracting Officer, the Contractor shall return to the Government or deliver to a successor Contractor all data, protocols, and mathematical models (including source codes) generated by the Immune Modeling Center. For the purpose of this BAA, data is defined as the research data that was used to test, refine, and validate the models. Proprietary data, developed by the Contractor, will not be distributed to the broader research community without written consent of the Contractor. During the contract's performance and upon its delivery, all other data, immune models, and protocols shall be made freely available to the research community. In addition, all licensing agreements entered into by the Contractor for completion of any or all of the research listed in this contract and proposed by the Contractor in their Statement of Work; as well as all data, protocols, reagents, and models generated by the Contractor under this contract shall be transferable to the Government upon completion of the contract.

PART I - THE SCHEDULE

SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL

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

http://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

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:

General Clauses for a Cost-Reimbursement Research and Development Contract

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

Alternate II (OCTOBER 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (OCTOBER 2002) 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 46: The following Alternates are applicable to this solicitation:

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

ITEM 47: FAR Clause **52.227-16, Additional Data Requirements** (JUNE 1987), is applicable to this solicitation.

ITEM 48: FAR Clause **52.227-17, Rights in Data--Special Works** (JUNE 1987), is applicable to this solicitation.

ITEM 49: FAR Clause **52.227-18, Rights in Data--Existing Works** (JUNE 1987), is applicable to this solicitation.

ITEM 50: FAR Clause **52.227-19, Commercial Computer Software--Restricted Rights** (JUNE 1987), is applicable to this solicitation.

ITEM 51: FAR Clause **52.227-23, Rights to Proposal Data (Technical)** (JUNE 1987), is applicable to this solicitation.

Excluded pages from the proposal dated *, are identified as follows:

*Information to be determined during negotiations.

HSSAR Clause **352.270-6. Publications and Publicity** (July 1991) **,** is applicable to this solicitation.

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 23, 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 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 *[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**
- **Report of Government Owned, Contractor Held Property**
- **Government Property – Schedule II-A**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Please refer to **http://www.niaid.nih.gov/contract/eproposal.htm** for 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.

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 at the above-referenced weblink. 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. -- SUBMISSION OF ONLY ELECTRONIC PROPOSALS WITHOUT PAPER COPIES IS NOT ACCEPTABLE.

WARNING: You are advised to read and carefully follow the instructions listed in this RFP. Failure to adhere to these instructions and to the specified limitations for size of paper and electronic proposals may result in the rejection of your proposal.

NUMBER OF COPIES:

Document	**Number of Copies**	**Page Limits**	**File Size**
Technical Proposal	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Twenty (20) bound copies.	Limited to not-to-exceed 100 pages.	Limited to not-to-exceed 5 mega-bytes
Technical Proposal Appendices All materials not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Twenty (20) bound copies.	This information is included in the total page limitation of 75 pages.	N/A
Business Proposal	One (1) unbound SIGNED ORIGINAL. One (1) unbound COPY Ten (10) bound copies.	Limited to not-to-exceed 150 pages	Limited to not-to-exceed 5 mega-bytes
Representations and Certifications	One (1) Original required to be submitted with the Original Business Proposal. (Extra copies are optional.)	N/A	N/A
All offerors are required to submit three (3) CDs that each contain electronic versions of all proposal information (both technical and business – clearly named). If information appended to the paper version is not available electronically, the CD shall contain a file listing all documents that are submitted in paper format only. **The offeror shall include certification that the documents provided electronically match the paper version of those same documents.**		Technical Proposal: 2 Compact Discs (CDs) Business Proposal: 1 Compact Disc (CD)	

THE TECHNICAL PROPOSAL 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.**

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED 100 PAGES. PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES. [THIS PAGE LIMIT INCLUDES: Statement of Work, 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.

Please note the two (2) electronic PDF files to be submitted are limited to the size of 5 MB. 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-DAIT-BAA-05-10
RFP Title: Modeling Immunity for BioDefense

Please review the attached Request for Proposal. Furnish the information requested below and return this page by October 22, 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: Robert J. Singman
RFP-NIH-NIAID-DAIT-BAA-05-10
FAX# (301)-480-4675
Email : rsingman@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).

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. Technical Proposal

The technical proposal page limit is one hundred (100) pages total, including the statement of work. The Statement of Work should not exceed ten (10) single spaced pages in length within the technical proposal.

The Technical Proposal consists of two major sections:

SECTION ONE - The Statement of Work which delineates each step or task to be carried out after award of the contract in order to accomplish the proposed research.

SECTION TWO - The Detailed Proposal which consists of three parts:

(1) Part 1 - a separate Technical Plan which describes the proposed approach, methodology, and outcome in detail, including preliminary data and other documentation supporting the proposed research project;

(2) Part 2 - Personnel - a description of the experience and qualifications of proposed personnel and a discussion of how the project will be organized and managed; and,

(3) Part 3 - Other Considerations.

SECTION ONE - Offeror's Proposed Statement of Work *(Maximum limit-10 pages)*

In contracts awarded under this Broad Agency Announcement, the Statement of Work will be the Statement of Work proposed by the offeror and negotiated and accepted by the NIAID. This section of the offeror's Technical Proposal should outline the steps to be taken by the contractor during performance of the contract. The offeror's proposed Statement of Work should begin as follows:

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

The opening paragraph should be followed by a full Statement of Work describing each step that the contractor shall perform after the award of the contract, including: the tasks that will be performed to carry out the research project; how these tasks will be accomplished; and the time frame within which each task will be accomplished. Each step described in the Statement of Work will begin with the words "The Contractor shall...." Where appropriate, divide the Statement of Work into separate tasks and subtasks. An outline format should be used. Briefly describe the work related to each task and describe the tasks in the sequence in which they will be carried out. More in depth descriptions of the proposed work should be provided in SECTION TWO of your Technical Proposal. The Statement of Work should also include a description of all items to be delivered to the Government during performance of the contract, such as progress reports, financial reports, end products, and deliverables.

SECTION TWO - Part 1-Technical Plan *(recommended limit-25 pages)*

(1) Objectives

State the overall objectives and the specific accomplishments you hope to achieve. Indicate the rationale for your plan, and its relationship to comparable work in progress elsewhere or as part of your own studies. Review pertinent work already published which is relevant to this project and your proposed approach. Provide a list of references to document published work cited in the proposal. Place the list at the end of SECTION TWO, Part 1. This section of the Technical Plan should support the scope of the project as you propose it to be accomplished, and as outlined in your proposed Statement of Work.

(2) Approach

Use as many subparagraphs, appropriately titled, as needed to clearly describe the general plan of work. Discuss phasing of research including rationale, experimental design, achievable milestones, and the possible or probable outcome(s) of the proposed approaches. Describe alternate approaches to be used if the primary approaches are unsuccessful. In addition, indicate the role of subcontractors in the plan of work, if applicable.

(3) Methods

Describe the methods 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 work and delivery of items specified in your proposed Statement of Work. Performance or delivery schedules should be indicated for phases or segments, as applicable, as well as for the overall project. Schedules should 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.

(5) Facilities

Describe facilities, equipment, and resources that will be used to perform all phases of the proposed project.

SECTION TWO - Part 2-Personnel-(recommended limit-10 pages excluding letters of commitment and resumes)

Describe the experience and qualifications of personnel who will be assigned for direct work on the project. Information is required which will show the composition of the task or work group, its general qualifications, and recent experience with similar research projects/programs and equipment/technologies. Special mention should be made of direct technical supervisors and key technical personnel, and the approximate percentage of the total time each will be available for the project, as well as how the project will be organized and managed. If staff are to be hired, include a description of the qualifications that will be used to identify appropriate staff to fill the position(s). Include an organizational chart that clearly shows reporting relationships and lines of authority.

OFFERORS SHOULD ASSURE THAT THE PRINCIPAL INVESTIGATOR, AND ALL OTHER PERSONNEL PROPOSED, SHALL NOT BE COMMITTED ON FEDERAL GRANTS AND CONTRACTS AND OTHER SUPPORT FOR MORE THAN A TOTAL 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 who serves as the key contact for technical aspects of the project. Even though there may be co-investigators, identify the Prinicipal Investigator/Project Director who will be responsible for the overall implementation of any contract awarded. Discuss the qualifications, experience, and accomplishments of the Principal Investigator/Project Director. State the estimated time to be spent on the project(s), his or her proposed duties, and the areas or phases of work 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 of each individual. 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 directly responsible.

(3) Additional Personnel

List names, titles, and proposed duties of additional personnel, if any, who will be required for full-time and part-time employment, or on a subcontract or consultant basis. Describe the technical areas, character, and extent of subcontract or consultant activity and specify anticipated sources for all such services. 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 each of the following items of information:

* 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; and
* How rights to publications and patents will be handled.

Letters of commitment should be placed at the end of SECTION TWO, Part 2.

(4) Resumes (recommended limit–2 single-sided pages per person)

Resumes of all key personnel are required. Each resume must indicate educational background, recent experience, specific or technical accomplishments, and a listing of relevant recent publications. Resumes should be placed as the last documents in SECTION TWO, Part 2 of the proposal.

SECTION TWO -Part-3-Other Considerations

Record and discuss specific factors, not included elsewhere, that support your proposal using specifically titled subparagraphs. Items may include:

(1) Any agreements and/or arrangements with subcontractor(s). Provide as much detail as necessary to explain how your Statement of Work will be accomplished within this working relationship and how intellectual property issues will be treated (if applicable).

(2) Unique arrangements, equipment, procedures, etc. that no or few organizations are likely to have which will be advantageous for effective implementation of the project.

(3) Equipment, training and unusual operating procedures established to protect personnel from any hazards associated with your project.

(4) Other factors you feel important to support your proposed research.

(5) For additional requirements to be addressed in your Technical Proposal, refer to the following Sections of this RFP, as applicable:

a. Section L, Part II (General Instructions)

Care of Live Vertebrate Animals
Possession, Use and Transfer of Select Biological Agents or Toxins
Sharing Research Data

b. Section L, Part III (Technical Proposal Instructions)

Information Technology Systems Security

Discussion of this subject should be placed at the end of SECTION TWO, Part 3 of the technical proposal.

2. Technical Evaluation

Proposals will be technically evaluated by an initial review panel in accordance with the factors, weights, and order of relative importance as described in the Technical Evaluation Criteria (see Section M.). This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

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 ACQUISTION, 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

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

It is anticipated that MULTIPLE AWARD(S) will be made from this solicitation and that the award(s) will be made on or about July 29, 2005

It is anticipated that the award(s) from this solicitation will be a multiple-year COST REIMBURSEMENT type COMPLETION contract with a Period Of Five (5) YEARS, and that incremental funding will be used [see Section L, PART IV - Business Proposal Instructions].

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/approximately equal to cost or price/significantly less important than cost or price. The relative importance of the evaluation factors is specified in SECTION M of this solicitation. However, the Government reserves the right to make an award to the best advantage of the Government, cost and other factors considered.

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 31: Sharing of Model Organisms for Biomedical Research, 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:

Identified below are the DHHS subcontracting goals. Offerors are encouraged to the greatest extent possible to identify subcontract dollars to these types of businesses.

_23_% for Small Business; _5_% for Small Disadvantaged Business; __3_% for Women-Owned Small Business; __5_% 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: The following provisions are applicable to this solicitation.

Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).

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

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

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

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

ITEM 55: Human Subjects, is applicable to this solicitation.

III. TECHNICAL PROPOSAL INSTRUCTIONS

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

ITEM 56: Information Technology Systems Security, is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation.

(a) Sensitivity and Security Level Designations.

The Statement of Work (SOW) requires the successful offeror to develop or access a Federal Automated Information System (AIS). Based upon the security guidelines contained in the *Department of Health and Human Services (DHHS) Automated Information Systems Security Program (AISSP) Handbook*, the Government has determined that the following apply:

(1) Category of Safeguarded Information

The safeguarded agency information that the successful offeror will develop or access is categorized as:

[X] Non Sensitive Information
[ ] Sensitive Information
[ ] Classified Information:
[ ] Confidential [ ] Secret [ ] Top Secret [ ] Special Access

(2) Security Level Designations

The information that the successful offeror will develop or access is designated as follows:

Level ___ applies to the sensitivity of the data.
Level ___ applies to the operational criticality of the data.

The overall Security Level designation for this requirement is Level 1C.

(3) Position Sensitivity Designations

Prior to award, the Government will determine the position sensitivity designation for each contractor employee that the successful offeror proposes to work under the contract. For proposal preparation purposes, the following designations apply:

[ ] Level 6C: Sensitive - High Risk (Requires Suitability Determination with a BI).
Contractor employees assigned to a Level 6C position are subject to a Background Investigation (BI).
[ ] Level 5C: Sensitive - Moderate Risk (Requires Suitability Determination with NACIC).
Contractor employees assigned to a Level 5C position with no previous investigation and approval shall undergo a National Agency Check and Inquiry Investigation plus a Credit Check (NACIC), or possibly a Limited Background Investigation (LBI).
[ ] Level 4C: Classified (Requires Special Access Clearance with an SSBI).

Contractor employees assigned to a Level 4C position are subject to a Single Scope Background Investigation (SSBI).

[ ] Level 3C: Classified (Requires Top Secret Clearance with an SSBI).

Contractor employees assigned to a Level 3C position are subject to a Single Scope Background Investigation (SSBI).

[ ] Level 2C: Classified (Requires Confidential or Secret Clearance with an LBI).

Contractor employees assigned to a Level 2C position shall undergo a Limited Background Investigation (LBI).

[X1C] Level 1C: Non Sensitive (Requires Suitability Determination with an NACI).

Contractor employees assigned to a Level 1C position are subject to a National Agency Check and Inquiry Investigation (NACI).

Contractor employees who have met investigative requirements within the past five years may only require an updated or upgraded investigation.

(b) Information Technology (IT) System Security Program

The offeror's proposal must:

(1) Include a detailed outline (commensurate with the size and complexity of the requirements of the SOW) of its present and proposed IT systems security program;

(2) Demonstrate that it complies with the AISSP security requirements, the Computer Security Act of 1987; Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems;" and the DHHS AISSP Handbook.

At a minimum, the offeror's proposed information technology systems security program must address the minimum requirements of a Security Level 1C identified in the DHHS AISSP Handbook,
Exhibit III-A, Matrix of Minimum Security Safeguards.

(3) Include an acknowledgment of its understanding of the security requirements.

(4) Provide similar information for any proposed subcontractor developing or accessing an AIS.

(c) Required Training for IT Systems Security

DHHS policy requires that contractors receive security training commensurate with their responsibilities for performing work under the terms and conditions of their contractual agreements.

The successful offeror will be responsible for assuring that each contractor employee has completed the following NIH Computer Security Awareness Training course prior to performing any contract work: http://irtsectraining.nih.gov/. The contractor will be required to maintain a listing of all individuals who have completed this training and submit this listing to the Government.

Additional security training requirements commensurate with the position may be required as defined in OMB Circular A-130 or NIST Special Publication 800-16, "Information Technology Security Training Requirements." These documents provide information about IT security training that may be useful to potential offerors..

(d) Prospective Offeror Non-Disclosure Agreement

The Government has determined that prospective offerors will require access to sensitive information described below in order to prepare an offer.

Any individual having access to this information must possess a valid and current suitability determination at the following level:

[ ] Level 6C: Sensitive - High Risk
[ ] Level 5C: Sensitive - Moderate Risk

To be considered for access to this sensitive information, a prospective offeror must:

(1) Submit a written request to the Contracting Officer identified in the solicitation;
(2) Complete and submit the "Prospective Offeror Non-Disclosure Agreement" provided as an attachment in Section J of this solicitation; and
(3) Receive written approval from the Contracting Officer.

Prospective offerors are required to process their requests for access, receive Government approval, and then access the sensitive information within the period of time provided in the solicitation for the preparation of offers.

Nothing in this provision shall be construed, in any manner, by a prospective offeror as an extension to the stated date, time, and location in the solicitation for the submission of offers.

(e) References

The following documents are electronically accessible:

(1) OMB Circular A-130, Appendix III: http://csrc.ncsl.nist.gov/secplcy/a130app3.txt
(2) DHHS AISSP Handbook: http://irm.cit.nih.gov/policy/aissp.html
(3) DHHS Personnel Security/Suitability Handbook: http://www.hhs.gov/ohr/manual/pssh.pdf
(4) NIH Applications/Systems Security Template: http://cit.nih.gov/security/secplantemp.html
(5) NIST Special Publication 800-16, "Information Technology Security Training Requirements:" http://csrc.nist.gov/publications/nistpubs/800-16/800-16.pdf
(6) NIH CIT-Policies, Guidelines and Regulations:
Table 1 - Categories of Safeguarded Agency Information:
http://irm.cit.nih.gov/security/table1.htm
Table 2 - Security Level Designations for Agency Information:
http://irm.cit.nih.gov/security/table2.htm
Table 3 - Positions Sensitivity Designations for Individuals Accessing Agency Information:
http://irm.cit.nih.gov/security/table3.htm

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.

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 :*

** (Specify format) **

*It is noted that the format specified above is also applicable to Alternate I, of FAR Clause 52.215-20, Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data.

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

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 the 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, cost/price, past performance, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price. In any case, the Government reserves the right to make an award(s) to that offeror whose proposal provides the best overall value to the Government.

All technical proposals will undergo evaluation by a peer review group also known as a Scientific Review Group (SRG).

The final stage of the evaluation is the establishment of an Order of Merit Ranking in which all competing proposals are ranked on the basis of their respective relevance and scientific merit evaluations. Final selection of awards will depend upon the availability of funds, scientific priority, and program balance that the NIAID determines to exist at the time of award selection.

The estimated cost of an offer must be reasonable for the tasks to be performed, and, in accordance with FAR 15.305, will be subject to a cost realism analysis by the Government.

Offerors must demonstrate in their proposals that they have the necessary expertise and capabilities for conducting the research as requested by this solicitation. Each proposal must document the feasibility of successful implementation of the requirements of the BAA.

EVALUATION OF DATA SHARING PLAN

The offeror's plan for the sharing of final research data shall be assessed for appropriateness and adequacy. If your proposal does not include a plan or if the plan in your proposal is considered “unacceptable,” you will be afforded the opportunity to further discuss, clarify or modify your data sharing plan during discussions and in your Final Proposal Revision (FPR). If your data sharing plan is still considered “unacceptable” by the Government after discussions, your proposal may not be considered further for award.

TECHNICAL EVALUATION CRITERIA

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

Evaluation Factors	**Points**
SCIENTIFIC RATIONALE AND TECHNICAL APPROACH	60

Feasibility and appropriateness of the scientific rationale and technical approach, including:

- procedures for development of mathematical models of host immunity and application of those models to understand immune responses to vaccination, immunotherapeutic strategies, or infection with NIAID Category A, B, or C pathogens.

- for those offerors that focus on immunological research that is not directed specifically at NIAID Category A, B and C Priority Pathogens: clear correlations and explanations for the use of model organisms to directly address a practical approach to inducing, controlling or improving the effectiveness of innate or adaptive immune responses to infection by NIAID Category A, B, or C pathogens or vaccines to prevent infection.

- methods to use laboratory experimentation to test and refine the models and adequacy of the methods to apply the models to guide future experimentations and make predictions about host immune functions .

- clearly defined milestones and timelines for progress of the research program, including availability of the models to the broader research community.

- development of education programs and measures of success of these programs, including the methods for providing participants with a knowledge of the power of applying mathematical principles to biological phenomena in immunology. The main goal of the education program will be to produce the next generation of researchers with multi-disciplinary expertise in mathematical modeling and immunology.

- plans for the development of methods and standards for data sharing and communication among the Centers, as well as with the broader research community.

- plans to make the predictive mathematical models user-friendly and widely available to the research community, including methods for training researchers to use the models efficiently.

- adequacy of plans to address animal welfare and human subjects information, for those Offerors using animals, human tissue/blood samples, or data from clinical trials.

OFFEROR'S QUALIFICATIONS AND CAPABILITIES 25

a) Principal Investigator : Documented training, expertise, leadership, commitment and availability with respect to technical and administrative competence to successfully manage a project of comparable size and complexity. It is expected that the Principal Investigator shall have expertise in either immunology or development of mathematical models, as needed to plan and direct the project. **(15 points)**

b) Scientific and Technical Staff : Documented training, experience, expertise, availability, and capability of the technical and support staff to perform their roles in the proposed studies including experience with similar projects. Adequacy of the management and organization of the Immune Modeling Center including the synergy of the multi-disciplinary team of researchers to conduct innovative research to develop novel or improved highly predictive mathematical models that simulate immune function for analysis of host immune responses to NIAID category A-C pathogens. **(10 points)**

OFFEROR'S FACILITIES AND RESOURCES 15

Documented availability and adequacy of the Organization (Institution or Business), facilities, equipment, and resources necessary to carry out and meet the goals and objectives of the Immune Modeling Center, including institutional commitment to the Center.