OMB No. 0990-0115

Electronic Request for Proposal

SECTION A – SOLICITATION/CONTRACT FORM

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

Purchase Authority: Public Law 92-218, as amended.
NOTE: The issuance of this solicitation does not commit the government to an award.

RFP Number:	***Just In Time:***	Small Bus. Set-Aside [ ]Yes [X]No 8(a) Set-Aside [ ]Yes [X]No NAICS Code: 541710 Size Standard: 500 employees	***Level of Effort:*** [ ] Yes [X] No ***Total Effort:*** [N/A]
NIH-NIAID-DMID-04-40	[ ] Yes [X] No		

TITLE: In Vitro and Animal Models for Emerging Infectious Diseases and BioDefense

Issue Date: 12/16/2003	***Due Date:*** 03/01/2003 ***Time:*** 4:00 PM EST	***Technical Proposal Page Limits:*** [X] Yes *(see "How to Prepare and Submit Electronic Proposals")* [ ] No

ISSUED BY:
Paul D. McFarlane
Senior Contracting Officer
PRCB, CMP, DEA, NIAID, NIH
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Bethesda, MD 20892-7612

[X] ***We reserve the right to make awards without discussion.***

NO. OF AWARDS:	***PERIOD OF PERFORMANCE:***
[ ] Only 1 Award [X] Multiple Awards	6 years beginning on or about 09/30/2004

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

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

POINT OF CONTACT -- Paquetta N. Myrick-Hancock, Contract Specialist

--COLLECT CALLS WILL NOT BE ACCEPTED--

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BACKGROUND

"In Vitro and Animal Models for Emerging Infectious Diseases and BioDefense"
NIH-NIAID-DMID-04-40

As concern is heightened about the use of biological agents in acts of terrorism or war, as well as the emergence of serious infectious agents, Federal health agencies are evaluating and accelerating measures to protect the public from the health consequences of such pathogens. Basic and applied research supported by the National Institutes of Health (NIH) complements the efforts of other Federal agencies by supplying the scientific foundation for developing essential tools—diagnostics, therapeutics, and vaccines—that are needed by physicians, nurses, epidemiologists, and other public health workers to prevent and control a disease outbreak. The National Institute of Allergy and Infectious Diseases (NIAID) is the primary NIH Institute that supports and conducts research on the diagnosis, prevention, and treatment of infections caused by a wide variety of emerging pathogens, including agents that could be intentionally introduced.

The uncertain market potential for therapeutic interventions and prophylaxes against BioDefense and emerging pathogens has limited private sector investment in this area. Given the urgent need to develop additional novel and specific therapies and prevention strategies, particularly for organisms with potential use in bioterrorism, NIAID seeks to expand the current capacity for therapeutic and vaccine development. *In vitro* and animal models are needed to ensure that testing and development of vaccines, therapeutics, and diagnostics will lead to licensure of new generation products. Animal models will be critical to FDA approval of BioDefense therapies and vaccines since efficacy trials in humans are not ethical. A number of promising candidate therapies and vaccines have already been identified for bioterrorism organisms/diseases. Access to established, relevant animal models, particularly inhalational models, is often the rate-limiting step in moving new therapeutics or vaccines from discovery to development. In other cases, development has been delayed because of the lack of relevant animal models in which to test these candidates. Particularly important is the development and validation of models in non-human primates other than rhesus macaques, where shortages may delay development of new vaccines and therapeutics.

In 2002, NIAID convened Blue Ribbon Panels on bioterrorism and its implications for biomedical research (reports at NIAID BioDefense Research Agenda for CDC Category A Agents and NIAID BioDefense Research Agenda for Category B and C Priority Pathogens). These panels recommended that NIAID expand the availability of animal models for preclinical research, and standardize and validate protocols involving animal models. NIAID's goal is to develop a ready capacity with both breadth and depth, to screen and test a wide variety of countermeasures *in vitro* and in animal models for efficacy against emerging infections, including NIAID Category A-C priority pathogens.

INTRODUCTION

NIAID's goal is to develop a ready capacity to screen and test potential countermeasures for efficacy against emerging infections, including Category A-C priority pathogens, *in vitro* and in animal models. The "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense" contract(s) will provide targeted screening to identify potential therapeutic and preventive modalities, as well as small animal and non-human primate models to test the safety and efficacy of therapeutic and preventive modalities that target BioDefense and emerging infectious agents, outlined in the NIAID Category A, B & C Priority Pathogens website.

The objective of this contract is to provide a broad and deep range of preclinical developmental resources to bring new therapies and preventive measures from the laboratory to initial clinical testing in humans and efficacy testing in animals. The contract consists of six parts (A-F), listed below, each of which contributes to the overall development effort. These contracts will provide a ready capacity in a number of needed areas and will be utilized as products become available for testing. Offerors are encouraged to submit proposals for one or more general Parts in which they have expertise to offer the Government. The Government anticipates a wide variety of needs, both amongst and within the Parts. Test articles that are found to have activity in one Part may progress through preclinical development using contractors from other parts. For Parts C, D, E and F, various vaccine concepts may be tested based on the following categories: (a) synthetic peptides, (b) recombinant subunits, (c) vector based vaccines, (d) virus-like particles/replicons, or (e) nucleic acid based vaccines. These contracts will also provide some reimbursement for equipment and renovations of contractors' facilities directly related to the requirements of specific Task Order awards. However, this reimbursement is NOT to be construed as "construction" reimbursement. NIAID is limiting this

reimbursement to $500,000 for Parts A, B, C, and D. There is no such reimbursement allowed for Parts E or F since these activities are not expected to deal with samples or animals that are infected with Category A, B or C priority pathogens.

CONTRACT TYPE

Multiple Indefinite Delivery – Indefinite Quantity (IDIQ) type contracts are planned. An IDIQ contract provides for an indefinite quantity (within stated limits) of supplies or services to be furnished during a fixed period, with deliveries or performance to be scheduled by placing task orders with the contractor. Each contract will have a six (6) year ordering period. It is anticipated that multiple awards will be made for each of the six general Parts (A through F) of this solicitation. Contractors will be designated as pre-qualified "Pools" of potential Offerors for each Part and will be eligible to receive future Task Order solicitations for their designated Parts, based on the specific requirements of the task orders. Should an offeror receive an award for more than one Part, these awards will be combined into one contract. NIAID reserves the right to award Task Orders to any contractor in the pool and to solicit to expand this pool as necessary throughout the six (6) year ordering period of this effort.

In response to this RFP, potential Offerors may submit proposals for one or more of the six (6) Parts described above. Offerors are required to submit for each Part, a proposal describing overall experience and capabilities generally within the Part, including a detailed technical approach to the Sample Task Order, specific for a particular project of the Offeror's choosing, encompassed within that Sample Task Order Statement of Work. Note that the proposal should contain separate technical and business (cost) documents. Successful Offerors will have the opportunity to respond to future, specific task order solicitations.

Offerors for Parts A and B should propose as many organisms or groups of organisms as possible. Offerors for Parts C and D should submit proposals describing in detail their best-characterized model, as well as the breadth of their model capabilities and plans, clearly identifying current capabilities. Offerors for Parts E and F should propose comprehensive services that cover all aspects of the Statement of Work for the Part(s) to which they are proposing. Proposals will undergo peer review based on the evaluation criteria in this RFP, and awards will be made to the most qualified proposals. Each Offeror qualified for the Pool under a given Part will receive a one-time, guaranteed minimum dollar award for the 6-year term of the Contract, according to the following scale:

Part A	$ 75,000
Part B	$ 75,000
Part C	$100,000
Part D	$150,000
Part E	$100,000
Part F	$100,000

As specific Requests for Task Order Request for Proposals (TORFP) are developed, they will be submitted to Offerors in the pool, during the six year ordering period. NIAID reserves the right to issue TORFP's to any or all Offerors in the prequalified pool. Proposals will be reviewed according to specific technical evaluation criteria in the RFP by NIAID. Award of a task order by 9/30/2004 will draw upon the minimum award for that Part; if no task order is issued within a Part by 9/30/2004, the Offeror is able to direct the minimum award as they see fit.

General Statement of Work for All Parts

Part A: *In Vitro* Screens for Antimicrobial Activity. Part A will provide the capacity to screen test articles for antimicrobial activity against emerging infectious agents including Category A-C agents. Materials for testing will be obtained by NIAID and provided to the contractor for testing.

Part B: Clinical Isolate Panels for Selected Bacterial Pathogens. Part B will provide the capacity to perform antimicrobial activity determination against clinical panels of bacterial pathogens to arrive at tentative susceptibility breakpoints. This activity is to be performed using bacterial pathogens classified as emerging infectious agents, including Bioterrorism Category A-C agents. Antimicrobial agents to be tested under this contract will be selected on the basis of their activity against select genera and species of bacterial pathogens using reference strains.

Part C: Small Animal Models for Selected Pathogens, to include GLP Studies. Part C will support the development, validation and use of various relevant, small animal models to screen new therapeutic, diagnostic and preventive compounds or test the efficacy of therapeutics, immunotherapies, diagnostics, and vaccines with activity against emerging infectious agents including, Bioterrorism Category A-C agents.

Part D: Non-human Primate Models for Selected Pathogens, to include GLP Studies. Part D will support the development, validation and use of various relevant, non-human primate models to test the efficacy of therapeutics, immunotherapies, diagnostics, and vaccines with activity against emerging infectious agents including, Bioterrorism Category A-C agents.

Part E: Safety/Toxicology and Immunogenicity Testing for Vaccines. Part E will support the testing of vaccine preparations as required prior to initial clinical evaluation (under GLP). This includes testing candidate products for safety and immunogenicity (both cellular and humoral) in small animals and, if appropriate, in non-human primates.

Part F: Safety/Toxicology and Pharmacology Testing for Therapeutics. Part F will support the testing of candidate products for safety, including reproductive toxicology and other appropriate tests, in small and large animal, and if necessary, in non-human primates. This activity includes all such tests as are required to support clinical use in humans; testing must be sufficient to meet requirements for IND filing (GLP).

DEFINITIONS

Clinical panels: standardized, defined panels of clinical isolates of infectious agents.

Infectious agent or agents: organisms responsible for causing the diseases listed in the Bioterrorism Category A-C agent list or the NIAID Priority Pathogens list, or emerging infectious agents.

Test article or articles or products: materials that are supplied to be tested in the contract. The test articles/products may include, but are not limited to, vaccines (of several types), therapeutic vaccines, antibodies, biological products, antitoxins, drugs, other therapeutic modalities, diagnostic materials or assays.

Relevant model: one that is well established and adequately characterized and employs, to the extent possible, validated assays.

Validated model: one that shows close correlation with the natural history of human infection and results from human or non-human primate trials, and is suitable to provide data relevant for obtaining FDA approval for an IND, licensure, or a specific new indication.

AWARDS MADE UNDER NIH-NIAID-DMID-03-39

The contracts awarded under this solicitation seek to add to the number of contractors awarded contracts under NIH-NIAID-DMID-03-39 for the project titled "In Vitro and Animal Models for Emerging Infectious Diseases and BioDefense." The following contractors received awards under 03-39 for the following Parts:

Contractor	Parts
Battelle Memorial Institute	A, B, C, and D
Centre for Applied Microbiology and Research	C, D, and E
University of Texas Medical Branch	C
Southern Research Institute	C, D, E
SRI International	A, E, and F
Oklahoma State University	A

STATEMENT OF WORK

"In Vitro and Animal Models for Emerging Infectious Diseases and BioDefense"
NIH-NIAID-DMID-04-40

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract, directly or through subcontractors and/or consultants, as needed to undertake targeted research essential to the development of therapeutics, diagnostics, and preventive measures for emerging infectious diseases, including bioterrorism agents. The emphasis of this RFP is to cover agents found at the NIAID Category A, B & C Priority Pathogens website. This list is a subset of the NIAID List of Emerging and Re-emerging Diseases 2003. The intent of this RFP is to establish the capacity for *in vitro* and animal studies that require biocontainment, rather than the study of all emerging pathogens. NIAID recognizes that an Offeror that has biocontainment facilities may also study other emerging infections; however, it is the ability to study Category A-C pathogens under biocontainment and required supportive studies that is the main subject of this RFP. The complete range of pathogens to be covered under these contracts cannot be fully anticipated at this time, and successful Offerors will be informed of pathogens that are included but are not Category A-C agents through the issuance of specific Task Order Requests for Proposals. The causative agent of Severe Acute Respiratory Syndrome is an example of a non-Category A-C, emerging infection that must be studied under biocontainment and would be appropriately included in these contracts.

This Statement of Work is divided into six Parts: A) *In vitro* screening, B) Clinical isolate panels, C) Small animal models, D) Non-human primate models, E) Safety/toxicology and immunogenicity testing of vaccines, and F) Safety/toxicology and pharmacology testing of therapeutics. Each Contractor will also be responsible for the General Statement of Work for all parts and for one or more of the six Parts to which they apply. Contractors for each Part will fully and formally cooperate with the relevant other Part Contractors and with the Project Officer and designees.

GENERAL STATEMENT OF WORK FOR ALL PARTS

Independently, and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified professional and technical personnel, materials, equipment, and facilities, not otherwise provided by the Government under the terms of this contract as needed to perform the work set forth below. All Contractors shall perform the work described below in addition to one or more sections A – F.

Specifically, the Contractor shall:

1. Receive, Store, and Record Compounds. Develop and maintain efficient, effective procedures for documentation of receipt of compound/test article shipments from the acquisition contractor or the Project Officer. Provide for a computerized inventory of compound/test article identifiers, amounts available, storage locations, and standardized microbiological activity.

2. Organize, maintain, and transfer information on protocols and test results, as well as provide reports of these, to the Project Officer. Establish electronic message and document transfer capability with the Project Officer.

   a. The Contractor shall report data generated under this contract to the Project Officer in the form of progress reports as described in the contract Reporting Requirements (written reports and computer files). To facilitate timely transmission of data and information, the Contractor shall establish and maintain an efficient data management system and electronic communication (electronic mail) with the Project Officer's office.

   b. The Contractor's Principal Investigator and key personnel shall meet with the Project Officer at periodic intervals, to be scheduled after contract award, to review progress, anticipated or existing problems, and discuss the work to be performed.

3. Abide by terms of the Confidentiality Agreement with drug sponsors signed by the NIAID. Copies will be

provided to the Contractor prior to or simultaneous with the delivery of the therapeutic compounds covered by the agreements. Provide specific procedures to safeguard proprietary information to maintain all confidential data and information in files accessible only to the Project Officer, Principal Investigator, and involved staff.

4. The Contractor shall provide advance copies of draft manuscripts for publication (including abstracts and public presentations) based on data generated under this contract to the Project Officer, and obtain clearance from the Project Officer before submitting for publication or presentation. Support from the Government must be acknowledged in all abstracts, presentations, and publications.

5. Provide safe facilities and resources and conduct work in accordance with the Biosafety in Microbiological and Biomedical Laboratories guidelines. Ensure that all requirements to store and process select agents are followed. Conduct work in accordance with the clause outlined under SAFETY CONTROLS AND STANDARDS, attached to this RFP.

    a. Conduct work under this contract under Biosafety Level 3 or 4 guidelines, when appropriate and in accordance with all applicable Federal, state and local laws, codes, ordinances and regulations, and with basic references and related modifications. (See SAFETY CONTROLS AND STANDARDS, attached to this RFP.)

    b. Provide facilities and equipment to receive, store, and manipulate infectious viral and bacterial agents and potentially hazardous compounds and maintain their stability; provide systems to track stocks of infectious agents, access to those stocks, their use, and disposal.

    c. Provide protective garments, equipment, and sufficient monitoring to assure safe handling of potentially hazardous microorganisms and materials. Specifically, the Contractor shall comply with all applicable health and safety regulations while conducting the work set forth herein.

    d. Ensure that no identifiable data on the compounds or products and the results of testing will be kept in files open to the public, and that facilities for computer operation, data entry, and file storage are secure from unauthorized access. Only those contract employees or government employees directly engaged in this project shall have access to the files of information regarding source and nature of confidential or proprietary materials and results of testing.

6. Provide documentation to meet the following requirements as a part of the task order proposal and ensure that the necessary registration, compliance and/or accreditation is maintained throughout the life of the contract:

    a. For Parts A-D, document access to BSL2 and/or 3 and/or 4 facilities as required to fulfill the statement of work and fully document capacity for testing the products as proposed.

    b. Document the availability of appropriate storage space to maintain necessary infectious agents and test articles.

    c. If working with animals, document access to an AAALAC-accredited (or equivalent) animal facility and the capacity (appropriate cage space, etc.) needed for testing the products (drugs, vaccines, etc.) as proposed.

    d. If working with animals, document the availability of animals sufficient for the proposed model(s) and number of studies and meeting the requirements of the Statement of Work.

    e. For Parts A-D, for U.S. Offerors, document Select Agent Registration (see CDC's Select Agent Program website for details). Foreign institutions or U.S. institutions with foreign components will receive similar Terms of Awards:

        Awards to non-US Institutions for research involving Select Agents will contain a Term of Award requiring U.S. review and approval of safety and security measures/practices prior to use of NIH funds for such research. An NIH-chaired committee of US federal employees (including representatives of NIH grants and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will assess the policies and procedures for comparability to the US requirements described in 42 CFR Part 73. Toward this end, awardee institutions must be willing to provide key information delineating any laws, regulations, policies, and procedures applicable to the

institution for the safe and secure possession, use, and transfer of Select Agents. This includes concise summaries of safety, security, and training plans, and applicable laws, regulations and policies. For the purpose of security risk assessments, awardee institutions must be willing to provide the names of all individuals who will have access to the Select Agents and procedures for ensuring that only approved/appropriate individuals have access to Select Agents that are the subject of the NIH award.

Awards to US Institutions with non-US components for research involving Select Agents will contain a Term of Award (or a Special Contract Requirements Clause under Section H in the case of contract awards) requiring U.S. review and approval of safety and security measures/practices prior to use of NIH funds for such research. An NIH-chaired committee of US federal employees (including representatives of NIH grants and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will assess the policies and procedures for comparability to the US requirements described in 42 CFR Part 73. Toward this end, the US awardee institution must be willing to provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes concise summaries of safety, security, and training plans, and applicable laws, regulations and policies. For the purpose of security risk assessments, awardee institutions must be willing to provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved/appropriate individuals have access to Select Agents that are the subject of the NIH award.

General Notes for All Parts

STATEMENT OF WORK for PART A: *IN VITRO* SCREENS FOR ANTIMICROBIAL ACTIVITY

The first activity under this contract is the capacity to screen test articles for antimicrobial activity against emerging infectious agents including Bioterrorism Category A-C agents. Materials for testing will be obtained by NIAID and provided to the Contractor for testing. This activity is not intended to cover antiviral screening against viral hemorrhagic fevers and poxviruses, which is covered by a separate contract (see NIAID Antiviral Preclinical Drug Screening and Animal Model Evaluation page for list of screens covered by other contracts).

Independently, and not as an agent of the Government, the Contractor shall develop, validate, and use *in vitro* assays to screen test substances for activity against emerging infectious agents.

Specifically, the Contractor shall:

1. Maintain quality controlled stocks of bacterial pathogens, control and test substances:

    a. Receive stocks of select BioDefense bacterial strains through the Project Officer.
    b. Provide stocks of reference/quality control strains of non-BioDefense pathogens as required for quality control assurance of control antibiotics.
    c. Maintain quality controlled, viable frozen or lyophilized stocks of all strains under appropriate conditions.
    d. Assure identity of stocks at least to the species level using appropriate assay methods.
    e. Maintain and document current inventory, purity and identity assessment for each strain.
    f. Provide detailed accounting for pathogen stock use and disposal.
    g. Maintain stocks of appropriate quality control antibiotics under recommended conditions as described in the relevant NCCLS standards.
    h. Maintain stocks of test substances under conditions specified by the Project Officer.
    i. Provide detailed and routine quality control assessment for the performance of all bacterial stains, control antibiotics and test substances using appropriate published testing guidelines, wherever available.
    j. Acquire, validate, and utilize assay/organism-specific standardized reagents and controls to the extent possible.

2. Perform evaluation of antimicrobial activity of test substances against panels of selected bacterial pathogens and standard reference strains. Determine the inhibitory effect on bacterial replication and/or infectivity based on meaningful endpoints, such as, but not limited to, Minimum Inhibitory Concentration Determinations. Evaluations shall incorporate both the substance under investigation, a positive control compound, and an

untreated control. The Offeror shall document preparation, lots, and use of test substances, bacterial growth media, and control antibiotics.

3. More detailed studies when compounds are found to have substantial activity. Perform preliminary screening procedures, apply criteria used to select compounds recommended for further evaluation, and initiate procedures for special studies. Perform special studies as directed by the Project Officer which shall include, but are not restricted to, evaluation and development of new assay systems, combination drug testing, mechanism of action studies targeting specific steps in bacterial life cycle, and other more detailed testing.

4. Meet all items outlined in the General Statement of Work for "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense."

Part A Sample Task Order
Notes for Part A
Part A Technical Evaluation Criteria
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STATEMENT OF WORK for PART B: CLINICAL ISOLATE PANELS FOR SELECTED BACTERIAL PATHOGENS

The second activity to be supported under this contract is the capacity to perform antimicrobial activity determination against clinical panels of bacterial pathogens to determine ranges of activity and arrive at tentative susceptibility breakpoints. These determinations are to be performed including, but not limited to, bacterial pathogens classified as emerging infectious agents, including Bioterrorism Category A-C agents.

These contracts will provide a ready capacity in a number of needed areas and be utilized as test articles become available for testing. Antimicrobial compounds to be tested under this contract will have been selected on the basis of their activity against select genera and species of bacterial pathogens using reference strains (see Part A of this solicitation), and are to be evaluated in Part B of this contract against clinical isolates of the same genera and species of bacterial pathogens to establish their range of activity (MIC50/90) and tentative susceptibility breakpoints.

Screening of currently licensed and marketed antibiotics, as well as promising new chemical entities, for antibacterial activity against *Bacillus anthracis*, *Yersinia pestis*, *Francisella tularensis*, *Burkholderia* species, *Shigella* and STEC infections, Category B enteric protozoa and other bacterial pathogens that are causative agents of emerging and reemerging infections are a priority for the NIAID. Additionally, a priority is to expand exploration into new classes of antimicrobial therapies as well as new targets, including strategies to prevent germination or kill spores during germination, to neutralize toxins, and to interfere with the attachment and entry of toxins into host target cells. Activity data against clinical panels, as well as establishment of tentative susceptibility breakpoints, should be suitable for inclusion in an IND.

Independently and not as an agent of the Government, the Contractor shall:

1. Maintain quality controlled stocks of bacterial pathogens, control and test reagents:

    a. Receive stocks of select clinical and reference bacterial strains through the Project Officer.
    b. Provide stocks of reference/quality control strains of non-bioterrorism pathogens as required for quality control assurance of control antibiotics.
    c. Maintain quality controlled, viable frozen or lyophilized stocks of select clinical and reference bacterial strains under appropriate conditions.
    d. Assure identity of stocks at least to the species level using appropriate assay methods.
    e. Maintain and document current inventory, purity and identity assessment for each clinical isolate and reference/quality control strain.
    f. Provide detailed accounting for pathogen stock use and disposal.
    g. Maintain quality controlled, viable frozen or lyophilized stocks of quality control strains to be included in all activities.
    h. Characterize antimicrobial susceptibility profile for each clinical strain against a panel of antibiotics as directed and approved by the Project Officer. This antibiogram will include both licensed and investigational antimicrobial compounds.

i. Prepare, when required for testing, fresh viable cultures of reference/quality select pathogen strains in or on appropriate culture medium.
j. Maintain stocks of appropriate quality control antibiotics under recommended conditions as described in the relevant NCCLS standards.
k. Maintain stocks of test products under conditions specified by the Project Officer.
l. Provide detailed and routine quality control assessment for the performance of all bacterial stains, control antibiotics and test products using appropriate published testing guidelines.
m. Acquire, validate, and utilize assay/organism-specific standardized reagents and controls to the extent possible.

2. Perform evaluation of antibacterial activity of test compounds against panels of clinical isolates for selected bacterial pathogens.

a. Conduct all MIC determinations according to the relevant NCCLS standards, where available or as directed by the Project Officer, in liquid or on solid medium.
b. Document preparation, lots, and use of test products, bacterial growth media, and control antibiotics.
c. Conduct appropriate standard format MIC evaluations with test products against clinical isolates of selected bacterial pathogens and at least one standard strain of the same species.
d. Include in each standard MIC evaluation the appropriate number of reference/quality control strains for each control antibiotic.
e. Conduct MIC50 and MIC90 determinations using at least the minimum acceptable number of clinical isolate strains to derive MIC50 and MIC90 values.
f. Provide documentation of all primary test results.
g. As part of quality control assurance, provide documentation of performance and results of test antibiotics and reference/quality control strains for same day experiments, as well as for experiments done on different days for the same strain/antibiotic combination.
h. Provide documentation of physical appearance (such as, but not limited to, cloudiness or precipitation in solution, etc) of test and control compounds, as well as documentation of any observations made during testing (such as, but not limited to, unexpected bacterial growth behavior, etc.)
i. Determine tentative clinical breakpoints for the test compounds.
j. If requested by the Project Officer, activity of combinations of test products and/or antibiotics against selected panels of strains shall be evaluated using a standard checkerboard format.

3. Perform special studies, as directed by the Project Officer, which may include but are not limited to standardization of assay conditions proposed and developed by the NCCLS for bioterrorism agents and reference organisms.

4. Meet all items outlined in the General Statement of Work for "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense."

Part B Sample Task Order
Notes for Part B
Part B Technical Evaluation Criteria
Back to Intro

STATEMENT OF WORK for PART C: SMALL ANIMAL MODELS FOR SELECTED PATHOGENS, TO INCLUDE GLP STUDIES

The third activity area to be supported under this contract is the development, validation and use of various relevant, small animal models to screen new therapeutic, diagnostic and preventive compounds or test the efficacy of therapeutics, immunotherapies, diagnostics, and vaccines with activity against emerging infectious agents including, Bioterrorism Category A-C agents. These contracts will provide a ready capacity in a number of needed areas and be utilized as products become available for testing. (*In vivo* safety testing, pharmacokinetics, pharmacodynamics, and toxicity testing to support therapeutic or vaccine development are covered under Part E and F of this solicitation.)

Independently, and not as an agent of the government, the Contractor shall develop small animal models to be used for screening and efficacy testing of new products including therapeutics, immunotherapies, diagnostics, and

vaccines. Conduct all *in vivo* testing as required for approval of a product for human administration. Testing must be sufficient to meet requirements for IND filing. Not intended for this solicitation are animal models for infection with Variola major (human smallpox), Filoviruses, Viral Hemorrhagic Fever agents (specifically: Punta Toro, Pichinde, Banzi, and Semlicki Forest viruses; see: NIAID Antiviral Preclinical Drug Screening and Animal Model Evaluation), TB (see NIAID Supported In Vivo Evaluation of Anti-Mycobacterium Tuberculosis Activity), and influenza. Proposals utilizing animal models for infection with TB or influenza will not be considered for award.

Some, but not all studies will require that they be performed in accordance with Good Laboratory Practice (GLP) regulations (21 CFR 58). Model development or refinement, proof of concept, screening or pilot studies may not require GLP compliance, while studies to support FDA applications will require GLP compliance. The necessity for GLP compliance will be identified in Specific Task Orders. Offerors should address their capability to perform GLP studies. Offerors that do not have the current capacity to perform GLP studies must present plans for meeting GLP requirements for Task Orders requiring GLP. Offerors are strongly encouraged to develop GLP compliance if they are currently unable to carry out GLP studies, and to present their plan as part of their proposal.

Model development capacity is a particular priority for emerging infections, including Category A-C pathogens. Some needed model development studies highlighted by the Blue Ribbon Panel are: development and evaluation of *in vivo* transmission and spore germination models of anthrax; development of animal models for studying pathogenesis and therapeutic and vaccine efficacy for smallpox; development of aerosol and/or humanized models for Category B inhalational bacteria; development of inhalational models of Category B arthropod-borne pathogens, including pathogenesis. These are just some research priorities, and Offerors with capabilities in other areas of emerging infections, including Category A-C small animal models are encouraged to submit proposals.

Specifically, the Contractor shall:

1. Utilize or provide one or more well-characterized and relevant animal models(s) of human infection and/or disease mediated by emerging infections, including Category A-C disease agents to evaluate candidate diagnostics, drugs, vaccines and immunotherapies for preliminary efficacy. For infection models, the infection of animals should be efficiently established. For other models, for example, mice transgenic with the human virus receptor gene or mice implanted with virus-infected human tissues, provide and use animals for evaluation of candidate therapies. For all models, the process and dosage level of infection/challenge and/or disease pathogenesis should resemble the corresponding human disease as closely as possible. Standardized protocols, when provided by the Project Officer, shall be incorporated.

2. Perform preclinical evaluations of experimental therapies, diagnostic, and preventive compounds as specified by the Project Officer. The test articles shall be evaluated for efficacy. When appropriate, conduct studies to evaluate novel strategies for drug delivery and dosing, including combination and sequential drug administration. These studies shall include appropriate uninfected and untreated controls and may involve aerosol challenge of some agents requiring specialized testing facilities. Federal guidelines for care and use of laboratory animals must be followed as well as requirements for approval of animal use protocols. Unless directed otherwise, submit each proposed protocol/experiment/effort to the Project Officer for review, prioritization, and approval. The NIAID Project Officer will provide compounds for evaluation.

   Evaluation capabilities of the animal model shall include, but not be limited to, the following:

   a. Quantitative assessments, which detect differences, with at least a minimal level of statistical confidence, between treatment groups of animals, with specific indicators including confirmation of infection, quantitation of organisms present in tissues of infected animals, markers of disease progression, and selected indicators of morbidity.

   b. Microbiological and histological analyses, including but not limited to special stains and cultures, to document the purity, severity, pathology, and location of the animal infection. Necropsy/pathology support shall be available as needed.

   c. Appropriate observations and measures of general toxicity, to include body weight, blood chemistries, hematologic measures, body temperature, behavior, and other indicators of general health.

   d. Immunogenicity and/or immune responses when appropriate for the test article.

   e. Sample collections. Offerors will be required only to have the capability of collecting and preparing blood,

cell, and tissue samples for shipment to another site for analysis. If the Offeror has limited pharmacokinetic capabilities exist (for example, peak and trough determinations) please describe those capabilities.

f. Acquire, validate, and utilize assay/organism-specific standardized reagents and controls to the extent possible.

3. Develop and evaluate new assays and models that may be required for new/emerging agents and models/species. The Contractor may be required to use animal models other than the one proposed if well-characterized animal models become available. Refinement and validation of animal models may be required in order to provide data of sufficient quality to support product licensure under the animal rule (CFR 314.600; CFR 601.90)

4. Conduct work with animals in accordance with NIH guidelines for animal care and use. Maintain awareness of evolving regulatory requirements for animal research and with the FDA regulatory guidelines for animal studies in support of licensure, such as the 21 CFR Parts 314 and 601 "New Drug and Biological Drug Products: Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible." When efficacy studies are intended to support the clinical use of a test article in humans, the Contractor shall also:

   a. Provide all data, information, and records required for the writing and submission of the Masterfile, Investigators Brochure, and all other documents related to IND submission and maintenance to the Project Officer or to a designated third party.

   b. Retain all records, samples, histopathological slides, etc. and make them available as indicated under GLP guidelines.

   c. Maintain awareness of evolving regulatory requirements for preclinical evaluations for chemicals or biologics, and develop new test systems or models as required to meet new needs.

   d. Participate as necessary in discussions with the FDA during pre-IND, IND, and pre-NDA meetings.

5. Meet all items outlined in the General Statement of Work for "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense."

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STATEMENT OF WORK for PART D: NON-HUMAN PRIMATE MODELS FOR SELECTED PATHOGENS, TO INCLUDE GLP STUDIES

This activity will support the development, validation and use of various relevant, non-human primate models to test the efficacy of therapeutics, immunotherapies, diagnostics, and vaccines with activity against emerging infectious agents including, Bioterrorism Category A-C agents. These contracts will provide a ready capacity in a number of needed areas and be utilized as products become available for testing. (*In vivo* safety testing, pharmacokinetics, pharmacodynamics, and toxicity testing are covered under Part E and F of this solicitation.)

Independently, and not as an agent of the Government, the Contractor shall develop non-human primate animal models to be used for efficacy testing of new products including therapeutics, immunotherapies, diagnostics, and vaccines. Conduct *in vivo* testing in an infection model as is required for approval of a product for human administration. Testing must be sufficient to meet requirements for IND filing. Bridging studies to develop model capability in non-human primate species other than rhesus macaques are also a priority for NIAID. Proposals utilizing animal models for infection with TB or influenza, or animal models using baboons or chimpanzees will not be considered for award.

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Some, but not all studies will require that they be performed in accordance with Good Laboratory Practice (GLP) regulations (21 CFR 58). Model development or refinement, proof of concept, screening or pilot studies may not

require GLP compliance, while studies to support FDA applications will require GLP compliance. The necessity for GLP compliance will be identified in Specific Task Orders. Offerors should address their capability to perform GLP studies. Offerors that do not have the current capacity to perform GLP studies must present plans for meeting GLP requirements for Task Orders requiring GLP. Offerors are strongly encouraged to develop GLP compliance if they are currently unable to carry out GLP studies, and to present their plan as part of their proposal.

Model development capacity is a particular priority for emerging infections, including Category A-C pathogens. Some needed model development studies highlighted by the Blue Ribbon Panel are: bridging studies for established models into new species, particularly from rhesus macaques into other non-human primate species; determination of correlates of immunity for rPA vaccines in non-human primate models; determination of correlates of immunity for plague and tularemia; develop and validate non-human primate model for West Nile Virus infection and disease suitable for testing candidate vaccines and therapeutics. Additionally, we seek Offerors that can provide models for testing of vaccines for Rift Valley Fever, Plague, and Tularemia. These are just some research priorities, and Offerors with capabilities in other areas of emerging infections, including Category A-C non-human primate models are encouraged to submit proposals.

Specifically, the Contractor shall:

1. Utilize or provide one or more well-characterized non-human primate models(s) for infection and/or disease caused by emerging infections, including Category A-C disease agents for evaluation of candidate diagnostics, drugs, vaccines, and immunotherapies. Models shall be representative of human disease, pathogenesis, and route of infection/challenge, and shall utilize a realistic size inoculum. If validated models are available, they should be included. Non-human primate models may require refinement to demonstrate relevancy on the basis of relevant data in other species.

2. Perform preclinical evaluations of experimental therapies, diagnostic, and/or preventive compounds/vaccines.

3. The test compounds shall be evaluated for efficacy. When appropriate, conduct studies to evaluate novel strategies for drug delivery and dosing, including combination and sequential drug administration. These studies shall include appropriate uninfected and untreated controls and may involve aerosol challenge of some agents requiring specialized testing facilities. Unless otherwise indicated, each proposed protocol/experiment/effort shall be submitted to the Project Officer for review, prioritization, and approval. The NIAID Project Officer will provide compounds for evaluation.

   Evaluation capabilities of the animal model shall include, but not be limited to, the following:

   a. Quantitative assessments, which detect statistically valid differences between treatment groups of animals, with specific confirmation of infection, quantitation of infection, markers of disease progression, selected indicators of morbidity, and other measures as are appropriate for the model.

   b. Microbiological and histological analyses, including but not limited to special stains and cultures, to document the purity of stocks and severity, pathology, and location of the animal infection.

   c. Appropriate observations and measures of general toxicity, to include but not limited to body weight, blood chemistries, hematologic measures, body weight, and other indicators of general health. Necropsy/pathology support shall be available as needed.

   d. Immunogenicity and/or immune responses when appropriate for the test article.

   e. Limited pharmacokinetic determinations, if available. Offerors will be required only to have the capability of collecting and preparing blood, cell, and tissue samples for shipment to another site for analysis. Offerors that have the capability to perform limited pharmacokinetic determinations (i.e. peak and trough determinations in infected models) may propose to do so.

   f. Acquire, validate, and utilize assay/organism-specific standardized reagents and controls to the extent possible.

4. Develop and evaluate new assays and models that may be required for new/emerging agents and models/species.

The Contractor may be required to use animal models other than the one proposed if well-characterized animal models become available. Refinement and validation of animal models may be required in order to provide data of sufficient quality to support product licensure under the animal rule (CFR 314.600; CFR 601.90).

5. Conduct work with animals in accordance with NIH guidelines for animal care and use. Maintain awareness of evolving regulatory requirements for animal research and with the FDA regulatory guidelines for animal studies in support of licensure, such as the 21 CFR Parts 314 and 601 "New Drug and Biological Drug Products: Evidence Needed to Demonstrate Effectiveness of New Drugs When Human Efficacy Studies Are Not Ethical or Feasible." When efficacy studies are intended to support the clinical use of a test article in humans, the Contractor shall also:

   a. Provide all data, information, and records required for the writing and submission of the Masterfile, Investigators Brochure, and all other documents related to IND submission and maintenance to the Project Officer or to a designated third party.

   b. Retain all records, samples, histopathological slides, etc. and make them available as directed by the Project Officer and as indicated under GLP guidelines.

   c. Maintain awareness of evolving regulatory requirements for preclinical evaluations for chemicals or biologics, and develop new test systems or models as required to meet new needs.

   d. Participate as necessary in discussions with the FDA during pre-IND, IND, and pre-NDA meetings.

6. Meet all items outlined in the General Statement of Work for "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense."

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STATEMENT OF WORK for PART E: SAFETY/TOXICOLOGY AND IMMUNOGENICITY TESTING for VACCINES

The fifth activity area to be supported under this contract is the testing of vaccine preparations as required prior to initial clinical evaluation. This includes testing candidate products for safety and immunogenicity (both cellular and humoral) in small animals and, if appropriate, in non-human primates.

Independently, and not as an agent of the Government, the Contractor shall test candidate products for safety and immunogenicity (both cellular and humoral) in small animals and, if necessary, in non-human primates, and other appropriate tests, including reproductive toxicology. Perform all such tests as are required to support clinical use in humans of a vaccine product. Testing must be sufficient to meet requirements for IND filing.

Specifically, the Contractor shall:

1. At the request of the Project Officer, the Contractor shall perform all tests required to qualify a vaccine product for human administration or to qualify relevant cell substrates for vaccine production, including but not limited to the list below. Such testing must also include all tests required for Investigational New Drug (IND) and Masterfile submission. All studies must be performed in accordance with Good Laboratory Practice (GLP) regulations (21 CFR 58) unless otherwise specified by the Project Officer in writing.

   a. Preclinical immunogenicity evaluation: The preclinical studies shall be designed to assess the immune response including seroconversion rates, antibody levels, and cell mediated immune responses in vaccinated animals.

   b. Preclinical safety evaluations shall include but are not limited to the following:

      1) Systemic toxicity: Preclinical studies shall include dose-ranging and dose escalation studies of systemic

toxicity as well as toxicity to potential target organs, including hematopoietic and immune systems, and histological evaluation of organs.

2) Local reactogenicity: Local site reactivity studies to include detailed clinical observations and histological evaluation of tissue at the injection site or other visible lesions from biopsies or term necropsy samples.

3) Genetic toxicity: In the case of DNA and vector-based vaccines the pivotal GLP preclinical study shall focus on assessment for the potential for the nucleic acid vaccine to recombine with endogenous host DNA sequences and integrate into cell chromosomes. Studies designed to address the potential for integration shall use the most sensitive methods available.

4) Tumorigenicity studies: Tumorigenicity studies may be appropriate under certain conditions, such as if the preclinical genetic testing demonstrates evidence of integration activity and/or broad tissue distribution, or to qualify cell substrates used in vaccine production. Such studies shall be performed when necessary.

5) Reproductive toxicity studies: Reproductive toxicity studies must be performed prior to the use of these vaccines in pregnant women. Such studies shall include but are not limited to fertility, general reproductive performance, teratology, and developmental toxicity.

6) All other safety tests as may be required for a particular vaccine type.

c. Adjuvant testing: The use of adjuvants and/or facilitators for the administration of a vaccine will necessitate specific preclinical evaluation procedures to ensure the safety of the candidate formulation to include but not limited to the evaluations listed in b) above.

2. In addition, the Contractor shall:

a. Provide all data, information, and records required for the writing and submission of the Masterfile, Investigators Brochure, and all other documents related to IND submission and maintenance to the Project Officer or to a designated third party.

b. Retain all records, samples, histopathological slides, etc. and make them available as directed by the Project Officer and as indicated under GLP guidelines.

c. Maintain awareness of evolving regulatory requirements for preclinical immunogenicity and safety evaluations for vaccines, and develop new test systems or models as required to meet new needs.

d. Acquire, validate, and utilize assay/organism-specific standardized reagents and controls to the extent possible.

e. Participate as necessary in discussions with the FDA during pre-IND, IND, and pre-NDA meetings.

3. Meet all items outlined in the General Statement of Work for "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense."

Part E Statement of Work
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STATEMENT OF WORK for PART F: SAFETY/TOXICOLOGY AND PHARMACOLOGY TESTING for THERAPEUTICS

The sixth activity under this contract is the testing of candidate products for safety, including reproductive toxicology and other appropriate tests, in small and large animal, and if necessary, in non-human primates. This activity includes all such tests as are required to support clinical use in humans; testing must be sufficient to meet requirements for IND filing (GLP).

Independently, and not as an agent of the Government, the Contractor shall test candidate products for safety/toxicity and perform pharmacology studies. Perform all such tests as are required to support clinical use in humans of a therapeutic or vaccine product.

Specifically, the Contractor shall:

1. At the request of the Project Officer, the Contractor shall perform all tests required to qualify a therapeutic product for human administration including but not limited to the list below. Such testing must also include all tests required for Investigational New Drug (IND) and Masterfile submission. All studies must be performed in accordance with Good Laboratory Practice (GLP) regulations (21 CFR 58) unless otherwise specified by the Project Officer in writing.

    a. Preclinical toxicity evaluations of experimental anti-infective therapies or other test articles in small animals, to include but not limited to:

        1) Determination in rodents of the maximally tolerated dose (MTD) of experimental therapies.
        2) Determination in rodents of the acute and subchronic systemic toxicity of experimental therapies,
        3) Determination of relevant pharmacokinetic/toxicokinetic parameters of experimental therapies in rodents.

    b. Preclinical toxicity and pharmacology evaluations of experimental anti-infective therapies or other test articles in large animals (non-rodents), to include but not limited to:

        1) Determination in a non-rodent large animal (e.g. dog or non-human primate) of the acute and subchronic systemic toxicity of experimental therapies, and establishment of relevant pharmacokinetic parameters in this species.

        2) Determination of the pharmacokinetics/pharmacodynamics of experimental therapies in non-human primates.

    c. Other preclinical toxicity/safety studies, using appropriate animal and *in vitro* assays, to include, but not limited to:

        1) Genetic toxicity of experimental therapies or test articles: Genetic toxicity studies must be performed for most therapies. Such studies shall include but are not limited to the ability of the test article to produce genetic damage in mammalian cells as indicated by the ability to induce mutations at the thymidine kinase locus (tk) in L5178Y mouse lymphoma cells and the ability of the test article to induce genetic damage in the Salmonella/ *E.coli* test system.

        2) Tumorigenicity studies: Tumorigenicity studies may be appropriate under certain conditions, such as when compounds are expected to be administered for extended periods of time. Such studies shall be performed when necessary.

        3) Reproductive toxicity studies: Reproductive toxicity studies must be performed prior to the use of these therapies in pregnant women. Such studies shall include but are not limited to fertility, general reproductive performance, teratology, and developmental toxicity.

        4) Immunotoxicity studies: Immunotoxicity studies to determine in rodents the toxicity of experimental therapies to the immune system, or other specialized target organ system.

        5) Biotransformation assays: Assays, conducted *in vitro* to evaluate the potential of experimental therapies to undergo biotransformation in test animals and humans.

        6) Additional pharmacologic assays: Assays and studies to determine additional pharmacologic parameters of experimental therapies, such as but not limited to: tissue distribution, mass balance, etc. May require use of radiolabeled material that would be provided by NIAID.

        7) All other safety and pharmacology assays and studies that may be required for a particular therapeutic compound.

2. In addition, the Contractor shall:

   a. Evaluate the data resulting from the conduct of the above studies and draw relevant conclusions about pharmacokinetics, target organ(s) of toxicity, and likely human adverse reactions to the evaluated therapies.

   b. Provide all data, information, and records required for the writing and submission of the Masterfile, Investigators Brochure, and all other documents related to IND submission and maintenance to the Project Officer or to a designated third party.

   c. Retain all records, samples, histopathological slides, etc. and make them available as directed by the Project Officer and as indicated under GLP guidelines.

   d. Maintain awareness of evolving regulatory requirements for preclinical toxicologic evaluations for chemicals or biologics, and develop new test systems or models as required to meet new needs.

   e. Acquire, validate, and utilize assay/organism-specific standardized reagents and controls to the extent possible**.**

   f. Participate as necessary in discussions with the FDA during pre-IND, IND, and pre-NDA meetings.

   3. Meet all items outlined in the General Statement of Work for "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense."

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STATEMENT OF WORK for SAMPLE TASK ORDER A
IN VITRO SCREENS FOR ANTIMICROBIAL ACTIVITY

The activity to be supported under this contract is screen compounds for antimicrobial activity against infectious agents listed below. Materials for testing will be provided by NIAID.

[NOTE #1 to Offerors: Include all steps necessary to establish and perform standardized screening assays for the organisms listed below. The proposal should be structured in terms of specific milestones to be accomplished. Reports will be provided upon completion of each milestone. Provide a timeline. Assume up to 500 compounds for testing within the first year, to be sent in groups of approximately 50 compounds. Assume test compounds will be provided as powders in limited amounts.

For the purposes of this sample task order, Offerors may propose studies using pathogens from those listed below. It is not expected that every Offeror will have expertise with all organisms listed below. The proposal should indicate the organisms for which the Offeror has expertise. The proposal should clearly indicate exactly what work is proposed.]

1. Specifically, the Contractor shall develop, validate, and use *in vitro* assays to screen compounds for antimicrobial activity against one or more of the following pathogens:

   a. Category A: *Bacillus anthracis*, *Francisella tularensis*, *Yersinia pestis*

   b. Category B bacteria: *Burkholderia pseudomallei, Coxiella burnetti, Brucella* species, *Burkholderia mallei*,

   c. Other Category B pathogens: *Staphylococcus* enterotoxin B, Typhus fever (*Rickettsia prowazekii*), diarrheagenic *E.coli*, pathogenic *Vibrios*, *Shigella* species, *Salmonella, Listeria monocytogenes, Campylobacter jejuni, Yersinia enterocolitica*

   d. Category B protozoa: *Cryptosporidium parvum, Cyclospora cayatanensis, Giardia lamblia, Entamoeba histolytica, Toxoplasma, Microsporidia*

2. Maintain quality controlled stocks of bacterial pathogens, control and test substances: as outlined in the Statement of Work for Part A of "In Vitro Screens for Antimicrobial Activity."

3. Perform evaluation of antimicrobial activity of test substances against panels of standard reference strains of selected bacterial pathogens. Determine the inhibitory effect on replication and/or infectivity based on MIC values or based on activity at one selected concentration. Evaluations shall incorporate both the substance under investigation, a positive control compound, and an untreated control. Document preparation, lots, and use of test substances, bacterial growth media, and control antibiotics.

4. Provide all data, information, and records required to support labeling to the Project Officer or to a designated third party. This information shall be submitted within three weeks of the time the Project Officer makes the request.

5. Complete all tasks as outlined in the General Statement of Work for "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense" and the Part A Statement of Work.

Notes for Part A

STATEMENT OF WORK for SAMPLE TASK ORDER B
CLINICAL ISOLATE PANELS FOR SELECTED BACTERIAL PATHOGENS

The activity to be supported under this contract is to determine the range of activity of antimicrobial compounds, as MIC50 and MIC90 values against clinical panels of pathogens. Materials for testing and clinical isolates will be provided by NIAID.

[NOTE #1 to Offerors: Include all steps necessary to establish and perform standardized antimicrobial activity assays for the organisms listed below to determine MIC50 and MIC90 values, as well as tentative susceptibility breakpoints for each antibiotic. The proposal should be structured in terms of specific milestones to be accomplished. Reports will be provided upon completion of each milestone. Provide a timeline. Assume that panels will be comprised of approximately 20 strains of each pathogen.

For the purposes of this sample task order, Offerors may propose studies using pathogens from Category A-C. It is not expected that every Offeror will have expertise with all organisms. The proposal should indicate the organisms for which the Offeror has expertise. The proposal should clearly indicate exactly what work is proposed.]

1. Specifically, the Contractor shall determine the antibacterial activity of antibiotics against panels of clinical strains of emerging infections, including Category A-C bacteria and shall be available to participate in the establishment of testing standards for the bacterial pathogens and antibiotics. Antibiotics to be tested include FDA-approved as well as new drugs. Conduct all evaluations as outlined in the Statement of Work for Part B of "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense."

2. Maintain quality controlled stocks of bacterial pathogens, control and test substances: as outlined in the Statement of Work for Part B of "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense."

3. Provide all data, information, and records required to support labeling to the Project Officer or to a designated third party. This information shall be submitted within three weeks of the time the Project Officer makes this request.

4. Complete all tasks as outlined in the General Statement of Work for "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense" and the Part B Statement of Work.

Notes for Part B

STATEMENT OF WORK for SAMPLE TASK ORDER C
SMALL ANIMAL MODELS FOR SELECTED PATHOGENS

The activity to be supported under this task order is the testing of a new therapeutic and/or a new vaccine for activity against an agent of the Offeror's choice, in particular Category A-C agent(s), in a small animal model of the Offeror's choice (see priorities in Background). This includes testing that may support licensure/labeling of these new compounds for use under the FDA's "animal efficacy rule."

[NOTE #1 to Offerors: Offerors are encouraged to give a detailed description of their best developed/characterized/utilized model in the Sample Task Order proposal, including technical details and rationale. If proposing therapeutic efficacy testing, include all testing required to support IND submission. If proposing vaccine efficacy testing, include all testing required to support Biologic License Application submission, as well as post-exposure use of the vaccine if appropriate. The proposal should be structured in terms of specific milestones (studies, with discrete objectives identified) to be accomplished. Include measures of therapeutic efficacy and/or vaccine efficacy in study descriptions. Reports will be provided upon completion of each milestone. Provide a timeline. Offerors who have the capability to perform the studies in accordance with GLP shall do so. Those who do not may propose to do the studies but should include a plan for achieving GLP compliance.

Offerors are encouraged to choose their best developed/characterized/utilized model for a detailed description in the Sample Task Order proposal, including technical details and rationale. Offerors are encouraged to summarize briefly in their Sample Task Order proposal the breadth of model and pathogen expertise. This summary may take the form of a table, indicating animal species, pathogen strains and routes of infection, inoculum, LD_{50}, and similar data. An indicator of the status of each model, such as 'validated' or 'in development' or 'planned for future development' should also be included. NIAID seeks breadth and depth, not from individual Offerors, but programmatically. Therefore proposals with depth in a single area will not be judged negatively for lack of breadth.]

1. Specifically, the Contractor shall perform all tests required to qualify the substance for labeling/approval, including but not limited to the list below. Such testing shall be performed in accordance with Good Laboratory Practice (GLP) regulations (21 CFR 58) where possible; Offerors who do not currently have the capability to perform the studies in accordance with GLP should include a plan for achieving GLP compliance. Describe positive and negative controls where they exist.

   a. Pharmacokinetic studies, if necessary to determine doses to be used in efficacy studies.
   b. Efficacy of the antibiotics/new compounds.
   c. Other tests as may be necessary for completion of the efficacy study.

2. Provide all data, information, and records required to support labeling to the Project Officer or to a designated third party. This information shall be submitted within three weeks of the time the Project Officer makes the request.

3. Complete all tasks as outlined in the General Statement of Work for "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense" and the Part C Statement of Work.

Notes for C

STATEMENT OF WORK for SAMPLE TASK ORDER D
NON-HUMAN PRIMATE MODELS FOR SELECTED PATHOGENS

The activity to be supported under this task order is the testing of a new therapeutic and/or a new vaccine for activity against an agent of the Offeror's choice, in particular Category A-C agent(s), in a non-human primate model of the Offeror's choice (see priorities in Background). This includes testing that may support licensure/labeling of these new compounds for use under the FDA's "animal efficacy rule".

[NOTE #1 to Offerors: Offerors are encouraged to give a detailed description of their best developed/characterized/utilized model in the Sample Task Order proposal, including technical details and rationale. If proposing therapeutic efficacy testing, include all testing required to support IND submission. If proposing vaccine efficacy testing, include all testing required to support Biologic License Application submission, as well as post-exposure use of the vaccine if appropriate. The proposal should be structured in terms of specific milestones (studies,

with discrete objectives identified) to be accomplished. Include measures of therapeutic efficacy and/or vaccine efficacy in study descriptions. Reports will be provided upon completion of each milestone. Provide a timeline. Offerors who have the capability to perform the studies in accordance with GLP shall do so. Those who do not may propose to do the studies but should include a plan for achieving GLP compliance.

Offerors are encouraged to choose their best developed/characterized/utilized model for a detailed description in the Sample Task Order proposal, including technical details and rationale. Offerors are encouraged to summarize briefly in their Sample Task Order proposal the breadth of model and pathogen expertise. This summary may take the form of a table, indicating animal species, pathogen strains and routes of infection, inoculum, LD_{50}, and similar data. An indicator of the status of each model, such as 'validated' or 'in development' or 'planned for future development' should also be included. NIAID seeks breadth and depth, not from individual Offerors, but programmatically. Therefore proposals with depth in a single area will not be judged negatively for lack of breadth.]

1. Specifically, the Contractor shall perform all tests required to qualify the substance for approval/labeled use, including but not limited to the list below. Such testing shall be performed in accordance with Good Laboratory Practice (GLP) regulations (21 CFR 58) where possible; Offerors who do not currently have the capability to perform the studies in accordance with GLP should include a plan for achieving GLP compliance. Discuss positive and negative controls where available.

   a. Bridging studies to move from rhesus macaques to cynomolgus macaques.
   b. Pharmacokinetic studies, if necessary to determine doses to be used in efficacy studies.
   c. Efficacy of the new compounds/antibiotics.
   d. Other tests as may be necessary for completion of the efficacy study.

2. Provide all data, information, and records required to support labeling to the Project officer or to a designated third party. This information shall be submitted within three weeks of the time the Project Officer makes the request.

3. Complete all tasks as outlined in the General Statement of Work for "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense" and the Part D Statement of Work.

Notes for Part D

STATEMENT OF WORK for SAMPLE TASK ORDER E
SAFETY AND IMMUNOGENICITY TESTING FOR VACCINES

The activity to be supported under this contract is the testing of vaccine, such as (a) synthetic peptides, (b) recombinant subunits, (c) vector based vaccines, (d) virus-like particles/replicons, or (e) nucleic acid based vaccines), as required prior to initial clinical evaluation and for continued clinical development. This includes testing candidate products for safety and immunogenicity (both cellular and humoral).

[NOTE #1 to Offerors: Include all testing required for an IND and for advanced clinical development (Phase II trials and including special populations) for this type of product. The proposal should be structured in terms of specific milestones to be accomplished. Reports will be provided upon completion of each milestone. Provide a timeline. The Government will provide the test vaccine.

Offerors who have the capability to perform the studies in accordance with GLP shall do so. Those who do not may propose to do the studies but should clearly include a plan for achieving GLP compliance. The Offeror should clearly identify the types of animal(s) that will be used in each study.

For the purposes of providing a cost proposal, Offeror(s) should provide a detailed budget based on the preclinical safety and immunogenicity evaluation of one recombinant protein vaccine product. Assume that tumorigenicity and reproductive toxicity studies are not required for the cost estimate. Include documentation for personnel costs and all specific animal, supply, and equipment costs.]

1. Specifically, the Contractor shall perform all tests to qualify a vaccine product for human administration including but not limited to the list below. Such testing must also include all tests required for Investigational New Drug (IND) and Masterfile submissions. In addition, include all testing that will be necessary to expand

clinical development to special populations. All studies must be performed in accordance with Good Laboratory Practice (GLP) regulations (21 CFR 58).

a. Preclinical immunogenicity evaluation: The preclinical studies shall be designed to assess the immune response including seroconversion rates, antibody levels, and cell mediated immune responses in vaccinated animals. Studies should also be designed to establish a model for determining potency.

b. Preclinical safety evaluations may include but are not limited to the following:

1) Systemic toxicity: Preclinical studies shall include dose-ranging and dose escalation studies of systemic toxicity as well as toxicity to potential target organs including hematopoietic and immune systems.

2) Local reactogenicity: Local site reactivity studies to include detailed clinical observations and histological evaluations of tissue of the injection site or other visible lesions from biopsies or term necropsy samples.

3) All other safety tests as may be required for a particular vaccine type and for advanced clinical development, such as genetic toxicity, tumorigenicity, and reproductive toxicity studies.

2. Provide all data, information, and records required to support regulatory filings to the Project Officer or to a designated third party. This information shall be submitted within three weeks of the time the Project Officer makes the request.

3. Complete all tasks as outlined in the General Statement of Work for "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense" and the Part E Statement of Work.

Notes for Part E

STATEMENT OF WORK for SAMPLE TASK ORDER F
SAFETY/TOXICOLOGY AND PHARMACOLOGY TESTING FOR THERAPEUTICS

The activity to be supported under this contract is providing pharmacokinetics and safety data for various new compounds or FDA-approved antibiotics that will be tested for activity against emerging infections, including Category A-C agents, in small animal and/or non-human primate models.

[NOTE #1 to Offerors: Include all testing required to support efficacy studies in animal models. This information will support licensure/labeling of these drugs for treatment. The proposal should be structured in terms of specific milestones to be accomplished. Reports will be provided upon completion of each milestone. Provide a timeline. Offerors who have the capability to perform the studies in accordance with GLP shall do so. Those who do not may propose to do the studies but should clearly indicate that the work cannot be performed according to GLP.

Offerors may propose studies in small animal models, non-human primates, or both. The proposal should clearly indicate exactly what work is proposed.]

1. Specifically, the Contractor shall perform all tests to determine the pharmacokinetics of the substances/antibiotics after a single parenteral administration in mice and rabbits. Such testing shall be performed in accordance with Good Laboratory Practice (GLP) regulations (21 CFR 58) where possible.

2. Perform all tests to determine the pharmacokinetics of the antibiotics after a single parenteral administration in non-human primates as listed below. Such testing shall be performed in accordance with Good Laboratory Practice (GLP) regulations (21 CFR 58) where possible.

3. Perform such safety studies as may be deemed necessary to support use of these substances/antibiotics in efficacy studies in mice, rabbits, and/or non-human primates. Safety/toxicity studies should be based on a review of available literature.

4. Provide all data, information, and records required to support labeling to the Project Officer or to a designated

third party. This information shall be submitted within three weeks of the time the Project Officer makes the request.

5. Complete all tasks as outlined in the General Statement of Work for "*In Vitro* and Animal Models for Emerging Infectious Diseases and BioDefense" and the Part F Statement of Work.

Notes for Part F

NOTES TO OFFERORS

"In Vitro and Animal Models for Emerging Infectious Diseases and BioDefense"
DMID-04-40

GENERAL STATEMENT OF WORK FOR ALL PARTS

[NOTE #1 TO ALL OFFERORS: All Offerors that receive a contract award are eligible for the guaranteed minimum(s). Offerors that receive awards for more than one Part will be eligible for the minimum for each Part awarded. Offerors that make the prequalified pool and can provide multiple organisms/models within a Part will be eligible for a single guaranteed minimum for that Part. It is anticipated that the maximum total funding available for all contracts awarded under this solicitation will be between $30 - 60 million per year. After the basic contract awards are made, task orders will be competed in accordance with FAR 16.505 under parts A, B, C, D, E or F based on the specific requirements of the task order. Contractor(s) will submit a detailed proposal in accordance with the Request for Task Order Proposal. These proposals will include established milestones to perform the work stated in the task order along with a detailed budget. The resulting task order award(s) will include specifics on deliverables and reporting.]

[NOTE #2 TO ALL OFFERORS: Because the Parts A - F of this solicitation are not highly related, single institutions may not have the expertise and facilities required to perform all requirements in the Statement of Work. Nor is it anticipated that every Offeror will have experience/capabilities with all priority pathogens. Thus it is acceptable for an Offeror to submit a task order proposal under Part A, B, C, D, E, or F or any combination of the six, as well as particular models/organisms within a part. See evaluation criteria. Each Part will be independently evaluated so that the Offeror will only be evaluated based on the specific Part(s) for which it applies. Lack of expertise in one Part will not affect the evaluation of other Parts. Separate review committees will likely be involved in the review of Parts A - F. Therefore, responses should be packaged as separate, stand-alone entities for each Part.

If the Offeror wishes to include in his/her proposal Parts or specific tasks for which he/she does not have direct expertise, then the Offeror may propose a subcontract in order to fulfill the requirements of activities in Parts A - F. The Contractor shall be directly responsible for all work performed under this contract, including work done by any subcontractor. If a subcontractor is proposed, similar technical information should be provided as part of the proposal as that required of the Contractor, i.e., technical approach, methods, experience, personnel qualifications, facilities, resources, etc., and cost details should also be provided by the subcontractor.

In responding to this RFP, Offerors should describe in detail the responsibilities and level of effort of all proposed personnel who will be assigned to the contract. In addition, Offerors should describe an administrative framework showing clear lines of authority.

Documentation should be provided on the qualifications, experience, education, competence, and availability of the Principal Investigator, Research, Technical and Administrative Support staff; the extent to which outside consultants shall be used as well as assurance of their availability. If a subcontractor is proposed, similar technical information should also be provided as part of the Technical Proposal. Proposed subcontractors should also provide cost details.

Technical proposals must describe specifically how the Offeror will fulfill each of the items in the Statement of Work below. The technical proposal should include:

* qualifications, experience, education, competence, availability, and specific assignment of each proposed member of the research team (include resumes/CVs); how they will interact regarding lines of authority (provide an administrative framework in flow chart format); the decision-making authority of the Principal Investigator in relation to the rest of the organization

* specific levels of effort proposed for each individual (hours/percentages of time) and availability in relation to other commitments

* procedures for initiation of this contract's projects in a timely manner (describe how other projects in general are

prioritized within their organization and the level of priority this contract will receive)

* all instrumentation, equipment, and laboratory space to be used to fulfill the work requirements (indicate what equipment and resources are under the control of the Principal Investigator and which are to be shared; if shared, indicate who is responsible for controlling access and how determination of priority usage is made). Indicate specifically which space, equipment, resources are to be used in completion of the proposed work. Documentation of BSL3/4 certification should be provided.

* documentation of access to animals as required by the statement of work; documentation of AALAC-accreditation.

[NOTE #3 TO ALL OFFERORS] The handling and transportation of all reagents and government-owned property under this contract should be in accordance with all applicable local, state, and federal regulations including health and safety standards. (See the attached HHS Safety and Health clause, the Safety Controls and Standards and item #4 of the General Work Statement.)

[NOTE #4 TO ALL OFFERORS: The Offeror should propose a plan for data management, analysis, and electronic digital communication with the Project Officer. Communications should include the ability to transmit and receive electronic mail with the Division of Microbiology and Infectious Diseases (DMID) computer network system. The Government will not authorize purchase of stand-alone computers under this contract for this purpose. The NIAID is connected to the Internet and uses IBM-compatible computer hardware for data management and communications. The Offeror should supply an IBM-compatible computer and should submit electronic reports in Microsoft Word^{tm} for Windows and Microsoft Excel^{tm} for Windows. In the Technical Proposal, please list and describe existing computer hardware and software resources available to or planned to be specifically dedicated this project. For the purpose of preparing a cost proposal, assume 1 visit of one key personnel per study to Bethesda MD to meet with the Project Officer and other key DMID personnel.]

[NOTE #5 TO ALL OFFERORS: Data, Data Rights, Copyrights, Confidentiality of Information, Publication, Patents -- The information required by the Government will be obtained through the required contract reports. The original data shall remain with the Contractor and shall be subject to certain contract clauses. HHSAR clause 352.224-70 Confidentiality of Information (April 1984), HHSAR clause 352.270-6 Publications and Publicity (July 1991), FAR clause 52.227-11 Patent Rights - Retention by the Contractor (Short Form) (June 1997) and FAR clause 52.227-14 Rights in Data - General (June 1987) will be incorporated by reference (or in full text) into any resultant contract. Most of the data provided to or generated by the Contractor shall require confidential treatment. It is not anticipated that this contract will result in the award of a patent to the Contractor. In addition, the Government may require the use of Screening Agreements or Material Transfer Agreements between the NIAID and providers of compounds in order to protect the intellectual property rights of third party compound suppliers. A sample DMID Screening Agreement is provided with this solicitation and shall be included in any resultant contract as a means of informing potential Offerors and Contractors.]

[NOTE #6 TO ALL OFFERORS: PLANNED DEVIATIONS TO REQUIRED GENERAL CONTRACT CLAUSES FAR 52.227-11 AND FAR 52.227-14 The NIAID plans to seek a deviation from FAR clause 52.227-11, Patent Rights-Retention by the Contractor (Short Form) (June 1989). Pursuant to a Determination of Exceptional Circumstances (DEC) as required by FAR 27.303, the NIAID plans to modify clause at FAR 52.227-11, Patent Rights-Retention by the Contractor (Short Form) (June 1989) to restrict the contractor's rights to subject inventions arising under the contract. Specifically, the contractor will be required to assign to the Government or, if deemed appropriate by the NIAID and subject to certain rights reserved to the Government, to a collaborating party designated by the Government the entire right, title and interest throughout the world to each subject invention, except to the extent that rights are retained by the Contractor under the Greater Rights Determination provision of the clause. The contractor may request greater rights to an identified invention, and the NIH will consider whether granting the requested rights will interfere with rights of the Government or any collaborating party or otherwise impede the ability of the Government or others to develop new candidates for therapies, disease prevention and diagnosis as well as potential enabling technologies that may result from data ensuing from evaluations performed under this contract useful for antimicrobial discovery and development. Contractors are encouraged to request greater rights where inventions relate to technology outside NIAID's program and where the contractor has negotiated with a supplier of a proprietary composition for the disposition of patent rights concerning a subject invention related to the composition.

Furthermore, the timing of data publication will need to be restricted to allow adequate time for patent applications to be filed on inventions arising from the contracts. This would be accomplished by a deviation from FAR clause 52.227-14, Rights in Data-General (June 1987). Specifically, although NIAID encourages the publication of articles on research results, FAR 52.227-14 Rights in Data-General (June 1987) will be narrowly modified to restrict the Contractor's right to use, release to others, reproduce, distribute, and publish data produced or used by the contractor in the performance of this contract or allow adequate time for the filing of patent applications and to protect data that will be submitted as part of a regulatory filing.

NIAID will reserve the right to coordinate the timing of data publication so that appropriate domestic and international invention applications may be filed as appropriate.

Because these clause deviations are not yet approved, their text is not available for publication. However, it is NIAID's intention that the finalized versions of the deviated FAR clauses will be available before award of any contract resulting from this initiative. Instead, the aforementioned description of how these clause deviations will be practiced under the resultant contract is provided. Potential Offerors are afforded an opportunity to comment on their understanding of what NIAID is planning and to identify what impact these deviations may have on their conduct of the work should they be awarded a contract. Responses should be provided, in writing, to the Point of Contact for this RFP. See the bottom of the front page of this RFP for this individual's name and contact information. Comments should be provided within 30 days of the issue date of this RFP. Thereafter, NIAID will consider this input and determine whether alternative courses of action may be necessary. Decisions regarding these deviations will be made in consideration of the success of this NIAID requirement.]

[NOTE #7 TO ALL OFFERORS: A copy of the applicable Biosafety guidelines can be obtained from NIAID upon request. These guidelines will apply to all animal models, which may apply to this RFC. The experience of the Offeror in working with potential biohazards such as viruses and animals, as well as toxic chemicals and radioisotopes should be addressed. The Offeror shall include a Safety and Health Plan for compliance with Biosafety Level 3/4 guidelines in the Technical proposal and include a summary of the Offertory's safety and health operating procedures manual. The Offeror should also include in his/her proposal a summary of contingency plans in the case of accidental exposure to an infectious agent. The summary should include plans and timelines for reporting to the safety officer, evacuation of exposed personnel, and decontamination procedures. In addition, procedures for the care of experimental animals should be discussed if animal use is proposed.

The DHHS Safety and Health Clause (Jan 2001) 352.223-70 and the Safety Controls and Standards (attached) will become part of any resultant contract. Written documentation from a Biosafety Officer (or equivalent) should be provided (e.g., a safety management program) to assure compliance with all safety guidelines and regulations, training and monitoring of personnel for exposure to infectious or hazardous reagents, and safe disposal of such agents.]

PART A: *IN VITRO* SCREENS FOR ANTIMICROBIAL ACTIVITY

[NOTE A-1 TO OFFEROR: It is expected that 500 experimental antimicrobial substances will be evaluated annually. The Project Officer will provide the substances, which will come from the NIAID supported Tuberculosis Antimicrobial Acquisition and Coordination Facility (contract N01-AI-95364, Southern Research Institute), NIAID staff contacts with drug sponsors, and contractors' contacts with drug sponsors. These substances may be irritating, toxic, and/or potentially carcinogenic or hazardous.

The Offeror shall provide validated screening systems for all of the designated bacteria selected. Methods of screening shall be appropriate for the assessment of the efficacy and toxicity of potential therapeutic and/or prevention approaches against the proposed bacteria. Assays can be manual or automatic format. Offerors shall justify the choice of method(s) proposed. Assume that compounds will be provided as limited amounts of powder.

[NOTE A-2 TO OFFEROR: More detailed testing will generally be required when the initial screening shows that a substance has a substantial level of activity. The technical proposal shall describe preliminary screening procedures, the criteria used to select compounds recommended for further evaluation, and procedures for the special studies. Offerors may propose subcontractors for special studies.

Each special study will have distinctive evaluation needs; thus, the Project Officer will designate specific assays after consultation with the Contractors. As requested by the Project Officer, assays pertinent to special studies shall be designed, developed, compared to existing assays, standardized, validated and performed, as necessary. The Offeror should include documentation of qualifications, expertise, and strategies to modify systems or develop new systems for such studies.]

[NOTE #A-3 TO OFFEROR: Stocks of bacterial pathogens of BioDefense will be transferred to the contractor through the Project Officer. As part of the proposal, the Offeror shall provide an outline of typical operating procedures to identify and maintain primary stocks and working stocks of bacterial pathogens and to prepare cultures for testing. This shall include description of a timetable for when and how often new, working stocks and cultures for testing are prepared. Quality control procedures to assure and track viability, purity and identity of bacterial pathogens shall be described in the proposal. The Offeror shall list all appropriate NCCLS standards for preparing cultures of reference/quality control strains for testing. Where no specific NCCLS standards are available, the Offeror shall describe which standards will be employed and provide a rationale for this selection. The Offeror shall provide discussion of any problems or issues anticipated for the use of strains of select agents for testing. Assume that the contractor shall maintain stocks of up to 10 aliquots of each pathogen strain, that

strain identity shall be determined upon receipt and when strains are used for testing. Assume that the Project Officer will provide about 20 selected strains for storage and use. Furthermore, assume that quality control assessment for working stocks shall be performed only when strains are used for testing.]

[NOTE #A-4 TO OFFEROR: As part of the proposal, the Offeror shall describe, as a sample protocol, typical standard operating procedures for conducting growth inhibition assays. This sample protocol may not be the final protocol employed for testing but will serve as a means to evaluate the proposal. This protocol shall also include examples of documentation that will be provided for each test, description of quality control assurance and expected performance of quality control standards. The Offeror shall describe limits for acceptable and unacceptable control performance. The Offeror shall list all appropriate NCCLS standards for MIC determination for bacterial pathogens listed in the CDC agents of BioDefense and for quality control strains. Where no specific NCCLS standards are available, the Offeror shall describe which standards will be employed and provide a rationale for this selection. The Offeror shall also provide discussion of any problems or issues anticipated for the use of strains of select agents for testing. The Offeror is to assume that test compounds will be provided by NIAID while provision of control antibiotics and non-bioterrorism reference/control strains will be the responsibility of the contractor.]

Back to Part A Sample Task Order

PART B: CLINICAL ISOLATE PANELS FOR SELECTED BACTERIAL PATHOGENS

[NOTE #B-1 TO OFFEROR: Stocks of clinical isolates of relevant bacterial pathogens will be transferred to the contractor through the Project Officer. As part of the proposal, the Offeror shall provide an outline of typical operating procedures to identify and maintain primary stocks and working stocks of bacterial pathogens and to prepare cultures for testing. This shall include description of a timetable for when and how often new, working stocks and cultures for testing are prepared. Quality control procedures to assure and track viability, purity and identity of bacterial pathogens shall be described in the proposal. The Offeror shall list all appropriate NCCLS standards, where available, for preparing cultures of reference, clinical and quality control strains for testing. The Offeror shall provide discussion of any problems or issues anticipated for the use of clinical strains of select agents for testing. Assume that the contractor shall maintain stocks of up to 10 aliquots of each pathogen strain, that strain identity shall be determined upon receipt and when strains are used for testing. Assume that the Project Officer will provide about 200 strains of selected clinical and reference strains for storage and use. Furthermore, assume that quality control assessment for working stocks shall be performed only when strains are used for testing.]

[NOTE #B-2 TO OFFEROR: As part of the proposal, the Offeror shall describe, as a sample protocol, typical standard operating procedures for conducting MIC50 and MIC90 evaluations, as well as tentative breakpoint determinations. This sample protocol may not be the final protocol employed for testing but will serve as a means to evaluate the proposal. This protocol shall also include examples of documentation that will be provided for each test, description of quality control assurance and expected performance of quality control standards. The Offeror shall describe limits for acceptable and unacceptable control performance. The Offeror shall also provide discussion of any problems or issues anticipated for the use of clinical strains of select agents for testing. The Offeror shall provide, a cost estimate for MIC50 and MIC90 determinations for one test compound against 20 clinical strains, one reference/quality control strain with 2 control antibiotics. The Offeror is to assume that test compounds will be provided by NIAID while provision of control antibiotics and non-bioterrorism reference/control strains will be the responsibility of the contractor. The Offeror shall describe how many test compounds and bacterial strains can be maximally evaluated per unit time (week or month) and per FTE. It is estimated that about 20 test products will be evaluated against about 200 clinical strains of bacterial pathogens per year (this number is an estimate and may be exceeded).]

[NOTE #B-3 TO OFFEROR: The Offeror shall provide documentation as to his/her expertise in working with pathogenic bacterial pathogens, as well as potentially hazardous or toxic chemicals. The Offeror shall include in the proposal a Safety and Health Plan for compliance with Biosafety Level 2/3 guidelines and shall include a summary of the Offeror's safety and health operating procedures manual.]

Back to Part B Sample Task Order

PART C: SMALL ANIMAL MODELS FOR SELECTED PATHOGENS INCLUDING GLP STUDIES

[NOTE C-1 TO OFFEROR: The pathologic and immunologic aspects of the model in association with infection should be discussed in detail and relate to the ability to use this model to predict clinical effectiveness of experimental agents. If a non-infection model is proposed the Offeror should explain in detail why the model is suitable. The infectious agent should be

either a human infectious agent or an animal agent with considerable homology to the comparable bioterrorism agent. Background, history and available data that correlate with data produced by the model with regard to comparison with human disease/protection should be provided.

Documentation of availability of animals and animal holding space must be included. Offerors should have capacity to house a minimum of 500 rodents and/or 100 small, non-rodent (e.g. rabbits) animals concurrently; capacity in excess of this requirement is strongly suggested, and may be through documented access of off-site facilities or subcontracts. Indicate capability and capacity to perform aerosol challenge studies and corresponding Biosafety level capacity (2, 3 and/or 4). Provide policies and/or procedures for evaluating and prioritizing projects with regard to organizational resources such as space, time and expertise.

[NOTE C-2 TO OFFEROR: Documentation of assays to monitor the effect of the test compound on the disease process shall be provided. The Offeror should describe in detail his/her technical approach for evaluating therapies/vaccines by providing a sample protocol. This protocol should include a description of the experimental design (sequence in which various types of studies will be carried out, number of arms per study, number of animals per group, number of doses to be explored, potential routes of administration, controls, etc.) and a description of the methods to be used to carry out evaluations; to quality assure/control test compounds and to analyze the data. A rationale for the design should be included, based on statistical considerations. A discussion of the logistical problems associated with the implementation of the protocol should be provided. A schedule showing the time required to analyze a therapeutic compound/vaccine should be provided with an estimate of the total number of compounds that could be examined at one time. Schedules will provide for acquisition of study animals, animal protocol preparation, review and approval, study execution, data analysis, draft report preparation, review of draft reports by the NIAID Project Officer and final report preparation.

Some but not all studies will require that they be conducted in accordance with Good Laboratory Practices (GLP). For example, proof of concept or pilot studies will not require GLP, while some studies submitted under the FDA's proposed "animal rule" might. Thus, Offerors should provide documentation of their experience conducting GLP studies. If available, Offerors should provide examples of recent studies that have been presented to the FDA.

It is understood that some Offerors may propose evaluations of therapeutics or vaccines, or both. For purposes of the cost proposal, each Offeror should include a protocol for non-GLP evaluation of a recombinant protein vaccine (such as rPA for anthrax) and/or a protocol to evaluate a new antibiotic (injectable form). Include documentation for personnel costs and all specific animal, supply, assay, and equipment costs. Offerors with the capacity to perform studies under GLP should separately provide costs for the same study(ies) done according to GLP.

The capability to conduct pharmacokinetic studies, safety, and toxicology evaluation is not a requirement, but may be included in the proposal; this should not be included in the budget. It is anticipated that the experimental therapeutic compounds will include conventional organic chemical molecules and some biological therapies such as nucleic acids, antibodies, or proteins. Vaccine candidates may come from each of the four general vaccine Categories. Test Article acquisition usually results from NIAID staff contact with drug sponsors, Contractor contacts with drug sponsors, and from identification of *in vitro* activity in NIAID screening facilities. These compounds may be irritating, toxic, and/or potentially carcinogenic or hazardous.]

[NOTE C-3 TO OFFEROR: These studies may include the characterization and definition of the model system in terms of the disease pathogenesis and host response. Delineation of the role of pathogen gene expression and replication, pathogen and host strain differences, and the significance of pathogen resistance may be included in these studies.]

[NOTE C-4 TO OFFEROR: Offerors should indicate their overall interest and capabilities in the proposal, clearly indicating which models are currently available, those currently in development, and those of interest for future development/refinement. A table, indicating model parameters, such as the stage of model development (planned, in progress, available, validated), route of infection, species, pathogen, results/outcomes if it is an existing model, is highly appropriate for the proposal. Offerors should describe in detail their best developed/characterized/utilized model in response to the Sample Task Order, including technical details and rationale. NIAID seeks breadth and depth, and breadth will be assessed in the overall program description, while depth will be assessed in Sample Task order technical approach. Breadth and depth is not required from individual Offerors, but is a programmatic need of NIAID; therefore proposals with depth in a single area will not be judged negatively for lack of breadth.]

[NOTE C-5 TO OFFEROR: The final "animal rule" is available at: http://www.fda.gov/cber/rules/humeffic.pdf]

Back to Part C Sample Task

PART D: NON-HUMAN PRIMATE MODELS FOR SELECTED PATHOGENS, INCLUDING GLP STUDIES

[NOTE D-1 TO OFFEROR: The pathologic and immunologic aspects of the model in association with infection should be discussed in detail and relate to the ability to use this model to predict clinical effectiveness of experimental compounds. If a non-infection model is proposed the Offeror should explain in detail why the model is suitable. The infectious agent should be either a human infectious agent or an animal agent with considerable homology to the comparable bioterrorism agent.

Documentation of availability of animals and animal holding space must be included. Offerors should have capacity to house a minimum of 24 animals concurrently; larger capacity should be proposed if possible. Indicate capability and capacity to perform aerosol challenge studies and corresponding Biosafety levels (2, 3 and/or 4).] Provide policies and/or procedures for evaluating and prioritizing projects with regard to organizational resources such as space, time and expertise.

[NOTE D-2 TO OFFEROR: Documentation of assays to monitor the effect of the test compound on infection and/or the disease process should be provided. The Offeror should describe in detail his/her technical approach for evaluating the test compound (therapeutic, vaccine, antibody, etc.) by providing a sample protocol. This protocol should include a description of the experimental design (sequence in which various types/parts of studies will be carried out, number of arms per study, number of animals per group, number of doses/schedules to be explored, potential routes of administration, etc.) and a description of the methods and assays to be used to carry out evaluations, to quality assure/control test compounds, and to analyze the data. A rationale for the design should be included, based on statistical considerations. A discussion of the logistical problems associated with the implementation of the protocol and proposed alternatives should be provided. A schedule showing the time required to analyze a therapeutic compound and/or vaccine should be provided with an estimate of the total number of compounds that could be examined at one time. Documentation of availability of animals for these evaluations should be included.

Some but not all studies will require that they be conducted in accordance with Good Laboratory Practices (GLP). For example, proof of concept studies will not require GLP, while some studies submitted under the FDA's proposed "animal rule" might. Thus, Offerors should clearly indicate their experience conducting GLP studies. If available, Offerors should provide examples of recent studies that have been presented to the FDA.

The capability to conduct pharmacokinetic studies, safety, immunogenicity, and toxicology evaluation is not a requirement but may be included in the proposal; this should not be included in the budget. It is anticipated that the experimental therapeutic compounds will include conventional organic chemical molecules and some biological therapies such as nucleic acids, antibodies, or proteins. Vaccine candidates may come from each of the four general vaccine Categories. Compound acquisition usually results from NIAID staff contacts with drug sponsors, Contractor contacts with drug sponsors, and from identification of *in vitro* activity in NIAID screening facilities. These compounds may be irritating, toxic, and/or potentially carcinogenic or hazardous.]

[NOTE D-3 TO OFFERORS: These studies may include the characterization and definition of the model system in terms of the disease pathogenesis and host response. Delineation of the role of pathogen gene expression and replication, pathogen and host strain differences, and the significance of pathogen resistance may be included in these studies. Offerors should provide examples of previous model development activities.]

[NOTE D-4 TO OFFEROR: Offerors should indicate their overall interest and capabilities in the proposal, clearly indicating which models are currently available, those currently in development, and those of interest for future development/refinement. A table, indicating model parameters, such as the stage of model development (planned, in progress, available, validated), route of infection, species, pathogen, results/outcomes if it is an existing model, is highly appropriate for the proposal. Offerors should describe in detail their best developed/characterized/utilized model in response to the Sample Task Order, including technical details and rationale. NIAID seeks breadth and depth, and breadth will be assessed in the overall program description, while depth will be assessed in Sample Task order technical approach. Breadth and depth is not required from individual Offerors, but is a programmatic need of NIAID; therefore proposals with depth in a single area will not be judged negatively for lack of breadth.]

[NOTE D-5 TO ALL OFFERORS: The final "animal rule" is available at: http://www.fda.gov/cber/rules/humeffic.pdf]

Back to Part D Sample Task Order

PART E: SAFETY AND IMMUNOGENICITY TESTING for VACCINES

[NOTE #E-1 TO OFFERORS: Documentation of experience in preclinical safety and evaluation of immune response testing should be provided. It is anticipated that the contractor will have the capacity to perform testing for each type of vaccine candidate covered by this contract, including each of the four general vaccine Categories. Offeror should outline in detail the tests and procedures it will use to qualify each type of vaccine product for human administration. Provide an appropriate model for determining the cellular and humoral immunogenicity of vaccine in small animals and, if necessary, in non-human primates. Offeror(s) should provide documentation of models/protocols that have been used successfully in previous investigations. Offeror(s) may propose subcontracts for any specific testing procedure (e.g., primate studies). Documentation of available equipment and access to an AAALAC-accredited (or equivalent) animal facility and the capacity for testing the safety and immunogenicity of products should be included.]

[NOTE #E-2 TO OFFERORS. Specific requirements listed in the Statement of Work are not meant to limit the scope or specifics of preclinical vaccine testing. Such testing will include all of the tests required to qualify a vaccine product for human administration.]

[NOTE #E-3 TO OFFERORS. In addition to the CFR, the FDA also provides "Points to Consider" (PTC) Documents. Testing should be conducted consistent with these guidelines. Examples of relevant guidelines include:

a) Points to consider in the Production and Testing of New Drugs and Biological Produced by Recombinant DNA Technology (4/10/85). Supplement (4/6/92).
b) Points to Consider in Human Somatic Cell Therapy and Gene Therapy (8/29/91).
c) Points to Consider in the Characterization of Cell Lines Used to Produce Biologicals (7/12/93).
d) Points to Consider for Plasmid DNA Vaccines for Preventive Infectious Disease Indications (10/96)

These documents, as well as additional guidelines relating to testing and manufacture, are available from the Division of Congressional and Public Affairs. To receive copies call 888-223-7329 then dial 999 to get a list of documents and their number. Consumer information number is 301-827-2000. On the Internet go to http://www.fda.gov/cber/.]

Back to Part E Sample Task Order

PART F: SAFETY/TOXICOLOGY AND PHARMACOLOGY TESTING for THERAPEUTICS

[NOTE #F-1 TO OFFERORS: Documentation of experience in preclinical toxicology and pharmacology testing should be provided. It is anticipated that 'therapies' will mainly be conventional organic chemical molecules. However, it is likely that some non-chemical (biological) therapies such as nucleic acids, antibodies, or proteins also will be studied. The Offeror should clearly describe their experience evaluating either or both conventional organic chemical molecules or/and biological therapies (e.g. nucleic acid plasmids, antibodies, or proteins). The Offeror should include any experience conducting GLP toxicology and pharmacokinetic studies using these biological therapeutics.

Documentation of available equipment and access to an AAALAC-accredited (or equivalent) animal facility and the capacity for testing the toxicology and pharmacology of products should be included.

Although every effort will be made by the NIAID to provide analytical methods for the detection of experimental therapeutics for use in the pharmacokinetic portion of these and other protocols, there may be instances where this information will not be available. In those cases, it is expected that the Contractor will have the ability to develop these techniques or modify existing literature techniques using their own internal chemistry support resources.]

[NOTE #F-2 TO OFFERORS. Specific requirements listed in the Statement of Work are not meant to limit the scope or specifics of preclinical testing for therapeutics or other test articles. Such testing will include all of the tests required to qualify a therapeutic product for human administration.]

[NOTE #F-3 TO OFFERORS. In addition to the CFR, the FDA also provides "Points to Consider" (PTC) Documents. Testing should be conducted consistent with these guidelines. These documents, as well as additional guidelines relating to testing and manufacture, are available from the Division of Congressional and Public Affairs. To receive copies call 888-223-

7329 then dial 999 to get a list of documents and their number. Consumer information number is 301-827-2000. On the Internet go to www.fda.gov/cder]

[NOTE #F-4 TO OFFERORS: The FDA has not published specific protocols to be used for determining immunotoxicity of anti-infective compounds, nor for the *in vitro* determination of metabolic potential. Therefore the Offeror should provide sample protocols, including rationale for use that might be utilized in such studies, and document experience in routinely conducting and evaluating these studies on anti-infective therapies. Sufficient detail should be provided to permit evaluation of experience, expertise, and competence in routine use of these protocols.]

Back to Part F Sample Task Order

REPORTING REQUIREMENTS

"In Vitro and Animal Models for Emerging Infectious Diseases and BioDefense"
NIH-NIAID-DMID-04-40

The Contractor shall prepare and submit the following reports in the manner stated below unless otherwise specifically stated in the request for task order proposal:

I. **Monthly Reports.** The Contractor shall submit electronic copies of the monthly report. One copy should be submitted to the Project Officer and one (1) copy to the Contracting Officer via email. Electronic reports shall utilize the Microsoft Office Suite ©2000 in their preparation. This report is due on the 15th of the month for the preceding month. The monthly report should include:

a. A title page containing:

- Contract number, task order number and title
- Period of performance being reported
- Contractor's name and address
- Date of submission

b. Progress on all milestones including timeline updates and budget variances;
c. Accomplishments to date;
d. Description of any technical or performance problems encountered, along with proposed corrective action;
e. Update on progress of renovations (if applicable);
f. Update on progress toward GLP compliance (if applicable); and
g. Update on expenditures in relation to planned activities and costs contained in the task order proposal.

II. Drafts and final copies of protocols, procedures and reports will be provided to DMID as directed by the Project Officer.

III. **Final Report**. At the end of the task order, the Contractor shall submit three (3) copies of the final report, two (2) copies to the Project Officer and one (1) copy to the Contracting Officer, which will summarize the results of all work completed. This report will be in sufficient detail to explain comprehensively the results achieved and will be submitted no later than the completion date of the task order. This report must be submitted in hard copy. The final report shall contain:

a. Title page as described above;
b. Introduction covering the purpose and scope of the task order;
c. Description of the overall progress, plus a separate description of each protocol, assay, and subcontract employed and modifications and performance on the task order during performance. Descriptions will include pertinent primary and summarized data in tables or graphs as appropriate to present significant results achieved, conclusions resulting from analysis, and a scientific evaluation of the data accrued under the contract;
d. Cumulative list of all studies and products tested to date, including number of bacterial strains tested, and dates for beginning and completion of studies;
e. Copies of any abstracts, manuscripts, and publications; and
f. A cumulative listing of all publications.

IV. **Other Deliverables**. The Contractor shall deliver to the Government or its designee by the completion date of the task order, the following items:

a. All data obtained from studies; and
b. All test products remaining from studies.

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 CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS RFP.

ARTICLE I.1. GENERAL CLAUSES FOR AN INDEFINITE-QUANTITY, INDEFINITE-DELIVERY CONTRACT WITH COST REIMBURSEMNT TASK ORDERS – FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

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

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

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

FAR Clause No.	Date	Title
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restriction on Subcontractor Sales to the Government
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 2003	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-11	Oct 1997	Price Reduction for Defective Cost or Pricing Data – Modifications
52.215-13	Oct 1997	Subcontractor Cost or Pricing Data - Modifications

52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Jan 2002	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (NOTE: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-21	Feb 1999	Prohibition of Segregated Facilities
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting
52.225-1	Jun 2003	Buy American Act - Supplies
52.225-13	Oct 2003	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost

52.232-23	Jan 1986	Assignment of Claims
52.232-25	Oct 2003	Prompt Payment
52.232-33	Oct 2003	Payment by Electronic Funds Transfer – Central Contractor Registration
52.233-1	July 2002	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement
52.244-2	Aug 1998	Subcontracts *If written consent to subcontract is required, the identified subcontracts are listed in Article B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	June 2003	Government Property (Cost-Reimbursement, Time and Material, or Labor Hour Contract)
52.249-5	Sep 1996	Termination for Convenience of the Government (Educational and Other Nonprofit Institutions)
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR Clause No.	Date	Title
352.202-1	Jan 2001	Definitions
352.202-1	Jan 2001	Definitions - with Alternate paragraph (h) (Jan 2001)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.249-14	Apr 1984	Excusable Delays
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity
352.270-7	Jan 2001	Paperwork Reduction Act

[END OF GENERAL CLAUSES FOR AN INDEFINITE-QUANTITY, INDEFINITE-DELIVERY CONTRACT WITH COST REIMBURSEMENT TASK ORDERS]

ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES

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

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

ALTERNATE II (APRIL 1998) of FAR Clause 52.215-2, Audit and Records – Negotiation (JUNE 1999) is hereby added.

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

ALTERNATE II (OCTOBER 2001) of FAR Clause 52.219-9, SMALL BUSINESS SUBCONTRACTING PLAN (JANUARY 2002) is added.

ALTERNATE I (APRIL 1984) of FAR Clause 52.227-1, AUTHORIZATION AND CONSENT (JULY 1995) is hereby added.

ALTERNATE IV (JUNE 1987) of FAR Clause 52.227-14, Rights in Data – General (JUNE 1987) is hereby added.

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

ALTERNATE I (FEBRUARY 2002) of FAR Clause 52.232-25, Prompt Payment (OCTOBER 2003) is hereby added.

ALTERNATE I, (DECEMBER 1991), of FAR Clause 52.233-1, DISPUTES (JULY 2002) is hereby added.

ALTERNATE I (JUNE 1985) of FAR Clause 52.233-3, Protest After Award (AUGUST 1996) is hereby added.

ALTERNATE V (APRIL 1984) of FAR Clause 52.243-2, Changes - Cost Reimbursement (AUGUST 1987) is hereby added.

ALTERNATE II (AUGUST 1998) of FAR Clause 52.244-2, Subcontracts (Aug 1998) is hereby added.

ALTERNATE I (JUNE 2003) of FAR Clause 52.245-5, Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour (JUNE 2003) is hereby added.

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

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

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

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

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

FAR 52.216-15, Predetermined Indirect Cost Rates (APRIL 1998).

FAR 52.216-18, Ordering (OCTOBER 1995).

"(a) ....Such orders may be issued from 09/30/2003 through 09/29/2010..."

FAR 52.216-22, Indefinite Quantity (OCTOBER 1995).

"(d) ...the Contractor shall not be required to make any deliveries under this contract after September 29, 2010..."

FAR 52.217-8, Option to Extend Services (NOVEMBER 1999).

"...The Contracting Officer may exercise the option by written notice to the Contractor within 30 days of contract expiration."

FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (JUNE 2003)

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

ALTERNATE I (JUNE 2003), FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (JUNE 2003).

FAR 52.227-23, Rights to Proposal Data (Technical) (JUNE 1987).

Excluded pages from the proposal dated [**to be completed at contract award**], are identified as follows: [**to be completed at contract award**]

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

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

FAR 52.230-4, Consistency in Cost Accounting Practices (AUGUST 1992).

FAR 52.230-5, Educational Institutions (APRIL 1998)

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

FAR 52.249-5, Termination for Convenience of the Government (Educational and Other Nonprofit Institutions) (SEPTEMBER 1996)

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

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

HHSAR 352.224-70, Confidentiality of Information (APRIL 1984).

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

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

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

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

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

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

This contract incorporates the following clauses in full text.

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

FAR Clause 52.216-19, ORDER LIMITATIONS (OCTOBER 1995)

(a) **Minimum Order**. When the Government requires supplies or services covered by this contract in an amount of less than [**to be completed at contract award**], the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) **Maximum Order**. The Contractor is not obligated to honor--

(1) Any order for a single item in excess of $40M.

(2) Any order for a combination of items in excess of $40M; or

(3) A series of orders from the same ordering office within 30 days that together call for quantities exceeding the limitation in subparagraph (1) or (2) above.

(c) If this is a requirements contract (i.e., includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) above.

(d) Notwithstanding paragraphs (b) and (c) above, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within 5 business days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

FAR Clause 52.244-6, SUBCONTRACTS FOR COMMERCIAL ITEMS (APRIL 2003)

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

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

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

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

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

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

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

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

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

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

PACKAGING AND DELIVERY OF PROPOSALS (Attached to this listing)

HOW TO PREPARE AN ELECTRONIC PROPOSAL: (Attached to this listing)

PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: Thursday, January 15, 2004 (Attached to this listing)

TASK ORDER PROCEDURES (Attached to this listing)

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

RFP FORMS AND ATTACHMENTS:

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

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

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

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

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

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

TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):

- **NIH(RC)-1: Invoice/Financing Request Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts**
- **NIH-2706: Financial Report of Individual Project Contract**
- **Instructions for Completing Form NIH-2706**
- **NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)**
- **Safety and Health, HHSAR Clause 352.223-70**
- **Government Property – Schedule ___**
- **Disclosure of Lobbying Activities, OMB Form LLL**

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

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

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

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

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

Shipment and marking of paper copies shall be as indicated below:

A. EXTERNAL PACKAGE MARKING:

In addition to the address cited below, mark each package as follows:

"RFP NO. NIH-NIAID-DMID-04-40 TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

B. NUMBER OF COPIES:

The number of copies required of each part of your proposal are as specified below.

Technical Proposal: One (1) unbound signed original and five (5) unbound copies. Ten (10) copies of all material not available electronically (i.e. SOPs, Pertinent Manuals, Nonscannable Figures or Data, and Letters of Collaboration/Intent).

Business Proposal: One (1) unbound signed original and 5 unbound copies.

C. PAPER COPIES and CD-Rom or ZipDisk to:

If Hand Delivery or Express Service	If using U.S. Postal Service
Paquetta Myrick-Hancock Contract Specialist Preclinical Research Contracts Branch CMP, DEA,NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Paquetta Myrick-Hancock Contract Specialist Preclinical Research Contracts Branch CMP, DEA, NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

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

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

HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL

PAGE LIMITS -- THE TECHNICAL PROPOSAL IS LIMITED TO A MAXIMUM OF 150 PAGES. PAGES THAT ARE 2-SIDED WILL COUNT AS 2 PAGES. [THIS PAGE LIMIT INCLUDES: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.]. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

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

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

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

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

Formatting Requirements:

- Do not embed sound or video (e.g., MPEG) files into the proposal documents. The evaluation system does not have the capability to read these files.
- 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-04-40
RFP Title: "In Vitro and Animal Models for Emerging Infectious Diseases and BioDefense"

Please review the attached Request for Proposal. Furnish the information requested below and return this page by Thursday, January 15, 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:

Paquetta Myrick-Hancock, Contract Specialist
Preclinical Research Contracts Branch
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: RFP NIH-NIAID-DMID-04-40
FAX# (301) 480-5253
Email : pmhancock@niaid.nih.gov

THE FOLLOWING TASK ORDER PROCEDURES WILL BE INCLUDED IN SECTION G OF THE BASIC CONTRACT(S) AWARDED UNDER THIS SOLICITATION:

TASK ORDER PROCEDURES

In providing services under this contract, the following procedures shall apply to the award of Task Orders.

All work required under this contract shall be authorized through execution of an agreement, "Task Order", signed by the contractor and the Contracting Officer. Task Orders may be awarded at any time within the contract period.

When the Government elects to fill a requirement that is estimated to exceed $2,500, the Contracting Officer shall provide a Request for Task Order Request for Proposals (TORFP) to the awardees that received contracts for the particular Part for which responses are being solicited. A RTOP shall, at a minimum, include a Statements of Work, evaluation criteria, specific reporting requirements, deliverables and delivery schedule, the relevant importance of technical and cost factors, and any special instructions.

If necessary, the Contracting Officer shall arrange a meeting between contractors and members of the sponsoring office to discuss the proposed Task Order prior to submitting Task Order proposals (technical and business). Business proposals shall include appropriate support for all costs proposed as necessary for performing the task. Task Order proposals shall generally be limited to twenty (20) pages, including attachments.

Within the time allowed for proposal preparation (time allowed for proposal preparation and submission will vary depending on the task and will be designated in each TORFP, Contractors shall submit their proposals in response to a TORFP, which shall include, but not necessarily be limited to the following information:

(i) A statement of the contractor's clear understanding of the task requirements;

(ii) A statement of technical and managerial resources and expertise the contractor can provide to satisfy the requirement;

(iii) An approach to perform the work;

(iv) The labor categories necessary, and the number of hours for each labor category necessary, and an explanation of the rationale for determining hours;

(v) Resumes with identification of the actual personnel proposed for the work;

(vi) A schedule of performance identifying major milestones, deliverables and delivery date, and task completion; and

(vii) An itemization of all costs, both direct and indirect, (i.e. personnel, fringe benefits, equipment, travel, supplies, other direct costs, overhead, etc.) necessary to complete the work.

The Government will evaluate proposals and conduct negotiations as necessary. Task Orders will be awarded to the contractor whose proposal is determined to be the most advantageous to the Government based on the technical and cost factors specified in the Requests for Task Order Request for Proposals. The Government reserves the right to make an award on the most favorable initial proposal without discussion.

The Contracting Officer is the only individual authorized to issue a TORFP or award a Task Order under this contract. Unless specifically authorized by the Contracting Officer, the contractor shall not commence work on a requirement until a fully executed Task Order has been awarded.

It is anticipated that Task Orders will be awarded within 30 – 60 calendar days from receipt of Task Order proposals. Each Task Order shall, at a minimum, contain the following information:

- Date of Task Order
- Contract number and Task Order number sequentially; e.g., N01-AI-30062 / Task Order 01, 02, etc. which will be generated automatically by the contract generating system.
- Description of services, estimated cost and fixed fee.
- Performance period.
- Name and address of sponsoring office.
- Name of Contracting Officer's Technical Representative.
- Place of performance.
- Packaging, packing, and shipping instructions, if any.
- Accounting and appropriation data.
- Pricing Arrangements
- Any other pertinent information.

Contractors are required to propose hourly rates for each labor classification in their response to each TORFP, with cost reimbursable contract line items proposed for other elements of cost (i.e. fringe benefits, supplies, travel, equipment, other direct costs, indirect costs, fee, etc.) The subsequent negotiation of Task Orders issued to successful contractors eligible to submit a proposal under a TORFP for which they qualify will focus on the number of hours proposed for each labor category and the estimated costs required for all other elements.

No protest under FAR Subpart 33.1 is authorized in connection with the issuance or proposed issuance of a Task Order under this contract except for a protest on the grounds that the order increases the scope, period, or maximum value of the contract. Task Orders awarded under this contract are not subject to the competition requirements of FAR Part 6. However, under FAR 16.505(b)(5), prime contractors may contact the customer-designated contract ombudsman with complaints on specific task orders on this contract. The ombudsman will review all complaints and ensure that all prime contractors are offered a "Fair-Opportunity-to-be-Considered." The designated NIH ombudsman for this contract is:

Anthony Demsey, Ph.D.
Senior Advisor for Policy, Office of Extramural Research
NIH Competition Advocate for Research and Development
Building 1, Room 152
9000 Rockville Pike
Bethesda, MD 20892

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

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

1. REPRESENTATIONS AND CERTIFICATIONS

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

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

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

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

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

1. GENERAL INFORMATION

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

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

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

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

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

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

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

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

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

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

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

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

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the solicitation after the exact time specified for receipt of offers is "late" and will not be considered unless it

is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and--

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

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

(3) It is the only proposal received.

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

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

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

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

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

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

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

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

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

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

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

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

Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.

The offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the Department's FOI officials must make that determination. The offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.

If a contract is awarded to the offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.

The offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(End of Provision)

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

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

Alternate II (October 1997). As prescribed in 15.209(a)(2), add a paragraph (c)(9) substantially the same as the following to the basic clause:

(9) Offerors may submit proposals that depart from stated requirements. Such proposals shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the terms and conditions of the solicitation, as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the solicitation to allow all Offerors an opportunity to submit revised proposals based on the revised requirements.

b. **NAICS CODE AND SIZE STANDARD**

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

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

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

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

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

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

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

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

It is anticipated that multiple awards will be made from this solicitation and that the award(s) will be made on/about September 30, 2004.

It is anticipated that the award(s) from this solicitation will be multiple-year, indefinite-delivery, indefinite-quantity type contract(s) with an ordering period of six (6) years. Cost-reimbursement type task orders will be competed and awarded under the contract in accordance with FAR Part 16.505. The Government reserves the right to incrementally-fund individual task orders [see Section L.2.c. Business Proposal Instructions].

e. **COMMITMENT OF PUBLIC FUNDS**

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

f. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

g. **RELEASE OF INFORMATION**

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

h. **COMPARATIVE IMPORTANCE OF PROPOSALS**

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

i. **PREPARATION COSTS**

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

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

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

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

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

(End of Provision)

k. **LATE PROPOSALS AND REVISIONS**, HHSAR 352.215-70

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors—Competitive Acquisition, a proposal received after the date specified for receipt may be considered if it offers significant cost or technical advantages to the Government; and it was received before proposals were distributed for evaluation, or within five calendar days after the exact time specified for receipt, whichever is earlier.

(End of provision)

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

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

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

2. **INSTRUCTIONS TO OFFERORS**

GENERAL INSTRUCTIONS

INTRODUCTION

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

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

It is contemplated that indefinite-delivery, indefinite-quantity type contract(s) that utilizes cost-reimbursement task orders will be awarded. (See General Information) Any resultant contract shall include the clauses applicable to the

selected Offeror's organization and type of contract awarded as required by Public Law, Executive Order, or acquisition regulations in effect at the time of execution of the proposed contract.

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

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

I. COVER PAGE

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

a. Project Objectives, NIH-1688-1

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

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

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

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

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

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

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

(e) **Alternate Proposals**

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

(f) **Evaluation of Proposals**

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

(g) **Potential Award Without Discussions**

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

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

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

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

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

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

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

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

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

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

   The Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals establishes a number of requirements for research activities involving animals. Before a PHS award may be made to an applicant organization, the organization shall file, with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), PHS, a written Animal Welfare Assurance which commits the organization to comply with the provisions of the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources. In accordance with the PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions, applicant organizations must establish a committee, qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. No PHS award involving the use of animals shall be made unless the Animal Welfare Assurance has been approved by OER. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Animal Welfare Assurance is required. The Contracting Officer will request that OER, OLAW negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OER, OLAW, may be contacted at Rockledge

Center I - Suite 1050, 6705 Rockledge Drive, Bethesda, MD 20817, (301) 496-7163, ext 234. FAX copies are of the PHS Policy are available at (301) 402-2803. This policy is also available on the internet at http://www.grants.nih.gov/grants/olaw/olaw.htm.

2. The following information must be included in the Offeror's technical proposal:

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

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

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

(j) **Possession, Use and Transfer of Select Biological Agents or Toxins**

The following notice is applicable when contract performance is expected to involve possession, use and/or transfer of select biological agents or toxins:

Notice to Offerors of Requirements of: 42 CFR Part 73, Select Agents and Toxins (relating to public health and safety)**; Agricultural Bioterrorism Protection Act of 2002,** which consists of **7 CFR Part 331, Possession, Use, and Transfer of Biological Agents and Toxins** (relating to plant health or plant products)**; and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins** (relating to human and animal health, animal health or animal products) - **December 13, 2002**

These regulations implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and the USA Patriot Act. They are designed to improve the United States Government's ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. Unless exempted, entities must receive a certificate of registration or be authorized to work with the applicable select agents as follows:

For possession, use and transfer of biological agents or toxins that have been determined to have the potential to pose a severe threat to: 1) public health and safety; 2) both human and animal health, animal health, or animal products; and/or 3) plant health or plant products, registration information must be submitted to the Centers for Disease Control and Prevention, Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Service (APHIS), U.S. Department of Agriculture (USDA) as applicable.

Listings of HHS Select Agents and Toxins, biologic agents and toxins, and Overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at http://www.cdc.gov/od/sap/.

(k) **Obtaining and Disseminating Biomedical Research Resources**

As a public sponsor of biomedical research, the National Institutes of Health (NIH) has a dual interest in accelerating scientific discovery and facilitating product development. Intellectual property restrictions can stifle the broad dissemination of new discoveries and limit future avenues of research and product development. At the same time, reasonable restrictions on the dissemination of research tools are sometimes necessary to protect legitimate proprietary interests and to preserve incentives for commercial development. To assist NIH contractors to achieve an appropriate balance, the NIH has provided guidance in the form of a two-part document, consisting of Principles setting forth the fundamental concepts and Guidelines that provide specific information to patent and license professionals and sponsored research administrators for implementation.

The purpose of these Principles and Guidelines is to assist NIH funding recipients in determining: 1) Reasonable terms and conditions for making NIH-funded research resources available to scientists in other institutions in the public and private sectors (disseminating research tools); and 2) Restrictions to accept as a conditions of receiving access to research tools for use in NIH-funded research (acquiring research tools). The intent is to help recipients ensure that the conditions they impose and accept on the transfer of research tools will facilitate further biomedical research, consistent with the requirements of the Bayh-Dole Act and NIH funding policy.

This policy, entitled, "Sharing Biomedical Research Resources: Principles and Guidelines for Recipients of NIH Research Grants and Contracts," (Federal Register Notice, December 23, 1999 [64 FR 72090] will be included in any contract awarded from this solicitation. It can be found at the following website: http://ott.od.nih.gov/NewPages/64FR72090.pdf.

(1) **Sharing Research Data**

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

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

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

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

(m) **Privacy Act (Treatment of Proposal Information)**

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

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

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

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

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

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

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

- to the cognizant audit agency and the General Accounting Office for auditing.

- to the Department of Justice as required for litigation.

- to respond to congressional inquiries.

- to qualified experts, not within the definition of Department employees, for opinions as a part of the review process.

(n) **Selection of Offerors**

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

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

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

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

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

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

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

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

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

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

(o) **Small Business Subcontracting Plan**

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

1) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS OR NON-U.S. CONCERNS.

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

3) The offeror understands that:

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

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

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

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

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

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

4) Each plan must contain the following:

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

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

(c) A description of the principal types of supplies and services to be subcontracted with an identification of

which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

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

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

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

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

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

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

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

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

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

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

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

(p) **HUBZone Small Business Concerns**

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

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

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

quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

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

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

The Department of Commerce website for the annual determination is:

http://www.arnet.gov/References/sdbadjustments.htm

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

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

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

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

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

(r) **Reimbursement of Costs for Independent Research and Development Projects** (Commercial Organizations Only)

The primary purpose of the Public Health Service (PHS) is to support and advance independent research within the scientific community. This support is provided in the form of contracts and grants totaling approximately 7 billion dollars annually. PHS has established effective, time tested and well recognized and accepted procedures for

stimulating and supporting this independent research by selecting from multitudes of proposals those research projects most worthy of support within the constraints of its appropriations. The reimbursement of independent research and development costs not incidental to product improvement, through the indirect cost mechanism, would circumvent this competitive process.

To ensure that all research and development projects receive similar and equal consideration, all Offerors may compete for direct funding for independent research and development projects they consider worthy of support by submitting those projects to the appropriate Public Health Service grant and/or contract office for review. Since these projects may be submitted for direct funding, the successful offeror agrees that no costs for any independent research and development project, including applicable indirect costs, will be claimed under any contract resulting from this solicitation.

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

*****NOTE: USE THE FOLLOWING NOTE ONLY FOR RFPs INTENDED FOR FY04 AWARD*****

NOTE: This award is intended to be made in Fiscal Year 2004. The current Fiscal Year 2003 Salary Rate Limitations should be adhered to in the preparation of your proposal. All costs associated with any resultant award will be required to be in compliance with the current Fiscal Year 2003 limitations and will be subject to change based on Fiscal Year 2004 Salary Rate Limitations.

Offerors are advised that pursuant to P.L. 108-7, no NIH Fiscal Year 2003 (October 1, 2002 - September 30, 2003) funds may be used to pay the direct annual salary of an individual through any contract awarded as a result of this solicitation at a rate in excess of the Executive Schedule, Level I (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses, also referred to as "indirect cost" or "facilities and administrative (F&A) costs"). Direct salary has the same meaning as the term "institutional base salary." An individual's direct salary (or institutional base salary) is the annual compensation that the contractor pays for an individual's appointment whether that individual's time is spent on research, teaching, patent care or other activities. Direct salary (or institutional base salary) excludes any income that an individual may be permitted to earn outside of duties to the contractor.

This does not preclude the offeror from absorbing that portion of an employee's annual salary (plus the dollar amount for fringe benefits and associated indirect costs) that exceeds a rate of the Executive Schedule, Level I. The salary rate limitation set by P.L. 108-7 applies only to Fiscal Year 2003 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Multi-year contracts awarded pursuant to this solicitation may be subject to unilateral modifications by the Government if an individual's annual salary exceeds any salary rate ceiling established in future appropriations acts. The Executive Schedule, Level I annual salary rate limit also applies to individuals proposed under subcontracts, however it does not apply to consultants. P.L. 108-7 states in pertinent part:

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

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

(t) **Institutional Responsibility Regarding Conflicting Interests of Investigators**

EACH INSTITUTION MUST:

(1) Maintain an appropriate written, enforced policy on conflict of interest that complies with 42 CFR Part 50 Subpart F and/or 45 CFR Part 94 as appropriate and inform each investigator of the Institution's policy, the Investigator's reporting responsibilities, and the applicable regulations. If the Institution carries out the NIH funded research through subgrantees, contractors or collaborators, the Institution must take reasonable steps to ensure that Investigators working for such entities comply with the regulations, either by requiring those

investigators to comply with the Institution's policy or by requiring the entities to provide assurances to the Institution that will enable the Institution to comply with the regulations.

(2) Designate an Institutional official(s) to solicit and review financial disclosure statements from each Investigator who is planning to participate in NIH-funded research.

(3) Require that by the time an application/proposal is submitted to the NIH each investigator who is planning to participate in the NIH-funded research has submitted to the designated official(s) a listing of his/her known Significant Financial Interests (and those of his/her spouse and dependent children): (i) that would reasonably appear to be affected by the research for which the NIH funding is sought; and (ii) in entities whose financial interests would reasonably appear to be affected by the research. All financial disclosures must be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

(4) Provide guidelines consistent with the regulations for the designated official(s) to identify conflicting interests and take such actions as necessary to ensure that such conflicting interests will be managed, reduced, or eliminated.

(5) Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the institution with respect to each conflicting interest for: (1) in the case of grants, at least three years from the date of submission of the final expenditures report or, where applicable, from other dates specified in 45 CFR Part 74.53(b) and (2) in the case of contracts, 3 years after final payment or, where applicable, for the other time period specified in 48 CFR Part 4 Subpart 4.7, Contract Records Retention.

(6) Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

(7) Certify, in each application/proposal for funding to which the regulations applies, that:

(a) there is in effect at the Institution a written and enforced administrative process to identify and manage, reduce or eliminate conflicting interests with respect to all research projects for which funding is sought from the NIH;

(b) prior to the Institution's expenditure of any funds under the award, the Institution will report to the awarding component the existence of a conflicting interest (but not the nature of the interest or other details) found by the Institution and assure that the interest has been managed, reduced or eliminated in accord with the regulations; and for any interest that the Institution identifies as conflicting subsequent to the expenditure of funds after award, the report will be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis within sixty days of that identification;

(c) the Institution agrees to make information available, upon request, to the awarding component regarding all conflicting interests identified by the Institution and how those interested have been managed, reduced, or eliminated to protect the research from bias; and

(d) the Institution will otherwise comply with the regulations.

(u) **INSTITUTIONAL MANAGEMENT OF CONFLICTING INTERESTS**

(1) The designated official(s) must: (a) review all financial disclosures; and (b) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests include, but are not limited to:

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;

(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

(2) An Institution may require the management of other conflicting financial interests in addition to those described in paragraph (a) of this section, as the Institution deems appropriate.

(v) **ROTC Access and Federal Military Recruiting on Campus**

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

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

(w) **Solicitation Provisions Incorporated by Reference**, FAR 52.252-1 (February 1998)

This Solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its quotation or offer. In lieu of submitting the full text provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its quotation or offer. Also, the full text of a solicitation provision may be accessed electronically at this address: http://www.arnet.gov/far/.

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

1) Facilities Capital Cost of Money, FAR Clause 52.215-16, (June 2003).

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

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

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

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

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

TECHNICAL PROPOSAL INSTRUCTIONS

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

(1) **Technical Discussions**

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

a) **Statement of Work**

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

b) **Personnel**

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

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

Principal Investigator/Project Director

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

(1) Other Investigators

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

(2) Additional Personnel

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

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

(3) Resumes

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

(2) **Technical Evaluation**

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

(3) **Additional Technical Proposal Information**

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

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

(4) **Other Considerations**

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

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

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

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

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

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

BUSINESS PROPOSAL INSTRUCTIONS

(1) Basic Cost/Price Information

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

(2) Information Other than Cost or Pricing Data

a) The information submitted shall consist of data to permit the Contracting Officer and authorized representatives to determine price reasonableness or cost realism, e.g., information to support an analysis of material costs (when sufficient information on labor and overhead rates is already available), or information on prices and quantities at which the offeror has previously sold the same or similar items.

Any information submitted must support the price proposed. Include sufficient detail or cross references to clearly establish the relationship of the information provided to the price proposed. Support any information provided by explanations or supporting rational as needed to permit the Contracting Officer and authorized representative to evaluate the documentation.

[Unless otherwise stated in this solicitation, the information may be submitted in the Offeror's own format.]

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

(a) Exceptions from cost or pricing data.

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

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

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

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

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

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

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

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

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

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

(End of provision)

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

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

Submission of all cost or pricing data shall be in accordance with Table 15-2 in FAR 15.408.

(4) Total Compensation Plan - Instructions

a) Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All Offerors [AS A PART OF THEIR BUSINESS PROPOSAL WILL SUBMIT] a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.

b) The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the Offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).

c) Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

(5) Total Compensation Plan - Evaluation

a) **Total Compensation Plan (Professional Employees)**

In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than

currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

b) **Cost (Professional Compensation)**

Proposals which are unrealistically low or do not reflect a reasonable relationship of compensation to the professional job categories so as to impair the Contractor's ability to recruit and retain competent professional employees, may be viewed as reflecting a failure to comprehend the complexity of the contract requirements. The Government is concerned with the quality and stability of the work force to be employed on this contract. The compensation data required will be used in evaluation of the Offeror's understanding of the contract requirements.

c) **Other (Labor Relations)**

An assessment of the potential for adverse effect upon performance and maintenance of the required number of professional employees with requisite skills resulting from an unrealistically low compensation structure will also be made.

d) **Federal Acquisition Regulation Clauses incorporated by Reference**

FAR Clause 52.222-46, Evaluation of Compensation for Professional Employees (FEBRUARY 1993).

(6) Qualifications of the Offeror

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

a) **General Experience**

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

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

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

c) **Performance History**

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

d) **Pertinent Contracts**

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

e) **Pertinent Grants**

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

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

(7) Other Administrative Data

a) **Property**

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

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

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

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

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

b) **Financial Capacity**

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

c) **Incremental Funding [this applies to task orders that will be awarded under the contract(s) awarded as a result of this solicitation only]**

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

HHSAR 352.232-75, Incremental Funding (January 2001)

(a) It is the Government's intention to negotiate and award a contract using the incremental funding concepts described in the clause entitled Limitation of Funds. Under the clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover the first year of performance. Additional funds are intended to be allotted to the contract by contract modification, up to and including the full estimated cost of the contract, to accomplish the entire project. While it is the Government's intention to progressively fund this contract over the entire period of performance up to and including the full estimated cost, the Government will not be

obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor will the Contractor be obligated to perform in excess of the amount allotted.

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

(End of provision)

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

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

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

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

(End of Provision)

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

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

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

(8) Subcontractors

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

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

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

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

d) Information on their cognizant field audit offices.

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

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

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

http://ocm.od.nih.gov/contracts/rfps/FDP/PDPclausecover.htm

(9) Proposer's Annual Financial Report

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

(10) Representations and Certifications

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

(11) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

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

b) **Travel Policy**

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

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

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

(13) Guidance Regarding Federal Government Collaborations

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

Section M - Evaluation Factors For Award

"In Vitro and Animal Models for Emerging Infectious Diseases and BioDefense"
DMID-04-40

1. GENERAL

The technical proposal will receive paramount consideration in the selection of the Contractors for this acquisition. All evaluation factors, other than cost or price, when combined are significantly more important than cost or price. However, cost/price may become a critical factor in source selection in the event that two or more Offerors are determined to be essentially equal following the evaluation of all factors other than cost/price. In any event, the Government reserves the right to make awards to those Offerors whose proposals 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.

The Technical Evaluation Criteria below will be evaluated against the proposals at the time of peer review. Separate competitive ranges will be established by Part, based on these Technical Evaluation Criteria. The same criteria will be applied to subsequent NIAID review of Task Order proposals, unless other criteria are specified with the Task Order Request for Proposal.

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. PAST PERFORMANCE

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

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

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

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

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

The 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.

4. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

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

Offers will be evaluated on the following sub-factors:

a. Extent of commitment to use SDB concerns
b. Complexity and variety of the work SDB concerns are to perform
c. Extent of participation of SDB concerns in terms of the value of the total acquisition

5. 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.

Part A – *In Vitro* Screens for Antimicrobial Activity

CRITERA	WEIGHT
A. Technical Approach	**40**

1) Technical approach, including SOPs for determination of antimicrobial activity, familiarity with NCCLS standards, development of new assay systems, and mechanism of action studies as requested in the Statement of Work, including logistics and coordination. 25 pts

2) Overall understanding of the project and adequacy and feasibility of plans to address all items in the Work Statement. This includes the detailed description of specific tasks to be performed, including controls, quality control measures and tracking, methods and resources to be used and the discussion of problems likely to occur with plans for addressing them. 15 pts.

B. Experience and Qualification of Personnel **35**

1) Documented availability, expertise, and proficiency of the Principal Investigator, in the performance of antimicrobial testing/screening and in managing a project of comparable size and complexity. 15 pts

2) Documented availability, experience, and capabilities of other professional and technical staff in the performance of antimicrobial testing and/or screening and documented availability. 10 pts

3) Previous institutional expertise and proven track record in the antimicrobial testing. 10 pts

C. Facilities and Resources **25**

1) Availability of adequate facilities, equipment, and resources necessary to safely and efficiently accomplish the work described in the Statement of Work. Adequacy of detailed floor plan, indicating space to be committed and documented for performance of this project. Adequacy of Biosafety containment, safety plans and accident contingency plans. 15 pts

2) Capacity to perform required testing in a timely and efficient manner (resources dedicated to this project). 10 pts

TOTAL POINTS: 100

Part B -- Clinical Isolate Panels for Selected Bacterial Pathogens

CRITERA	WEIGHT
A. Technical Approach	**40**

1) Technical approach, including appropriateness of NCCLS standards and SOPs for determination of antimicrobial activity, MIC50/90 and tentative MIC breakpoints as requested in the Statement of Work, including logistics and coordination. 25 pts

2) Overall understanding of the project and adequacy and feasibility of plans to address all items in the Work Statement. This includes the detailed description of specific tasks to be performed, including controls, quality control measures and tracking, methods and resources to be used and the discussion of problems likely to occur with plans for addressing them. 15 pts.

B. Experience and Qualification of Personnel	**35**

1) Documented availability, expertise, and proficiency of the Principal Investigator, in the performance of antimicrobial testing using large panels of clinical strains and in managing a project of comparable size and complexity. 15 pts

2) Documented availability, experience, and capabilities of other professional and technical staff in the performance of antimicrobial testing using large panels of clinical strains and documented availability. 10 pts

3) Previous institutional expertise and proven track record in the antimicrobial testing in general and specifically to evaluate activities against clinical stains; previous experience in conducting work under NCCLS. 10 pts

C. Facilities and Resources	**25**

1) Availability of adequate facilities, equipment, and resources necessary to safely and efficiently accomplish the work described in the Statement of Work. Adequacy of detailed floor plan, indicating space to be committed and documented for performance of this project. Adequacy of Biosafety containment, safety plans and accident contingency plans. 15 pts

2) Capacity to perform required testing in a timely and efficient manner (resources dedicated to this project). 10 pts

TOTAL POINTS: 100

Part C: Small animal models for selected pathogens, to include GLP studies

CRITERA	WEIGHT
A. Technical Approach	**40**

1) Technical approach for efficacy testing of vaccines and/or therapeutics as requested in the Statement of Work including logistics and coordination. This includes the detailed description of specific tasks to be performed, methods and resources to be used. GLP compliance is demonstrated or plan to develop compliance is adequate. 20 pts

2) Overall understanding of the project and adequacy and feasibility of plans to address all items in the Work Statement. This includes the discussion of problems likely to occur and plans for addressing them. 10 pts.

3) Model development: Scientific and technical potential of the proposed animal model to be developed or modified to enhance its usefulness in the evaluation of therapies/strategies. Scoring will be based on the requested discussion of how the Offeror could further extend or adapt the proposed model(s). Summary of available and planned animal models is presented. 10 pts

B. Experience and Qualification of Personnel	**35**

1) Documented expertise and proficiency of the Principal Investigator, in prior animal model testing and development, managing a project of comparable size and complexity, and documented availability. 15 pts

2) Documented experience and capabilities of other professional and technical staff in the performance of animal model testing and documented availability. 10 pts

3) Previous institutional expertise and proven track record in the evaluation of vaccines and/or therapeutics. 10 pts

C. Facilities and Resources **25**

1) Availability of adequate facilities, animals, equipment, and resources necessary to safely and efficiently accomplish the work described in the Statement of Work. Adequacy of detailed floor plan, indicating space to be committed for performance of this project. Adequacy of animal facilities. Adequacy of safety plans and accident contingency plans. 15 pts

2) Capacity to perform required testing in a timely and efficient manner (resources dedicated to this project). 10 pts

TOTAL POINTS: 100

Part D: Non-human primate models for selected pathogens, to include GLP studies.

CRITERA	WEIGHT
A. Technical Approach	**40**

1) Technical approach for efficacy testing of vaccines and/or therapeutics as requested in the Statement of Work including logistics and coordination. This includes the detailed description of specific tasks to be performed, methods and resources to be used. GLP compliance is demonstrated or plan to develop compliance is adequate. 20 pts

2) Overall understanding of the project and adequacy and feasibility of plans to address all items in the Work Statement. This includes the discussion of problems likely to occur and plans for addressing them. 10 pts.

3) Model development: Scientific and technical potential of the proposed animal model to be developed or modified to enhance its usefulness in the evaluation of therapies/strategies. Scoring will be based on the requested discussion of how the Offeror could further extend or adapt the proposed model(s). Summary of available and planned animal models is presented. 10 pts

B. Experience and Qualification of Personnel **35**

1) Documented expertise and proficiency of the Principal Investigator, in the performance of efficacy testing in non-human primates and in managing a project of comparable size and complexity and documented availability. 15 pts

2) Documented experience and capabilities of other professional and technical staff in the performance of animal model testing and documented availability. 10 pts

3) Previous institutional expertise and proven track record in the evaluation of vaccines and/or therapeutics; expertise in performing studies under GLP, if appropriate. 10 pts

C. Facilities and Resources **25**

1) Availability of adequate facilities, animals, equipment, and resources necessary to safely and efficiently accomplish the work described in the Statement of Work. Adequacy of detailed floor plan, indicating space to be committed for performance of this project. Adequacy of animal facilities. Adequacy of safety plans and accident contingency plans. 15 pts

2) Capacity to perform required testing in a timely and efficient manner (resources dedicated to this project). 10 pts

TOTAL POINTS: 100

Part E: Safety and Immunogenicity Testing for Vaccines

CRITERA	WEIGHT
A. Technical Approach	**40**

1) Technical approach for safety and immunogenicity testing of vaccines as requested in the Statement of Work, including logistics and coordination. 25 pts

2) Overall understanding of the project and adequacy and feasibility of plans to address all items in the Work Statement. This includes the detailed description of specific tasks to be performed, methods and resources to be used, and the discussion of problems likely to occur and plans for addressing them. 15 pts.

B. Experience and Qualification of Personnel	**35**

1) Documented expertise and proficiency of the Principal Investigator, in the performance of safety and immunogenicity testing suitable for vaccines destined for human trials and in managing a project of comparable size and complexity and documented availability. 15 pts

2) Documented experience and capabilities of other professional and technical staff in the performance of safety and immunogenicity testing and documented availability. 10 pts

3) Previous institutional expertise and proven track record in the evaluation of vaccines; previous experience in conducting work under GLP. 10 pts

C. Facilities and Resources	**25**

1) Availability of adequate facilities, animals, equipment, and resources necessary to safely and efficiently accomplish the work described in the Statement of Work. Adequacy of detailed floor plan, indicating space to be committed for performance of this project. Adequacy of animal facilities. 15 pts

2) Capacity to perform required testing in a timely and efficient manner (resources dedicated to this project). 10 pts

TOTAL POINTS: 100

Part F: Safety/Toxicology and Pharmacology Testing for Therapeutics

CRITERA	WEIGHT
A. Technical Approach	**40**

1) Technical approach for pharmacologic/toxicologic testing of therapeutics as requested in the Statement of Work, including logistics and coordination. 25 pts

2) Overall understanding of the project and adequacy and feasibility of plans to address all items in the Work Statement. This includes the detailed description of specific tasks to be performed, methods and resources to be used, and the discussion of problems likely to occur and plans for addressing them. 15 pts.

B. Experience and Qualification of Personnel	**35**

1) Documented expertise and proficiency of the Principal Investigator, in the performance of toxicology and pharmacology testing suitable for therapeutics destined for human trials and in managing a project of comparable size and complexity and documented availability. 15 pts

2) Documented experience and capabilities of other professional and technical staff in the performance of toxicology and pharmacology testing and documented availability. 10 pts

3) Previous institutional expertise and proven track record in the evaluation of therapeutics; previous experience in conducting work under GLP. 10 pts

C. Facilities and Resources **25**

1) Availability of adequate facilities, animals, equipment, and resources necessary to safely and efficiently accomplish the work described in the Statement of Work. Adequacy of detailed floor plan, indicating space to be committed for performance of this project. Adequacy of animal facilities. 15 pts

2) Capacity to perform required testing in a timely and efficient manner (resources dedicated to this project). 10 pts

TOTAL POINTS: 100