OMB No. 0990-0115

Electronic Request for Proposal
SOLICITATION COVER PAGE

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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. THIS OFFICE WILL PROVIDE NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS.

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 (SIC 8731) ***Size Standard:*** 500 Employees	***Level of Effort:*** [ ] Yes [X] No ***Total Effort:***
NIH-NIAID-DMID-02-01	[ ] Yes [X] No		

TITLE: Evaluation of Control Measures Against Diseases Other than AIDS

Issue Date:	***Due Date/Time:***	***Technical Proposal Page Limits:***
December 6, 2000	**March 12, 2001**	[X] Yes *(see Addendum To Statement of Work")* [ ] No

ISSUED BY:

Rosemary McCabe Hamill
Contract Management Branch, DEA
NIH, NIAID
6700-B Rockledge Drive
Room 2230, MSC 7612
Bethesda, MD 20892-7612

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

NO. OF AWARDS:

[ ] Only 1 Award
[X] Multiple Awards

PERIOD OF PERFORMANCE:

5 Years beginning on or about April 1, 2002.

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

The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. If 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 PHS Clause 352.215-10 entitled "Late Proposals, Modifications of Proposals and Withdrawals of Proposals" located in this Solicitation.

POINT OF CONTACT **-- Lawrence M. Butler --** ***COLLECT CALLS WILL NOT BE ACCEPTED --***

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BACKGROUND/STATEMENT OF WORK/NOTES TO OFFERORS

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BACKGROUND

The capacity to evaluate new and improved vaccine and therapy candidates in Phase I and Phase II clinical trials is an essential element of the efforts of the Division of Microbiology and Infectious Diseases (DMID) of the National Institute of Allergy and Infectious Diseases (NIAID). DMID has supported the Vaccine and Treatment Evaluation Units (VTEUs) since the 1960's. In addition, DMID supports an Adult/Elderly VTEU (MIRG) – University of Maryland, Contract Number NO1-AI-85342, a Respiratory Pathogens Research Unit (RPRU) – Baylor College of Medicine, Contract Number NO1-AI-65298, a Maternal Immunization Group (MIG) - Baylor College of Medicine, Contract Number NO1-AI-65316, an Enteric Pathogens Research Unit (EPRU) – University of Maryland, Contract Number NO1-AI-65299 and a Sexually Transmitted Diseases Clinical Trials Unit (STD CTU) – University of North Carolina, Contract Number NO1-AI-75329. A Data Coordinating Center contract provides data management and data analysis support to VTEU multi-center studies and to other DMID studies. The current Data Coordinating Center is the EMMES Corporation, Contract Number NO1-AI-65313. The Data Coordinating Center is currently being competed under RFP NIH-NIAID-DMID-01-14. A Clinical Regulatory Support contract (McKesson BioServices Corporation, Contract Number NO1-AI-05413) provides regulatory support for filing of INDs and clinical site monitoring.

The VTEUs have conducted Phase I and Phase II clinical trials of bacterial, viral and parasitic vaccines, other biologicals, and drugs, as preventive and therapeutic measures against infectious diseases in people of all ages and risk categories. In selected circumstances, Phase III and IV vaccine trials have also been undertaken. In the past seven years, the VTEUs have conducted a broad range of studies to evaluate the following vaccines: acellular pertussis, cold adapted live attenuated influenza virus, pneumococcus, tetanus, tuberculosis, malaria, cholera, salmonella, shigella, E. coli, rotavirus reassortant vaccines. They have also participated in respiratory and enteric challenge studies.

In February 2000, a programmatic review of the VTEUs took place. The primary purpose of this review was to evaluate the quality, direction and extent of work undertaken by the VTEUs in the context of the overall vaccine research efforts supported by NIAID. A second purpose was to identify the unique role(s) that the VTEUs could or should play in the complex and extensive context of national and international vaccine evaluation. The review panel consisted of twelve eminent scientists representing industry, academia and the federal government, who are experts in the fields of vaccinology, immunology, microbiology, pediatrics and internal medicine. The major findings of the review panel included support for the need for both specialized and general VTEUs. The reviewers recommended that DMID develop an integrated program with the capability to conduct "general" Phase I and Phase II studies, as well as the ability to conduct more focused, "specialized" studies on special populations, such as pregnant women. In addition, challenge studies and a need for assessing new techniques and approaches and generating new knowledge about human immunity and pathogenesis were noted as important areas of research to be continued in the VTEUs. The reviewers saw a need for a VTEU program that continues to be responsive to DMID programmatic needs, and has the capability to conduct timely clinical studies in response to new developments in vaccine research.

This RFP differs from the current VTEU network. The current VTEUs have the capability to do any kind of Phase I and II studies, challenge studies, as well as the capability to do expanded trials. This RFP includes the Phase I and II studies in Part A, and other studies in Parts B through F. A separate RFP (RFP NIH-NIAID-DMID-02-03) solicits proposals to conduct expanded Phase II and IV clinical trials. In addition, a decision was made to change the duration of the VTEU contract awards to 5 years, rather than 7 years.

The offeror must provide appropriate populations, staff, expertise, and facilities to test the full range and number of candidate vaccines and therapies in Phase I and II studies. Examples of candidate vaccines that would be of interest include vaccines for respiratory pathogens, enteric pathogens, sexually transmitted pathogens, parasitic pathogens, as well as combination vaccines. This RFP provides for re-competition of work ongoing with the current VTEU contractors:

Cincinnati Children's Medical Center	N01-AI-45252
Harbor-UCLA Medical Center	N01-AI-45249
University of Maryland	N01-AI-45251
University of Rochester	N01-AI-45248
St. Louis University	N01-AI-45250

Award of the contracts from this solicitation does not commit the Government to approve any of the studies presented in offerors' proposals. The Project Officer will determine which studies are actually undertaken. The Project Officer will also determine the necessity of arranging and attending meetings related to contract activities.

INTRODUCTION

This RFP is entitled "Evaluation of Control Measures Against Diseases Other than AIDS." It solicits proposals for the operation of the Vaccine and Treatment Evaluation Units (VTEUs) to address programmatic priorities in vaccine development, with a focus on Phase I and Phase II clinical trials of candidate vaccines in general populations, including infants and children, adolescents, adults and the elderly. Separate proposals are solicited for separate parts of this solicitation: challenge studies for respiratory and enteric pathogens, the evaluation of vaccines in pregnant women and the use of human specimens collected from clinical studies to characterize host responses to vaccinations and vaccine interactions. In addition, there is an option for malaria challenge studies.

This solicitation comprises six parts:

Part A - Phase I and II clinical trials of vaccine candidates in general populations, including infants and children, adolescents, adults and the elderly. Occasional studies of therapeutic vaccines, other biologicals and drugs in human subjects are also anticipated. The epidemiology of pathogens is of interest in the development of a Phase I or Phase II protocol. When a candidate vaccine shows promise, Phase III and IV trials will be considered.

Every offeror must submit a proposal for Part A and must also submit a proposal to do at least one of the following:

Part B – Respiratory challenge studies in which infections, with or without symptoms, are experimentally induced under carefully controlled and monitored conditions. Pathogens for which challenge studies have been performed and are anticipated include influenza and RSV.

Part C – Enteric challenge studies in which infections with or without symptoms are experimentally induced under carefully controlled and monitored conditions. Pathogens for which challenge studies have been performed and are anticipated include cholera, E. coli, and shigella.

Part D - Phase I and II clinical trials of candidate vaccines in pregnant women volunteers. The purpose of these trials is to prevent sequelae of infectious pathogens in neonates resulting from maternal transmission of pathogens. Pathogens that have been studied include Group B streptococcus, RSV, Hib and pneumococci. Anticipated is the evaluation of Group B streptococcal vaccines.

Part E – Use of human specimens to determine host responses to vaccinations or vaccine interactions. These studies should be conducted in the context of Phase I and Phase II trial development.

Part F – Experimental challenge studies of human volunteers with malaria parasites. This option would be exercised only at the discretion of the government.

For an Offeror to be considered for review and award, it must respond to Part A and, at a minimum, one of the other Parts B, C, D, E or F. Proposals for Part A alone will not be considered for review or award. Separate evaluations of each Part will be conducted.
An Offeror's proposal must be submitted as a single package. For the purposes of review, each Part, A, B, C, D, E and/or F, must be able to stand-alone. Thus, Parts A, B, C, D, E and/or F should be bound separately, but submitted together as a single package.

Negotiations will take place with Offerors whose proposals are determined to be in the competitive range. An Offeror must have a Part A proposal in the competitive range to be considered for award. If an Offeror responds to more than one Part (B, C, D, E or F), only those parts placed in the competitive range will enter the negotiation phase. Separate competitive ranges will be established for each Part.

Awards will be determined based upon the best value to the Government. The need to create a balanced vaccine network, e.g. geographic considerations, disease patterns, population diversity, that can meet DMID priorities and fill gaps in vaccine development and clinical trials is critical, and will be considered in making awards.

It is anticipated that a total of four to five contracts will be awarded to successful Offerors demonstrating capability of responding to the requirements of the solicitation. Each contract award will comprise at least a Part A award, and may include other parts, B, C, D, E and/or F. For example, a contract could be a Part A alone award, or the contract could be Part A and C, or Part A, B and E, depending upon initial review and source selection. A successful Offeror's Statement of Work will comprise the relevant Parts of that award. Successful part F offeror(s)' options will be exercised when the need arises and funds are available. Proposals for Part F must be submitted as part of an Offeror's package. Proposals for Part F will not be requested after contract awards are made.

STATEMENT OF WORK

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WORK STATEMENT - Part A

Independently, and not as an agent of the Government, the Contractor shall exert its best efforts to furnish all necessary services, qualified professional and technical personnel, volunteer populations, 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.

Specifically, the Contractor shall:

(1) Provide facilities and staff necessary to conduct prophylactic studies on candidate vaccines, as well as occasional studies of therapeutic vaccines, other biologicals and drugs in human volunteers.

SEE NOTES TO OFFEROR: A, B.

(2) Provide subjects from target populations. The target populations for most vaccines (and other preventive/therapeutic regimens) are infants and children, adolescents, adults and the elderly. These studies will require testing in healthy volunteers of different ages before progressing into target populations. Depending upon the vaccine or the study, there will be a need for seropositive and/or seronegative volunteers.

(3) Determine vaccine safety, immunogenicity, reactogenicity, optimal dose and schedule, infectivity, degree of virulence or attenuation, transmissibility, and genetic stability, depending on the vaccine being tested, using Phase I and Phase II trials. Studies for vaccine efficacy will be considered in the event vaccines under study warrant it, the disease incidence is sufficient to make an efficacy trial doable and affordable, and at the direction of the Project Officer.

SEE NOTES TO OFFEROR: C, D, AND E.

(4) Conduct appropriate immunologic assays (humoral and cellular) to determine volunteer eligibility, baseline levels on entry into a study, and response to the candidate vaccine.

SEE NOTE TO OFFEROR: F.

(5) Collect and store sera, other body fluids, tissues and cells from study participants using methods consistent with approved study protocols. Amounts and types shall depend upon individual protocols.

SEE NOTE TO OFFEROR: G.

(6) Follow subjects for up to three years to document duration of antibody or immune response, resistance to infection in the event of natural challenge within the community, and potential hazards of immunization as requested by the Project Officer.

(7) Establish and/or maintain the capability for occasional Phase I and Phase II studies of drugs and/or biologicals other than vaccines such as prophylactic or therapeutic agents for infections, e.g. monoclonal antibodies.

SEE NOTE TO OFFEROR: H.

(8) Prepare protocols, consent forms, case report forms, and other Investigational New Drug (IND) information for submission to the Project Officer and the local Institutional Review Board (IRB) for approval and for NIAID submission to the FDA as part of an IND package. Amend as necessary after comments by the Project Officer, the DMID Office of Regulatory Affairs, the local IRB, and regulatory authorities.

(9) At the direction of the Project Officer, initiate and maintain focused epidemiologic and laboratory surveillance for infection in the proposed study populations as background information in the context of protocol development for phase I and phase II studies. This focused surveillance shall provide the necessary background information for phase I and phase II vaccine studies. This shall include, but not be limited to, the following enteric and respiratory pathogens: rotavirus, calicivirus, respiratory syncytial virus, parainfluenza viruses, influenza virus, pneumococci, and *B. pertussis*. The purpose of this activity is to aid in the following:

a. Interpretation of the volunteers' response to vaccination;
b. Initiation of clinical trials with vaccine at a time when the wild-type pathogen is not at its peak circulation in the population chosen for the study;
c. Determination of the impact of a particular pathogen in a selected high-risk population as directed by the Project Officer.

(10) Organize and administer the clinical research activities of the contract.

a. Plan, conduct, and report on the proposed clinical studies and associated research studies. This shall include developing the specifics of experimental design, receiving and shipping of reagents and samples, coding and collection of subject's records and samples, and coordinating all of the subcontractors' activities (if applicable). This shall also include conducting all clinical studies in compliance with DMID/NIAID policy, in coordination with the Office of Regulatory Affairs, DMID/NIAID and in compliance with FDA regulations governing clinical trials;
b. Manage the information generated, including transmission, storage, confidentiality, retrieval, validation, analysis, and publication;
c. Establish and/or implement a quality assurance/quality control plan for the information generated;
d. Establish and manage laboratory facility(ies) to support the various studies;
e. Establish and/or implement a quality assurance/quality control plan for the management of the laboratory facility(ies);
f. Supervise, coordinate, and perform the project(s).

SEE NOTES TO OFFEROR: I, J.

(11) Attend and participate in one, 2-day meeting per year in Bethesda, MD, to discuss results and future plans.

(12) Attend and participate in one, 2-day meeting per year in Bethesda, MD, to discuss clinical trial coordination and regulatory issues related to clinical trials.

(13) Report to the DMID Office of Regulatory Affairs and to the Project Officer all adverse reactions to comply with FDA regulations.

WORK STATEMENT - Part B

Independently, and not as an agent of the Government, the Contractor shall exert its best efforts to furnish all necessary services, qualified professional and technical personnel, volunteer populations, 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.

Specifically, the Contractor shall:

(1) Provide facilities and staff necessary to conduct human challenge studies of respiratory pathogens to:

a. Clinically characterize a challenge strain (bacteria and/or viruses) by infecting healthy volunteers, and documenting clinical signs and symptoms of the disease caused by the challenge strain;
b. Assess the safety and efficacy of control measures, including vaccines and therapeutic agents, using characterized challenge strains;
c. Evaluate how behavioral factors, including psychological and social factors, influence susceptibility to respiratory infections.

SEE NOTES TO OFFEROR: A, B.

(2) Provide subjects from target populations as required for the conduct of challenge studies. At this time, the target population for respiratory challenge studies should be healthy adults.

SEE NOTES TO OFFEROR: K, M.

(3) Provide specialized isolation facilities for study subjects to prevent transmission to other individuals and to prevent environmental contamination.

SEE NOTE TO OFFEROR: L.

(4) Conduct appropriate immunologic assays (humoral and cellular) to determine volunteer eligibility, baseline levels on entry into a study, response to the candidate vaccine, and response to the challenge material.

(5) Collect and store sera, other body fluids, tissues and cells from study participants using methods consistent with approved study protocols. Amounts and types shall depend upon individual protocols.

SEE NOTE TO OFFEROR: F.

(6) Follow subjects to document duration of antibody or immune response and/or resistance to infection in the event of natural challenge within the community as directed by the Project Officer.

(7) Prepare protocols, consent forms, case report forms, and other Investigational New Drug (IND) information for submission to the Project Officer and the local Institutional Review Board (IRB) for approval and for NIAID submission to the FDA as part of an IND package. Amend as necessary after comments by the Project Officer, the DMID Office of Regulatory Affairs, local IRB, and regulatory authorities.

(8) Organize and administer the clinical research activities of the contract.

a. Plan, conduct and report on the proposed clinical studies and associated research studies. This shall include developing the specifics of experimental design, receiving and shipping of reagents and samples, coding and collection of patient's records and samples, and coordinating all of the subcontractors' activities (if applicable). This shall also include conducting all clinical studies in compliance with DMID/NIAID policy, in coordination with the Office of Regulatory Affairs, DMID/NIAID and in compliance with FDA regulations governing clinical trials;
b. Manage the information generated, including transmission, storage, confidentiality, retrieval, validation, analysis, and publication;
c. Establish and/or implement a quality assurance/quality control plan for the information generated;
d. Establish and manage challenge facility(ies) to support the various studies;
e. Establish and manage laboratory facility(ies) to support the various studies;
f. Establish and/or implement a quality assurance/quality control plan for the management of the laboratory facility(ies);
g. Supervise, coordinate, and perform the project(s).

SEE NOTES TO OFFEROR: I, J, M.

(9) Attend and participate in one, 2-day meeting per year in Bethesda, MD, to discuss results and future plans.

(10) Attend and participate in one, 2-day meeting per year in Bethesda, MD, to discuss clinical trial coordination and regulatory issues related to clinical trials.

(11) Report to the DMID Office of Regulatory Affairs and to the Project Officer all adverse reactions to comply with FDA regulations.

WORK STATEMENT - Part C

Independently, and not as an agent of the Government, the Contractor shall exert its best efforts to furnish all necessary services, qualified professional and technical personnel, volunteer populations, 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.

Specifically, the Contractor shall:

(1) Provide facilities and staff necessary to conduct human challenge studies of enteric pathogens to:

a. Clinically characterize a challenge strain (bacteria and/or viruses), by infecting healthy volunteers, causing clinical signs and symptoms of the infection or disease caused by the challenge strain;
b. Challenge subjects with pathogenic strains in order to assess the safety and efficacy of control measures, including vaccines and therapeutic agents.

SEE NOTES TO OFFEROR: A, B.

(2) Provide subjects from target populations as required for the conduct of challenge studies. At this time, the target population for enteric challenge studies should be healthy adults.

SEE NOTES TO OFFEROR: K, M.

(3) Provide specialized isolation facilities for study subjects to prevent transmission to other individuals and to prevent environmental contamination.

SEE NOTE TO OFFEROR: L.

(4) Conduct appropriate immunologic assays (mucosal, humoral and cellular) to determine volunteer eligibility, baseline levels on entry into a study, response to the challenge material, as well as immune response to vaccines, prior to and following challenge, as a measure of efficacy.

(5) Collect and store sera, other body fluids, tissues and cells from study participants using methods consistent with approved study protocols. Amounts and types shall depend upon individual protocols.

SEE NOTE TO OFFEROR: F.

(6) Follow subjects given challenge strains or following vaccination with candidate vaccines, to document duration of antibody or immune response and/or resistance to infection in the event of natural challenge within the community, as directed by the Project Officer.

(7) Prepare protocols, consent forms, case report forms, and other Investigational New Drug (IND) information for submission to the Project Officer and local Institutional Review Board (IRB) for approval and for NIAID submission to the FDA as part of an IND package. Amend as necessary after comments by the Project Officer, the DMID Office of Regulatory Affairs, the local IRB, and regulatory authorities.

(8) Organize and administer the clinical research activities of the contract.

a. Plan, conduct, and report on the proposed clinical studies and associated research studies. This shall include developing the specifics of experimental design, receiving and shipping of reagents and samples, coding and collection of patient's records and samples, and coordinating all of the subcontractors' activities (if applicable). This shall also include conducting all clinical studies in compliance with DMID/NIAID policy, in coordination with the Office of Regulatory Affairs, DMID/NIAID and in compliance with FDA regulations governing clinical trials;
b. Manage the information generated, including transmission, storage, confidentiality, retrieval, validation, analysis, and publication;
c. Establish and/or implement a quality assurance/quality control plan for the information generated;
d. Establish and manage challenge facility(ies) to support the various studies;
e. Establish and manage laboratory facility(ies) to support the various studies;
f. Establish and/or implement a quality assurance/quality control plan for the management of the laboratory facility(ies);
g. Supervise, coordinate, and perform the project(s).

SEE NOTES TO OFFEROR: I, J, M.

(9) Attend and participate in one, 2-day meeting per year in Bethesda, MD, to discuss results and future plans.

(10) Attend and participate in one, 2-day meeting per year in Bethesda, MD, to discuss clinical trial coordination and regulatory issues related to clinical trials.

(11) Report to the DMID Office of Regulatory Affairs and to the Project Officer all adverse reactions to comply with FDA regulations.

WORK STATEMENT - Part D

Independently, and not as an agent of the Government, the Contractor shall exert its best efforts to furnish all necessary services, qualified professional and technical personnel, volunteer populations, 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.

Specifically, the Contractor shall:

(1) Provide facilities and staff necessary to conduct prophylactic studies on candidate vaccines in pregnant women volunteers.

SEE NOTES TO OFFEROR: A, B.

(2) Provide subjects from the target population of pregnant women for Phase I and II clinical vaccine studies. Depending upon the vaccine or the study, there will be a need for seropositive and/or seronegative volunteers.

SEE NOTE TO OFFEROR: M.

(3) Determine vaccine safety, reactogenicity, transplacental transfer of antibody, breast milk transfer of antibody, optimal dose, timing, immunogenicity and isotyping, using Phase I and Phase II trials.

SEE NOTE TO OFFEROR: K.

(4) Conduct appropriate immunologic assays (humoral and cellular) to determine volunteer eligibility, baseline levels on entry into a study, and response to the candidate vaccine.

(5) Collect and store sera, other body fluids, tissues and cells, including placentas and cord blood, from study participants using methods consistent with approved study protocols. Amounts and types shall depend upon individual protocols.

SEE NOTE TO OFFEROR: F.

(6) Follow subjects and offspring infants for up to three years to document duration of antibody or immune response, resistance to infection in the event of natural challenge within the community, and potential hazards of immunization as requested by the Project Officer. Follow-up of mothers may include assessment of immune response(s) in subsequent pregnancies.

SEE NOTE TO OFFEROR: N.

(7) Prepare protocols, consent forms, case report forms, and other Investigational New Drug (IND) information for submission to the Project Officer and local Institutional Review Board (IRB) for approval and for NIAID to submit to the FDA as part of an IND package. Amend as necessary after comments by the Project Officer, the DMID Office of Regulatory Affairs, the local IRB, and regulatory authorities.

SEE *NOTES TO OFFEROR: I, O.*

(8) Organize and administer the clinical research activities of the contract.

a. Plan, conduct, and report on the proposed clinical studies and associated research studies. This shall include developing the specifics of experimental design, receiving and shipping of reagents and samples, coding and collection of patient's records and samples, and coordinating all of the subcontractors' activities (if applicable). This shall also include conducting all clinical studies in compliance with DMID/NIAID policy, in coordination with the Office of Regulatory Affairs, DMID/NIAID and in compliance with FDA regulations governing clinical trials;
b. Manage the information generated, including transmission, storage, confidentiality, retrieval, validation, analysis, and publication;
c. Establish and/or implement a quality assurance/quality control plan for managing the information generated;
d. Establish and manage laboratory facility(ies) to support the various studies;
e. Establish and/or implement a quality assurance/quality control plan for the management of the laboratory facility(ies);
f. Supervise, coordinate, and perform the project(s)

SEE NOTES TO OFFEROR: I, J, M.

(9) Attend and participate in one, 2-day meeting per year in Bethesda, MD, to discuss results and future plans.

(10) Attend and participate in one, 2-day meeting per year in Bethesda, MD, to discuss clinical trial coordination and regulatory issues related to clinical trials.

(11) Report to the DMID Office of Regulatory Affairs and to the Project Officer all adverse reactions to comply with FDA regulations.

WORK STATEMENT - Part E

Independently, and not as an agent of the Government, the Contractor shall exert its best efforts to furnish all necessary services, qualified professional and technical personnel, volunteer populations, 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.

Specifically, the Contractor shall:

(1) Provide facilities and staff necessary to conduct pre-clinical research activities, which are designed to validate or lead to clinical studies. Research activities to be performed include, but are not limited to:

a. Basic and mechanistic studies of pathogenesis, host/pathogen interaction and immune correlates of protection;
b. Development of new assays to improve and refine assessment of immune responses in humans;
c. Use of animal models to demonstrate proof of concept relating to pathogenesis, new vaccine strategies, adjuvants, delivery vehicles, assays, diagnostics, etc;
d. Identification of genes that are potentially involved in adverse reactions to vaccines.

(2) Provide facilities and staff necessary to conduct clinical research activities related to vaccinology. Research activities to be performed include, but are not limited to:

a. Increasing immune response to optimum levels through the use of vaccines, adjuvants or delivery methods;
b. Use of human specimens collected from vaccine studies to explore the impact of genetics in host responses to vaccine antigens;
c. Use of human specimens collected from vaccine studies to explore the mechanisms and host factors related to adverse reactions to vaccines.

SEE NOTES TO OFFEROR: A, B, P, AND Q.

(3) Collect and store sera, other body fluids, tissues and cells from study participants using methods consistent with approved study protocols. Amounts and types shall depend upon individual protocols.

SEE NOTE TO OFFEROR: F.

(4) Prepare protocols, consent forms and other information for submission to the Project Officer and the local Institutional Review Board (IRB) for approval. Amend as necessary after comments by the Project Officer, the DMID Office of Regulatory Affairs, local IRB, and regulatory authorities.

(5) Organize and administer the clinical research activities of the contract.

a. Plan, conduct, and report on the proposed clinical studies and associated research studies. This shall include developing the specifics of experimental design, receiving and shipping of reagents and samples, coding and collection of patient's records and samples, and coordinating all of the subcontractors' activities (if applicable). This shall also include conducting all clinical studies in compliance with DMID/NIAID policy, in coordination with the Office of Regulatory Affairs, DMID/NIAID and in compliance with FDA regulations governing clinical trials;
b. Manage the information generated, including transmission, storage, confidentiality, retrieval, validation, analysis, and publication;
c. Establish and/or implement a quality assurance/quality control plan for managing the information generated;
d. Establish and manage laboratory facility(ies) to support the various studies;
e. Establish and/or implement a quality assurance/quality control plan for the management of the laboratory facility(ies);
f. Supervise, coordinate, and perform the project(s)

SEE *NOTES TO OFFEROR: I, J, P.*

(6) Attend and participate in one, 2-day meeting per year in Bethesda, MD, to discuss results and future plans.

(7) Attend and participate in one, 2-day meeting per year in Bethesda, MD, to discuss clinical trial coordination, and regulatory issues related to clinical trials.

WORK STATEMENT - Part F - Option

Independently, and not as an agent of the Government, the Contractor shall exert its best efforts to furnish all necessary services, qualified professional and technical personnel, volunteer populations, 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.

The Part F option will be exercised at the sole discretion of the government.

Specifically, the Contractor shall:

(1) Provide facilities and staff necessary to conduct experimental challenge studies of human volunteers with malaria parasites to:

a. Access well characterized strains or clones of *Plasmodium* species infectious to humans and suitable for human challenge studies. At this time, only experimental challenge with *Plasmodium falciparum* is anticipated.
b. Insectary capability to maintain Anopheline species of mosquitos suitable for transmitting malaria parasites of *Plasmodium* strains or clones to human volunteers in experimental challenge studies.

(2) Provide subjects from target populations as required for experimental malaria challenge studies. At this time, the target population for malaria challenge studies should be healthy adults.

(3) Provide facilities and specialized clinical expertise for clinical monitoring of human volunteers participating in malaria challenge studies, and for timely diagnosis and treatment of clinical malaria.

SEE NOTES TO OFFEROR: A, B, K, L, M, AND R.

(4) Provide capability to conduct appropriate clinical laboratory and immunologic assays (mucosal, humoral and cellular) to determine volunteer eligibility, baseline levels on entry into a study, response to immunization with investigational vaccine, including prior to and following experimental challenge.

(5) Collect and store sera, other body fluids, tissues and cells from study participants using methods consistent with approved study protocols. Amounts and types shall depend upon individual protocols.

SEE NOTE TO OFFEROR: F.

(6) Follow subjects given experimental malaria infections or vaccination with candidate vaccines, to document duration of antibody or immune response, as directed by the Project Officer.

(7) Prepare protocols, consent forms, case report forms, and other Investigational New Drug (IND) information for submission to the Project Officer and local Institutional Review Board (IRB) for approval and for NIAID submission to the FDA as part of an IND package. Amend as necessary after comments by the Project Officer, the DMID Office of Regulatory Affairs, the local IRB and regulatory authorities.

(8) Organize and administer the clinical research activities of the contract.

a. Plan, conduct, and report on the proposed clinical studies and associated research studies. This shall include developing the specifics of experimental design, receiving and shipping of reagents and samples, coding and collection of patient's records and samples, and coordinating all of the subcontractors' activities (if applicable). This shall also include conducting all clinical studies in compliance with DMID/NIAID policy, in coordination with the Office of Regulatory Affairs, DMID/NIAID and in compliance with FDA regulations governing clinical trials;
b. Manage the information generated, including transmission, storage, confidentiality, retrieval, validation, analysis, and publication;
c. Establish and/or implement a quality assurance/quality control plan for the information generated;
d. Establish and manage challenge facility(ies) to support the various studies;
e. Establish and manage laboratory facility(ies) to support the various studies;
f. Establish and/or implement a quality assurance/quality control plan for the management of the laboratory facility(ies);
g. Supervise, coordinate, and perform the project(s)

SEE NOTES TO OFFEROR: I, J, M.

(9) Attend and participate in one, 2-day meeting per year in Bethesda, MD, to discuss results and future plans.

(10) Attend and participate in one, 2-day meeting per year in Bethesda, MD, to discuss clinical trial coordination and regulatory issues related to clinical trials.

(11) Report to the DMID Office of Regulatory Affairs and to the Project Officer all adverse reactions to comply with FDA regulations.

NOTES TO OFFERORS

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VTEU Notes to Offeror for Statement of Work

A. *A well-trained, committed and balanced team of staff to conduct clinical trials is required. The PI should have an M.D. and/or Ph.D. degree, or equivalent, and should be experienced in clinical trials involving appropriate populations. The team of professional personnel, including the nursing staff, should have composite expertise in pediatrics, infectious diseases, immunology, clinical trials, host response to pathogens and vaccines, epidemiologic-based studies, and biostatistics. Collaborations must be in place by the time the contract is awarded. Other expertise will be required for parts B, C, D, E and F. For example, personnel with expertise in respiratory challenge studies will be required for Part B, expertise in enteric challenge studies will be required for Part C, expertise in clinical studies of pregnant women will be required for Part D, expertise in pre-clinical studies will be required for Part E and expertise in malaria challenge studies will be required for Part F. Effective nursing staff are critical to the success of vaccine trials and a designated Research Nurse Coordinator/Supervisor is essential. There should be experience with the recruitment, retention and follow-up of study subjects. Individuals to be responsible for coordination of regulatory issues should be identified and are also essential. The technical personnel should be trained and experienced in performing assay and laboratory procedures. The support staff should possess the requisite experience to perform their clerical and administrative duties. Curricula Vitae of all proposed professional personnel must be included in the proposal. The NIAID continues to support the training of investigators in vaccine related clinical research. It is both feasible and desirable to provide training opportunities for suitable individuals through effort expended on the activities of this contract. If appropriate and relevant, the offeror is free to propose inclusion of training opportunities for international scientists and clinicians. International scientists are MDs or PhDs from countries other than the US who come to the VTEUs to learn specific clinical or laboratory techniques relevant to on-going VTEU studies. Training opportunities could also include US scientists going to countries other than the US to learn specific clinical or laboratory techniques relevant to on-going VTEU studies.*

B. *Each VTEU should have an external scientific advisory committee of non-involved research scientists and clinicians to provide independent assessment and advice to the Principal Investigator and staff. This committee should be appointed by the Principal Investigator and should meet at least twice each year. Offerors should provide generic identification of the number and types of experts for the advisory committee. To maintain the largest number of possible expert reviewers, potential members of the advisory committee should not be named in the proposal, and should not be contacted or selected until after awards are made.*

C. *The range and number of studies anticipated requires a minimum of 300 subjects per year for general, open Phase I and II studies plus a minimum of 100 subjects per year for more detailed studies such as those that evaluate live, vectored or attenuated candidate vaccines, or those requiring intensive care and/or follow-up.*

D. *Examples of infectious agents for which vaccines might be tested in the first eighteen months of the contract and onward include, but are not restricted to: respiratory pathogens, enteric pathogens, sexually transmitted pathogens, malaria, tuberculosis and schistosomiasis. Combination vaccines and vaccines in new delivery systems such as microencapsulation, delivery modes such as edible and transcutaneous, and live vectors such as Salmonella are expected to be available for testing. Progress is also being made in the development of malaria, schistosomiasis, and fungal vaccines and such vaccine candidates may be available for clinical testing during the period of this contract. Evaluation of vaccines for bioterrorism agents such as anthrax and smallpox may be initiated under this contract, Evaluation of*

vaccines as therapeutics for chronic infections or to prevent development of chronic sequelae; e.g. Hepatitis C, Group A Streptococcus, Helicobacter pylori may also be considered. Vaccine types may include, but are not restricted to: 1) inactivated, live attenuated, and subunit vaccines; 2) live recombinant vector vaccines; 3) polysaccharide conjugate vaccines; 4) recombinant peptides; and 5) naked DNA.

E. *Sample protocols and consent forms should be submitted with the proposal and should demonstrate that the offeror thoroughly understands testing different types of vaccines. A maximum of two vaccine protocols may be submitted in the proposal. These protocols are to be chosen by the offeror, demonstrating the scientific and technical capabilities and merits of the proposed protocols.*

F. *Assays will include humoral assays and cellular assays such as measurement of cytokines and proliferative assays. To ensure standardization, assays on selected samples may be undertaken by other Contractors of the Government. When necessary, other testing will be arranged by the Government.*

G. *Studies may require collection of blood by venipuncture from infants as well as nasopharyngeal swabs and/or aspirates from infants.*

H. *DMID/NIAID supports in vitro and in vivo animal model testing of antivirals and other biologicals that may become available for clinical testing. Examples of clinical studies of drugs and biologicals other than vaccines conducted during the current contract period are a study of treatment of herpes labialis, a study of the adjuvant QS 21 and a study of therapeutic monoclonal antibodies. In addition to the two other protocols requested in NOTE E, one protocol and consent form demonstrating the offeror's approach to the Phase I/II clinical evaluation of a drug or biological other than vaccine should be submitted with the proposal. The offeror may select a real or hypothetical drug or biological of their choice and should assume that it has shown promise in an <u>in vitro</u> screen and in animal models, and that the preclinical safety profile is good. The protocol should include evaluation of safety, pharmacokinetics, and preliminary evidence of efficacy of the drug or biological.*

I. *A detailed organizational chart should be provided that shows the administrative structure, reporting structure, supervisory roles, the interactions between the groups and projects, etc.*

J. *Biostatistical and data management capabilities for analysis of clinical data must be documented. It is anticipated that for most single site studies, the offeror will take the lead on biostatistical aspects of studies. For multi-center studies, the DMID data coordinating center will be utilized.*

K. *A detailed description of demonstrated expertise and experience in the conduct of respiratory challenge studies (Part B), enteric challenge studies (Part C), vaccine studies in pregnant women (Part D), experimental challenge studies of human volunteers with malaria parasites (Part F) should be submitted with the proposal and should demonstrate that the offeror thoroughly understands the conduct and clinical management of the appropriate studies under each Part the Offeror is applying for.*
Each detailed description should include explanations of recruitment and follow-up of study subjects, case management of subjects, medical management of subjects, types of specimens to be collected, procedures for collection of specimens, assays to be conducted to determine immunogenicity, pathogenesis and/or immune response as well as safety and efficacy where appropriate, data management including quality control and quality assurance, laboratory facilities and laboratory quality control and quality assurance. For Part D, vaccine studies in pregnant women, the protocol should examine the use of a Group B streptococcal vaccine in third trimester pregnant women to prevent transmission of Group B streptococcus and its sequelae in offspring infants. The protocol should include descriptions of the unique staff needed to recruit and follow-up mothers and their infants.

L. *Offerors must be capable of providing special isolation facilities for the conduct of human challenge studies of respiratory pathogens (Part B) and/or enteric pathogens (Part C). Offerors should assume that subjects will be studied as inpatients. Provide a detailed description of the facilities available for this solicitation, indicating understanding of the requirements for respiratory challenge studies (Part B), enteric challenge studies (Part C), and/or experimental challenge studies of human volunteers with malaria parasites (Part F), as well as the availability of such facilities. Include description of infection control procedures to prevent environmental contamination For Part F, Offerors must have insectary capability to maintain appropriate mosquito species.*

M. *It is anticipated that 2-4 respiratory human challenge studies per year will be conducted at each challenge study site, and that between 50-150 subjects will be enrolled per year at each site in Part B. It is anticipated that approximately 2-4 enteric human challenge studies per year will be conducted at each challenge study site, and that a total of 50-150 subjects will be enrolled per year at each site in Part C. It is anticipated that 2 vaccine studies in pregnant women per year will be conducted at each study site, and that a total of 70-100 subjects will be enrolled per year at each site in Part D. It is anticipated that approximately 1-2 experimental challenge studies of human volunteers with malaria parasites per year will be conducted at each challenge study site, and that a total of 40-100 subjects will be enrolled per year at each site in Part F.*

N. *It is likely that all studies will require follow-up of mothers and their infants for up to three years to document antibody decline. In addition, subsequent pregnancies in the mothers may require follow-up or re-enrollment into a study.*

O. *Offerors should provide documentation of experience in the ability to conduct vaccine studies in pregnant women, including local Institutional Review Board (IRB) approvals from previously conducted studies.*

P. *The investigations in Part E might include the basic biology of the organisms of interest, pathogenesis of the infection and disease, and host immunity. The latter may include identification and refinement of correlates of immunity and protection. Although some of these studies may need to employ either animal models or cultured cells, it is not the intent of this solicitation to support a basic research program that is unrelated to human vaccine development and evaluation efforts of DMID/NIAID. In addition, it is not the intent of this solicitation to develop a basic research program that would be better supported by the R01, investigator- initiated funding mechanism. It is anticipated that 1-2 pre-clinical studies and 1-2 clinical studies will be conducted per year at each site.*

Q. *Two sample research protocols that demonstrate the offeror's approach to research activities designed to validate or lead to clinical studies, should be submitted with the proposal: one protocol should be a pre-clinical research activity and one protocol should be a vaccine-related research activity using human specimens.*

R. *A detailed concept sheet for a malaria challenge study should be submitted with the proposal, demonstrating how resources would be used to conduct a clinical study. The concept sheet should include explanations of how access to strains or clones of Plasmodium species would be accomplished, and how insectary capability would be established and maintained.*

Addendum to Notes to Offeror - VTEU

Part A – Required components 150 page limit, excluding Appendix:

1. Description of facilities.
2. Listing of staff for Part A contained in CVs (maximum 3 pages per professional staff person) in Appendix.
3. Description of available patient populations.
4. Description of immunologic assays.
5. Maximum of two vaccine protocols and consent forms, to include list of case report forms needed, plus sample case report forms for inclusion/exclusion criteria and medical assessment.
6. Description of focused epidemiologic and laboratory surveillance.
7. One biological protocol and consent form, to include list of case report forms needed, plus sample case report forms for inclusion/exclusion criteria and medical assessment.
8. Organizational chart/administrative structure.
9. Description of biostatistical and data management capabilities.

The text of the proposal should include all figures, charts, tables and diagrams, as well as literature cited.

Appendices should include CVs and pertinent reprints only. CVs are limited to a maximum of 3 pages per professional staff person. A maximum of 10 reprints may be submitted for the entire proposal, Parts A-F; reprints should be included in the Appendix of the appropriate Part(s) A-F.

Materials other than CVs and reprints included in Appendices will not be reviewed.

Part B – Required components 50 page limit, excluding Appendix:

1. Description of expertise and experience in respiratory challenge studies, including recruitment and follow-up of study subjects, case management of subjects, medical management of subjects, types of specimens to be collected, procedures for collection of specimens, assays to be conducted, data management including quality control and quality assurance, laboratory facilities and laboratory quality control and quality assurance.
2. Listing of staff for Part B, contained in CVs (maximum 3 pages per staff person) in Appendix.
3. Description of isolation facilities.
4. Organizational chart/administrative structure.
5. Description of biostatistical and data management capabilities.

Part C – Required components 50 page limit, excluding Appendix:

1. Description of expertise and experience in enteric challenge studies, including recruitment and follow-up of study subjects, case management of subjects, medical management of subjects, types of specimens to be collected, procedures for collection of specimens, assays to be conducted, data management including quality control and quality assurance, laboratory facilities and laboratory quality control and quality assurance.
2. Listing of staff for Part C, contained in CVs (maximum 3 pages per staff person) in Appendix.
3. Description of isolation facilities.
4. Organizational chart/administrative structure.
5. Description of biostatistical and data management capabilities.

Part D – Required components 50 page limit, excluding Appendix:

1. Description of expertise and experience in vaccine studies in pregnant women, including recruitment and follow-up of study subjects for up to three years (as well as re-enrollment of mothers with subsequent pregnancies), case management of subjects, medical management of subjects, types of specimens to be collected, procedures for collection of specimens, assays to be conducted, data management including quality control and quality assurance, laboratory facilities and laboratory quality control and quality assurance.
2. Protocol examining the use of a Group B streptococcal vaccine in third trimester pregnant women to prevent transmission of Group B strep and its sequelae in offspring infants.
3. Listing of staff for Part D, contained in CVs (maximum 3 pages per staff person) in Appendix.
4. Documentation of experience in the conduct of vaccine studies in pregnant women, including local Institutional Review Board (IRB) approvals from previously conducted studies.
5. Organizational chart/administrative structure.
6. Description of biostatistical and data management capabilities.

Part E – Required components 50 page limit, excluding Appendix:

1. Listing of staff for Part E, contained in CVs (maximum 3 pages per staff person) in Appendix.
2. Two sample research protocols – one pre-clinical and one vaccine related using human specimens.
3. Description of assays.
4. Organizational chart/administrative structure.
5. Description of biostatistical and data management capabilities.

Part F – Required components 50 page limit, excluding Appendix:

1. Description of expertise and experience in experimental challenge studies of human volunteers with malaria parasites, including recruitment and follow-up of study subjects, case management of subjects, medical management of subjects, types of specimens to be collected, procedures for collection of specimens, assays to be conducted, data management including quality control and quality assurance, laboratory facilities and laboratory quality control and quality assurance.
2. Listing of staff for Part F, contained in CVs (maximum 3 pages per staff person) in Appendix.
3. Description of facilities.
4. Organizational chart/administrative structure.
5. Description of biostatistical and data management capabilities.

Pages in excess of those listed above will be removed from the proposal and will not be read or evaluated. Offerors are encouraged to limit the overall size of the Technical Proposal (excluding appendices). Note that although no page limit has been placed on Business Proposals, offerors are encouraged to limit their content to only those documents necessary to provide adequate support for the proposed costs.

REPORTING REQUIREMENTS AND DELIVERABLES

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The Contractor shall submit to the Contracting Officer and to the Project Officer technical progress reports covering the work accomplished during each reporting period. For specific clinical studies, special reports may be required, at the request of the Project Officer.

A. Technical Reports

In addition to those reports required by the Statement of Work and other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below:

(1) Semi-Annual Technical Progress Reports - by the fifteenth working day of the month following the end of each six month period, the Contractor shall submit three (3) copies of a semi-annual Technical Progress Report, comprising two (2) copies to the Project Officer and one (1) copy to the Contracting Officer. Such reports shall include the following specific information:

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

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

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

d. SECTION III - Substantive performance; a description of current technical or substantive performance and any problems encountered and/or which may exist along with proposed corrective action. Each clinical study should be reported separately according to the number assigned by the Project Officer. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and corrective steps should be provided.

e. An anticipated work plan for the following six months.

f. Preprints, reprints, and abstracts shall be submitted along with the report.

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

(2) Annual Reports - On the anniversary date of the contract, the Contractor shall submit three (3) copies of an Annual Technical Progress Report, as above, comprising two (2) copies to the Project Officer and one (1) copy to the Contracting Officer. Such reports shall detail, document, and summarize the results of the entire contract work for the period covered. These reports shall be in sufficient detail to explain comprehensively the results achieved. A summary of work proposed for the next reporting period should also be included in the report. An annual report will not be required for the period when the final report is due. Preprints and reprints of papers and abstracts not submitted in the semi-annual report shall be submitted.

(3) Final Report - By the expiration date of the contract, the Contractor shall submit three (3) copies of a comprehensive Final Report, two (2) copies to the Project Officer and one (1) copy to the Contracting Officer. This final report shall detail, document and summarize the results of the entire contract work for the period covered. This report shall be in sufficient detail to explain comprehensively the results achieved. Preprints and reprints not included previously shall be submitted.

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

C. Copies of the technical reports shall be submitted as follows:

Type of Report	No. of Copies	Addresses:
Semi-annual	2	Project Officer
Final	2	OD, DMID, NIAID, NIH 6700-B Rockledge Drive MSC 7628 Bethesda, MD 20892-7628
Semi-annual	1	Contract Officer
Final	1	CMB, DEA, NIAID, NIH 6700-B Rockledge Drive MSC 7612 Bethesda, MD 20892-7612

TECHNICAL EVALUATION FACTORS FOR AWARD-PART A

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1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: Technical, Programmatic Balance, Cost/Price, and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, programmatic balance, cost/price, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

The need to create a balanced vaccine network, e.g. geographic considerations, disease patterns, population diversity, that can meet DMID priorities and fill gaps in vaccine development and clinical trials is critical, and will be considered in making awards.

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 carefully evaluated. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

This research project involves human subjects. NIH Policy requires that women and members of minority groups and their subpopulations and children must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification is provided with respect to the health of the subjects or the purpose of the research.

Where inclusion of women, minority populations, and/or children is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The NIAID will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research. If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions or include women, minorities and/or children in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

2. MANDATORY QUALIFICATION CRITERIA - NOT APPLICABLE

3. TECHNICAL EVALUATION CRITERIA - PART A

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

Criterion Element	Weight
A.1. TECHNICAL APPROACH.....	**70**

Documented technical adequacy and feasibility of the proposed plans for Phase I and Phase II prophylactic studies on candidate vaccines, drugs and other biologics and performance of assays and laboratory procedures. Adequacy, suitability and availability of necessary populations, and plans for their recruitment, retention and follow-up, including women, minorities and children as documented in the proposal.

a) Phase I and II trials: This includes the methods and approaches for evaluating bacterial, viral, parasitic and fungal vaccines, as well as drugs or biologicals, suitability and originality of the sample clinical protocols, appropriateness of consent forms, handling of data and data analyses (including data QA/QC plans), plans for performing assays on sera and other body fluids, and for other relevant laboratory procedures including QA/QC, as required in the protocols, and as requested in the Statement of Work. 30

b) Population: Offeror should demonstrate an ability to recruit, retain and follow target populations. Strategies for follow-up of vaccinees and therapy recipients should be presented. The recruitment plan should describe specific plans to include minorities, women and children. 20

c) Epidemiology: This includes the proposed methods and approaches for collecting focused epidemiological data to support trials of vaccines, drugs and other biologicals, evaluating risk factors for infection, evaluating screening protocols, suitability of the sample protocols, appropriateness of the consent forms (if necessary), strategies for follow-up of patients, handling of data and data analyses and plans for integrating the epidemiological findings with the Phase I and Phase II clinical trials. 10

d) Administration : Proposed plans for managing the clinical and research activities to ensure a cooperative, integrated scientific effort. 10

A.2. FACILITIES AND RESOURCES..... 10

Offeror must demonstrate capability to provide facilities and staff necessary to conduct prophylactic studies on candidate vaccines, as well as occasional studies of therapeutic vaccines, other biologicals and drugs in human volunteers, as requested in the Statement of Work.

A.3. PERSONNEL..... 20

Documented adequacy and relevance of expertise, experience, education, and availability of personnel for performing all the requirements of the Statement of Work.

The PI should have an M.D. and/or Ph.D. degree, or equivalent, and should provide documented evidence of experience in clinical trials involving appropriate populations. The team of professional personnel (including the nursing personnel) should have composite expertise in pediatrics, infectious diseases, immunology, clinical trials (including recruitment, retention and follow-up of target populations),

immunodiagnostics, epidemiologic-based studies and biostatistics and data management. The technical personnel should have documented training and experience to perform the assays and laboratory procedures. The support staff should possess the requisite experience to perform their clerical and administrative duties.

TOTAL POSSIBLE POINTS..... 100

4. EVALUATION OF TARGETS FOR EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusion 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 (SDB) 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:

1) The extent of participation of SDB concerns in terms of the value of the total acquisition.

2) The complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.

TECHNICAL EVALUATION FACTORS FOR AWARD-PART B

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1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: Technical, Programmatic Balance, Cost/Price, and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, programmatic balance, cost/price, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

The need to create a balanced vaccine network, e.g. geographic considerations, disease patterns, population diversity, that can meet DMID priorities and fill gaps in vaccine development and clinical trials is critical, and will be considered in making awards.

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 carefully evaluated. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

This research project involves human subjects. NIH Policy requires that women and members of minority groups and their subpopulations and children must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification is provided with respect to the health of the subjects or the purpose of the research.

Where inclusion of women, minority populations, and/or children is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The NIAID will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research. If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions or include women, minorities and/or children in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

2. MANDATORY QUALIFICATION CRITERIA - NOT APPLICABLE

3. TECHNICAL EVALUATION CRITERIA - PART B

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

Criterion Element	Weight
B.1. TECHNICAL APPROACH.....	**60**

Documented technical adequacy and feasibility of the proposed description of capability to conduct human challenge studies of respiratory pathogens, and performance of assays and laboratory procedures. Adequacy, suitability and availability of necessary populations, and plans for their recruitment, retention and follow-up, as documented in the proposal.

a) Challenge Studies: Offeror must demonstrate expertise and experience in the conduct of respiratory challenge studies, handling of data and data analyses (including QA/QC), ability to perform assays on sera and other secretions/tissues, and for other relevant laboratory procedures. 30

b) Population: Offeror should demonstrate an ability to recruit, retain and follow subjects as inpatients. Strategies for subject recruitment and follow-up, medical management of subjects and plans to prevent environmental contamination and transmission of pathogens. 20

c) Administration : Proposed plans for managing the clinical and research activities to ensure a cooperative, integrated scientific effort. 10

B.2. FACILITIES AND RESOURCES..... 20

Offeror must demonstrate capability to provide adequate and suitable special isolation facilities, equipment and resources for the conduct of human challenge studies of respiratory pathogens, including a description of the facilities available, and a description of appropriate infection control procedures.

B.3. PERSONNEL..... 20

Documented adequacy and relevance of expertise, experience, education, and availability of personnel for performing all the requirements of the Statement of Work.

The PI should have an M.D. and/or Ph.D. degree, or equivalent, and should provide documented evidence of experience in the conduct of human challenge studies of respiratory pathogens in healthy adult populations. The team of professional personnel (including the nursing personnel) should have composite expertise in the conduct of challenge studies (including recruitment, retention and follow-up of target populations), infectious diseases, immunology, infection control, host response to pathogens and vaccines, and biostatistics and data management. The technical personnel should have documented training and experience to perform the assay and laboratory procedures. The support staff should possess the requisite experience to perform their clerical and administrative duties.

TOTAL POSSIBLE POINTS..... 100

4. EVALUATION OF TARGETS FOR EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusion 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 (SDB) 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:

1) The extent of participation of SDB concerns in terms of the value of the total acquisition.

2) The complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.

TECHNICAL EVALUATION FACTORS FOR AWARD-PART C

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1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: Technical, Programmatic Balance, Cost/Price, and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, programmatic balance, cost/price, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

The need to create a balanced vaccine network, e.g. geographic considerations, disease patterns, population diversity, that can meet DMID priorities and fill gaps in vaccine development and clinical trials is critical, and will be considered in making awards.

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 carefully evaluated. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

This research project involves human subjects. NIH Policy requires that women and members of minority groups and their subpopulations and children must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification is provided with respect to the health of the subjects or the purpose of the research.

Where inclusion of women, minority populations, and/or children is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The NIAID will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research. If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions or include women, minorities and/or children in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

2. MANDATORY QUALIFICATION CRITERIA - NOT APPLICABLE

3. TECHNICAL EVALUATION CRITERIA - PART C

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

Criterion Element	Weight
C.1. TECHNICAL APPROACH.....	**60**

Documented technical adequacy and feasibility of the description of capability to conduct human challenge studies of enteric pathogens, and performance of assays and laboratory procedures. Adequacy, suitability and availability of necessary populations, and plans for their recruitment, retention and follow-up, as documented in the proposal.

a) Challenge Studies: Offeror must demonstrate expertise and experience in the conduct of enteric challenge studies, handling of data and data analyses (including QA/QC), ability to perform assays on sera and other secretions/tissues, and for other relevant laboratory procedures. 30

b) Population: Offeror should demonstrate ability to recruit, retain and follow subjects as inpatients. Strategies for subject recruitment and follow-up, medical management of subjects and plans to prevent environmental contamination and transmission of pathogens. 20

c) Administration : Proposed plans for managing the clinical and research activities to ensure a cooperative, integrated scientific effort. 10

C.2. FACILITIES AND RESOURCES..... 20

Offeror must demonstrate capability to provide adequate and suitable special isolation facilities, equipment and resources for the conduct of human challenge studies of enteric pathogens, including a description of the facilities available, and a description of appropriate infection control procedures.

C.3. PERSONNEL..... 20

Documented adequacy and relevance of expertise, experience, education, and availability of personnel for performing all the requirements of the Statement of Work .

The PI should have an M.D. and/or Ph.D. degree, or equivalent, and should provide documented evidence of experience in the conduct of human challenge studies of enteric pathogens in adult populations. The team of professional personnel (including the nursing personnel) should have composite expertise in the conduct of challenge studies (including recruitment, retention and follow-up of target populations), infectious diseases, immunology, infection control, host response to pathogens and vaccines, and biostatistics and data management. The technical personnel should have documented training and experience to perform the assay and laboratory procedures. The support staff should possess the requisite experience to perform their clerical and administrative duties.

TOTAL POSSIBLE POINTS..... 100

4. EVALUATION OF TARGETS FOR EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusion 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 (SDB) 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:

1) The extent of participation of SDB concerns in terms of the value of the total acquisition.

2) The complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.

TECHNICAL EVALUATION FACTORS FOR AWARD-PART D

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1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: Technical, Programmatic Balance, Cost/Price, and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, programmatic balance, cost/price, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

The need to create a balanced vaccine network, e.g. geographic considerations, disease patterns, population diversity, that can meet DMID priorities and fill gaps in vaccine development and clinical trials is critical, and will be considered in making awards.

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 carefully evaluated. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

This research project involves human subjects. NIH Policy requires that women and members of minority groups and their subpopulations and children must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification is provided with respect to the health of the subjects or the purpose of the research.

Where inclusion of women, minority populations, and/or children is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The NIAID will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research. If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions or include women, minorities and/or children in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

2. MANDATORY QUALIFICATION CRITERIA - NOT APPLICABLE

3. TECHNICAL EVALUATION CRITERIA - PART D

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

Criterion Element	Weight
D.1. TECHNICAL APPROACH.....	**60**

Documented technical adequacy and feasibility of the proposed plans for a Phase I or Phase II trial of a Group B streptococcal vaccine in third trimester pregnant women, collection of human specimens, performance of assays and laboratory procedures, access to appropriate populations, and plans for their recruitment, retention and follow-up, including plans to follow-up current and subsequent offspring, as documented in the proposal.

a) Phase I or II trial in third trimester pregnant women: 30
This includes the methods and approaches, suitability and feasibility of the sample clinical protocol, appropriateness of consent forms, handling of data and data analyses (including data QA/QC plans), plans for obtaining specimens including cord bloods, plans for performing assays on sera, other body fluids and cord bloods, and for other relevant laboratory procedures including QA/QC, as required in the protocol and as requested in the Statement of Work. Offerors must provide documentation of experience in the conduct of clinical trials in pregnant women, including documentation of such experience from the institution's IRB.

b) Population: Offeror must demonstrate ability to recruit, 20
retain, and follow-up pregnant women and their offspring, as well as subsequent pregnancies and offspring. Strategies for follow-up of pregnant women, their offspring and subsequent pregnancies should be presented.

c) Administration : Proposed plans for managing the clinical and 10
research activities to ensure a cooperative, integrated scientific effort.

D.2. FACILITIES AND RESOURCES..... 10

Offeror must demonstrate capability to provide facilities and staff necessary to conduct prophylactic studies on candidate vaccines in pregnant women volunteers, as requested in the Statement of Work.

D.3. PERSONNEL..... 30

Documented adequacy and relevance of expertise, experience, education, and availability of personnel for performing all the requirements of the Statement of Work.

The PI should have an M.D. and/or Ph.D. degree, or equivalent, and should provide documented evidence of experience in clinical trials of vaccines in pregnant women. The team of professional personnel (including the nursing personnel) should have composite expertise in infectious diseases, immunology, obstetrics, pediatrics and/or family practice, clinical trials (including recruitment, retention and follow-up of target populations), and biostatistics and data management. The technical personnel should have documented training and experience to perform the assay and laboratory procedures. The support staff should possess the requisite experience to perform their clerical and administrative duties.

TOTAL POSSIBLE POINTS..... 100

4. EVALUATION OF TARGETS FOR EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusion 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 (SDB) 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:

1) The extent of participation of SDB concerns in terms of the value of the total acquisition.

2) The complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.

TECHNICAL EVALUATION FACTORS FOR AWARD-PART E

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1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: Technical, Programmatic Balance, Cost/Price, and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, programmatic balance, cost/price, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

The need to create a balanced vaccine network, e.g. geographic considerations, disease patterns, population diversity, that can meet DMID priorities and fill gaps in vaccine development and clinical trials is critical, and will be considered in making awards.

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 carefully evaluated. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

This research project involves human subjects. NIH Policy requires that women and members of minority groups and their subpopulations and children must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification is provided with respect to the health of the subjects or the purpose of the research.

Where inclusion of women, minority populations, and/or children is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The NIAID will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research. If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions or include women, minorities and/or children in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

2. MANDATORY QUALIFICATION CRITERIA - NOT APPLICABLE

3. TECHNICAL EVALUATION CRITERIA - PART E

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

Criterion Element	Weight
E.1. TECHNICAL APPROACH.....	**50**

Documented technical adequacy and feasibility of the proposed plans for the conduct of pre-clinical and clinical research activities designed to validate or lead to clinical studies. Documented understanding of disease pathogenesis and host immunity. Capability to perform assays and laboratory procedures. Adequacy, suitability and availability of animal or human specimens, where appropriate, as documented in the proposal.

a) Pre-Clinical Research Activities: This includes the methods and approaches for conduct of pre-clinical research, including the suitability and originality of the sample protocol, handling of data and data analyses (including data QA/QC plans), plans for performing or developing assays and for other relevant laboratory procedures including QA/QC. 20

b) Clinical Research Activities: This includes the methods and approaches for conduct of clinical research activities, including the suitability and originality of the sample protocol, appropriateness of populations and consent forms, handling of data (including data QA/QC plans), plans for performing assays on sera and other body fluids, and for other relevant laboratory procedures including QA/QC. 20

c) Administration : Proposed plans for managing the clinical and research activities to ensure a cooperative, integrated scientific effort. 10

E.2. FACILITIES AND RESOURCES..... 20

Offeror must demonstrate capability to provide facilities and staff necessary to conduct pre-clinical research activities designed to validate or lead to clinical studies, as requested in the Statement of Work.

E.3. PERSONNEL..... 30

Documented adequacy and relevance of expertise, experience, education, and availability of personnel for performing all the requirements of the Statement of Work.

The PI should have an M.D. and/or Ph.D. degree, or equivalent, and should provide documented evidence in the conduct of basic biology and immunology, as well as experience in clinical trials involving appropriate populations. The team of professional personnel (including the nursing personnel) should have composite expertise in infectious diseases, immunology, as well as clinical trials (including recruitment, retention and follow-up of target populations), immunodiagnostics, and biostatistics and data management. Expertise in other areas, such as cell biology, molecular biology and animal studies, should reflect the proposed research protocols. The technical personnel should have documented training and experience to perform the assays and laboratory procedures. The support staff should possess the requisite experience to perform their clerical and administrative duties.

TOTAL POSSIBLE POINTS..... 100

4. EVALUATION OF TARGETS FOR EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusion 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 (SDB) 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:

1) The extent of participation of SDB concerns in terms of the value of the total acquisition.

2) The complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.

TECHNICAL EVALUATION FACTORS FOR AWARD-PART F

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1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against four factors. The factors in order of importance are: Technical, Programmatic Balance, Cost/Price, and Small Disadvantaged Business (SDB) Participation. Although technical factors are of paramount consideration in the award of the contract, programmatic balance, cost/price, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

The need to create a balanced vaccine network, e.g. geographic considerations, disease patterns, population diversity, that can meet DMID priorities and fill gaps in vaccine development and clinical trials is critical, and will be considered in making awards.

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 carefully evaluated. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Offerors must submit information sufficient to evaluate their proposals based on the detailed criteria listed below.

This research project involves human subjects. NIH Policy requires that women and members of minority groups and their subpopulations and children must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification is provided with respect to the health of the subjects or the purpose of the research.

Where inclusion of women, minority populations, and/or children is not feasible, a detailed rationale and justification for exclusion of one or both groups from the study population must be submitted with the technical proposal. The NIAID will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research. If the rationale is not considered acceptable by the Government and you are included in the competitive range, you will be afforded the opportunity to further discuss and/or clarify your position during discussions or include women, minorities and/or children in your Final Proposal Revision (FPR). If your exclusion position is still considered unacceptable by the Government after discussions, your proposal may not be considered further for award.

2. MANDATORY QUALIFICATION CRITERIA - NOT APPLICABLE

3. EVALUATION OF OPTIONS

It is anticipated that any contract(s) awarded from this solicitation will contain option provision(s) and period(s).

In accordance with FAR Clause 52.217-5, Evaluation of Options, (July 1990), the Government will evaluate offers for award purposes by adding the total price for all options to the total price for the basic requirement, except when it is determined in accordance with FAR 17.206(b) not to be in the Government's best interests. Evaluation of options will not obligate the Government to exercise the option(s).

4. TECHNICAL EVALUATION CRITERIA - PART F

The evaluation criteria are used by the technical evaluation committee when reviewing the technical proposals. Proposals will be judged solely on the written material provided by the Offeror. The criteria below are listed in the order of relative importance with weights assigned for evaluation purposes.

Criterion Element	Weight
F.1. TECHNICAL APPROACH.....	**60**
Documented technical adequacy and feasibility of the description of capability to conduct experimental challenge studies of human volunteers with malaria parasites, and performance of assays and laboratory procedures. Documented technical adequacy and feasibility of proposed concept sheet. Documented availability of necessary population, and plans for their recruitment, retention and follow-up.	
a) Challenge Studies: Offeror must demonstrate expertise and experience in the conduct of experimental challenge studies of human volunteers with malaria parasites, handling of data and data analyses (including QA/QC), ability to perform assays on sera and other secretions/tissues, and for other relevant laboratory procedures.	30
b) Population: Offeror should demonstrate an ability to recruit, retain and follow subjects as inpatients and outpatients. Strategies for subject recruitment and follow-up, medical management of subjects and plans to prevent environmental contamination and transmission of pathogens.	20
c) Administration : Proposed plans for managing the clinical and research activities to ensure a cooperative, integrated scientific effort.	10
F.2. FACILITIES.....	**20**
Offeror must demonstrate capability to provide special isolation facilities for the conduct of experimental challenge studies of human volunteers with malaria parasites, including a description of the facilities available, and a description of infection control procedures. Offeror must demonstrate insectary capability to maintain appropriate mosquito species.	
F. 3. PERSONNEL.....	**20**
Documented adequacy and relevance of expertise, experience, education, and availability of personnel for performing all the requirements of the Statement of Work.	
The PI should have an M.D. and/or Ph.D. degree, or equivalent, and should provide documented evidence of experience in the conduct of experimental challenge studies of human volunteers with malaria parasites, in adult populations. The team of professional personnel (including the nursing personnel) should have composite expertise in the conduct of malaria studies, infectious diseases, immunology, infection control, host response to pathogens and vaccines and biostatistics. Professional personnel should have experience in the	

recruitment, retention and follow-up of target populations. The technical personnel should have documented training and experience to perform the assay and laboratory procedures. The support staff should possess the requisite experience to perform their clerical and administrative duties.

TOTAL POSSIBLE POINTS..... 100

5. EVALUATION OF TARGETS FOR EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

SDB participation will not be scored, but the Government's conclusion 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 (SDB) 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:

1) The extent of participation of SDB concerns in terms of the value of the total acquisition.

2) The complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the statement of work.

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

SECTION I. GENERAL CLAUSES

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

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

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Oct 1995	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures(Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes

52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications
52.216-7	Mar 2000	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Oct 2000	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
52.223-6	Jan 1997	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	Feb 2000	Buy American Act - Balance of Payments Program - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Jun 1997	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	Oct 1995	Penalties for Unallowable Costs (Over $500,000)

52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
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	Apr 1984	Definitions - Alternate I (Apr 1984)
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.232-9	Apr 1984	Withholding of Contract Payments
352.233-70	Apr 1984	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.270-5	Apr 1984	Key Personnel
352.270-6	Jul 1991	Publication and Publicity
352.270-7	Apr 1984	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT - Rev. 10/2000].

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

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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/.

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Oct 1995	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures(Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Government's 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), Alternate II (Apr 1998)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications
52.216-7	Mar 2000	Allowable Cost and Payment (Paragraph (a) is modified to delete the words "Subpart 31.2" and to add the words "Subpart 31.3")
52.216-11	Apr 1984	Cost Contract - No Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Oct 2000	Small Business Subcontracting Plan (Over $500,000)

52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
52.223-6	Jan 1997	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	Feb 2000	Buy American Act - Balance of Payments Program - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data - General, Alternate IV (Jun 1987)
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Jun 1997	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)
52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract), Alternate I (Jul 1985)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)

52.249-5	Sep 1996	Termination for the 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	Apr 1984	Definitions - Alternate I (Apr 1984)
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	Apr 1984	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH EDUCATIONAL INSTITUTIONS - Rev. 10/2000].

ARTICLE I.1. GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH NONPROFIT ORGANIZATIONS OTHER THAN EDUCATIONAL INSTITUTIONS - FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

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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/.

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Oct 1995	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Jul 1995	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures(Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.209-6	Jul 1995	Protecting the Government's 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), Alternate II (Apr 1998)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications
52.216-7	Mar 2000	Allowable Cost and Payment (Paragraph (a) is modified to delete the words "Subpart 31.2" and to add the words "Subpart 31.7")
52.216-11	Apr 1984	Cost Contract - No Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over $100,000)

52.219-9	Oct 2000	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Feb 1999	Equal Opportunity
52.222-35	Apr 1998	Affirmative Action for Disabled Veterans and Veterans of the Vietnam Era
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Jan 1999	Employment Reports on Disabled Veterans and Veterans of the Vietnam Era
52.223-6	Jan 1997	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	Feb 2000	Buy American Act - Balance of Payments Program - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data - General
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Jun 1997	Prompt Payment
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	Dec 1998	Disputes
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	Oct 1995	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Aug 1998	Subcontracts, Alternate II (Aug 1998) *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (Over $100,000)

52.245-5	Jan 1986	Government Property (Cost-Reimbursement, Time and Material, or Labor-Hour Contract), Alternate I (Jul 1985)
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.249-5	Sep 1996	Termination for the 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

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352.270-6	Jul 1991	Publication and Publicity
352.270-7	Apr 1984	Paperwork Reduction Act

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT CONTRACT WITH NONPROFIT ORGANIZATIONS OTHER THAN EDUCATION INSTITUTIONS - Rev. 10/2000].

SECTON J
LIST OF ATTACHMENTS

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

- Packaging and Delivery of Proposals
- Proposal Intent Response Sheet ***Submit on/before: February 9, 2001 at 4:00 P.M. EST***

  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.

- How to Prepare and Submit an Electronic Proposal

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 - 1

Applicable to Technical Proposal

- **Technical Proposal Cover Sheet**
- **Technical Proposal Cost Summary**
- **Summary of Related Activities**
- **Optional Form 310, Protection of Human Subjects Assurance Identification/Certification/Declaration** *[When applicable, all institutions must have the form reviewed and approved by their Institutional Review Committee.]*
- **Government Notice for Handling Proposals**

Applicable to Business Proposal

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

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

- **Annual Technical Progress Report Format for Each Study** *[Applicable when contract involves Human Subjects unless it has been determined by the Government that the inclusion of Women and Minority Groups in the Study Population is not appropriate.]*
- **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**
- **Procurement of Certain Equipment, NIH(RC)-7 (OMB Bulletin 81-16)**
- **NIH(RC)-11: Research Patient Care Costs**
- **NIH-2706: Financial Report of Individual Project Contract**
- **Instructions for Completing Form NIH-2706**
- **Privacy Act System of Records, #09-25-0200**
- **Safety and Health (Deviation), PHS Clause 352.223-70**

PROPOSAL INTENT RESPONSE SHEET

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RFP No.: NIH-NIAID-DMID 02-01
RFP Title: Evaluation of Control Measures Against Diseases Other than AIDS.

Please review the attached Request for Proposal. Furnish the information requested below and return this page by February 9, 2001. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

Since your proposal will be submitted electronically, please include the name and e-mail of the individual to whom the electronic proposal instructions, login code, and password should be provided.

[ ] DO INTEND TO SUBMIT A PROPOSAL
[ ] DO NOT INTEND TO SUBMIT A PROPOSAL FOR THE FOLLOWING REASONS:

Company/Institution Name (print): _____
Address (print): _____
_____
_____
_____

Project Director's Name (print): _____
Title (print): _____
Signature/Date: _____
Telephone Number and E-mail Address (print clearly):
_____
_____

***Name of individual to whom electronic proposal instructions should be sent:**

Name: _____
Title: _____
E-Mail Address: _____
Telephone Number: _____

Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):
_____
_____
_____
_____
(Continue list on a separate page if necessary)

RETURN VIA FAX OR E-MAIL TO:
CMB, NIAID, NIH
Room 2230
6700-B Rockledge Drive, MSC 7612
Bethesda, MD 20892-7612
Attn: Lawrence M. Butler
RFP-NIH-NIAID-DMID-02-01
FAX# (301) 402-0972
Email : lb13t@nih.gov

PACKAGING AND DELIVERY OF THE PROPOSAL

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[Note to Offeror: Listed below are delivery instructions for the submission of the PAPER copies of your proposal. An electronic copy of your proposal with the original proposal on a diskette, CD-Rom or ZipDisk, will also be required from only those offerors who receive contract awards.]

Shipment and marking 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-02-01
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 30 unbound copies, including appendices **(CURRICULUM VITAES (CVS) IN A MAXIMUM OF 3 PAGES PER STAFF PERSON AND UP TO A TOTAL OF 10 REPRINTS FOR THE ENTIRE PROPOSAL [ALL PARTS A-F]).**

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

C. PAPER COPIES TO:

If hand delivery or express service	*If using U.S. Postal Service*
Lawrence M. Butler Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Lawrence M. Butler Contract Specialist Contract Management Branch, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

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

NOTE: The U.S. Postal Service's "Express Mail" does not deliver to the hand delivered (20817 zip code) address. Any package sent to this address via this service will be held at a local post office for pick-up. THE GOVERNMENT IS NOT RESPONSIBLE FOR PICKING UP ANY MAIL AT A LOCAL POST OFFICE. If a proposal is not received at the place, date, and time specified herein, it will be considered a "late proposal," in accordance with PHSAR 352.215-10, Late Proposals, Modifications of Proposals and Withdrawals of Proposals (NOV 1986).

SECTION K

REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

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

1. REPRESENTATIONS AND CERTIFICATIONS

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

http://rcb.nci.nih.gov/forms/rcneg.pdf

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

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE THE REPRESENTATIONS AND CERTIFICATIONS AND SUBMIT THEM AS PART OF YOUR BUSINESS PROPOSAL.

SECTION L
INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

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1. GENERAL INFORMATION

a. **INSTRUCTIONS TO OFFERORS--COMPETITIVE ACQUISITION** [FAR Clause 52.215-1 (February 2000)]

(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" or "written" means any worded or numbered expression, which 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;
  (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).

(e) Restriction on disclosure and use of data. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall--

(1) Mark the title page with the following legend:

This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed--in whole or in part--for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of--or in connection with--the submission of this data, the Government shall have the right to

duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [*insert numbers or other identification of sheets*]; and

(2) Mark each sheet of data it wishes to restrict with the following legend:

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

(f) Contract award.

(1) The Government reserves the right 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) The Government may disclose the following information in post award debriefings to other offerors:

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

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

(f) (4) The Government intends to evaluate proposals and award a contract after conducting discussions with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the

most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

b. **NAICS CODE AND SIZE STANDARD**

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

(1) The North American Industry Classification System (NAICS) code for this acquisition is 541710.

(2) The small business size standard is 500 employees.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in EVERY solicitation, (except for foreign acquisitions) the inclusion of the 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 awards will be made on/about April 1, 2002.

It is anticipated that the awards from this solicitation will be multiple-year COST REIMBURSEMENT type COMPLETION contracts with a PERIOD OF PERFORMANCE OF 5 Years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

e. **ESTIMATE OF EFFORT**

It is expected that completion type contracts will be awarded as a result of this RFP. To assist you in the preparation of your proposal, the Government considers the total 5-year effort to be approximately 248,560 labor hours. This information is furnished for the offeror's information only and is not to be considered restrictive for proposal purposes.

f. **COMMITMENT OF PUBLIC FUNDS**

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

g. **COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

h. **RELEASE OF INFORMATION**

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

i. **COMPARATIVE IMPORTANCE OF PROPOSALS**

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

j. **PREPARATION COSTS**

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

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

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

Brenda J. Velez
Chief, Contract Management Branch
National Institutes of Allergies and Infectious Diseases
6700 B Rockledge Dr., Room 2230 MSC 7612
BETHESDA MD 20892-7612

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

(End of Provision)

l. **LATE PROPOSALS, MODIFICATIONS OF PROPOSAL, AND WITHDRAWALS OF PROPOSALS, PHS 352.215-10**

Notwithstanding the procedures contained in the provision of this solicitation entitled Late Submissions, Modifications, and Withdrawals of Proposals, 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)

2. INSTRUCTIONS TO OFFERORS

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a. GENERAL INSTRUCTIONS

INTRODUCTION

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

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

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

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

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

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

It is recommended that the technical proposal consist of a cover page, a table of contents, and the information requested in the Technical Proposal Instructions.

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.

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

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

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

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

(5) **Alternate Proposals**

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

(6) **Confidentiality of Proposals --HHSAR 352.215-12, Restriction on Disclosure and Use of Data (April 1984)**

The proposal submitted in response to this request for proposals 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:

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 the 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)

In addition, the offeror should mark each page of data it wishes to restrict with the following legend:

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

NOTE: Offerors are cautioned that proposals submitted with the 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.

(7) **Evaluation of Proposals**

The Government will evaluate technical proposals in accordance with the criteria set forth in the Technical Evaluation Factors for Award.

(8) **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.

(9) **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 procurement, 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.

(10) **Human Subjects**

The following notice is applicable when contract performance is expected to involve risk to human subjects:

Notice to Offerors of Requirements of 45 CFR Part 46, Protection of Human Subjects (SEPTEMBER 1985)

a) Copies of the Department of Health and Human Services (Department) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protection (OHRP), Department of Health and Human Services [http://ohrp.osophs.dhhs.gov/index.htm]. The regulations provide a systematic means, based on established ethical principles, to safeguard the rights and welfare of individuals who participate as subjects in research activities supported or conducted by the Department.

b) The regulations define a human subject as a living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written or recorded information derived from individually identifiable human subjects. The use of autopsy materials is governed by applicable State and local law and is not directly regulated by 45 CFR, Part 46.

c) Activities in which the only involvement of human subjects will be in one or more of the categories set forth in 45 CFR 46.101(b)(1-6) are exempt from coverage.

d) Inappropriate designations of the noninvolvement of human subjects or of exempt categories of research in a project may result in delays in the review of a proposal. The Public Health Service will make a final determination of whether the proposed activities are covered by the regulations or are in an exempt category, based on the information provided in the proposal. In doubtful cases, prior consideration with OHRP, is recommended.

e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. Prospective Contractors proposing research that involves human subjects shall be contacted by OHRP and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.

f) It is recommended that OHRP be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects.

(11) **Required Education in the Protection of Human Research Participants**

NIH policy requires education on the protection of human subject participants for all investigators submitting NIH proposals for contracts for research involving human subjects. This policy announcement is found in the NIH Guide for

Grants and Contracts Announcement dated June 5, 2000 at the following website: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html. Offerors should review the policy announcement prior to submission of their offers. The following is a summary of the Policy Announcement:

For any solicitation for research involving human subjects, the offeror shall provide in its technical proposal the following information: (1) a list of the names of the principal investigator and any other individuals proposed under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program completed (or to be completed prior to the award of the contract) for each named personnel; (3) a one sentence description of the program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Curricula that are readily available and meet the educational requirement include the NIH on-line tutorial, titled "Protection of Human Research Subjects: Computer-Based Training for Researchers," available at http://ohsr.od.nih.gov/cbt/. This site may be downloaded at no cost and modified for use by the offeror, if desired. In addition, the University of Rochester has made available its training program for individual investigators, and completion of this program will also satisfy the educational requirement. The University of Rochester manual can be obtained through Centerwatch, Inc. at http://www.centerwatch.com/order/pubs_profs_protect.html. If an institution has already developed educational programs on the protection of research participants, completion of these programs will also satisfy the educational requirement.

In addition, prior to the substitution of the principal investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the contractor shall provide the following written information to the contracting officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

(12) **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is the policy of the NIH that women and members of minority groups and their subpopulations must be included in all NIH supported biomedical and behavioral research projects involving human subjects, unless a clear and compelling rationale and justification is provided that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. This new policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43) and supersedes and strengthens the previous policies (Concerning the Inclusion of Women in Study Populations, and Concerning the Inclusion of Minorities in Study Populations), which have been in effect since 1990. The new policy contains some new provisions that are substantially different from the 1990 policies.

All investigators proposing research involving human subjects should read the "NIH Guidelines For Inclusion of Women and Minorities as Subjects in Clinical Research" which have been published in the Federal Register of March 28, 1994 (FR 59 14508-14513), [(this was reprinted to correct typesetting errors from Federal Register dated March 9, 1994 (FR 59 11146-11151)], and reprinted in the NIH GUIDE FOR GRANTS AND CONTRACTS of March 18, 1994, Volume 23, Number 11.

Offerors may obtain copies from these sources or from the contact person listed in the RFP.

Unless otherwise specified in this solicitation, the Government has determined that the work set forth herein does not involve a gender specific study or a single or limited number of minority population groups. Therefore, the Institute believes that the inclusion of women and minority populations is appropriate for this project.

The format for the Annual Technical Progress Report for Clinical Research Study Populations (See LIST OF ATTACHMENTS of this RFP) shall be used in proposal preparation.

(13) **Inclusion of Children in Research Involving Human Subjects**

It is NIH policy that children (defined below) must be included in all human subjects research, including, but not limited to, clinical trials, conducted under a contract funded by the NIH, unless there are scientific or ethical reasons not to include them. For the purposes of this policy, contracts involving human subjects include categories that would otherwise be exempt from the DHHS Policy for Protection of Human Research Subjects (sections 101(b) and 401(b) of 45 CFR 46), such as surveys, evaluation of educational interventions, and studies of existing data or specimens that should include children as participants. This policy applies to both domestic and foreign research contracts.

For purposes of this policy, a child is defined as an individual under the age of 21 years.

Inclusion of children as participants in research must be in compliance with all applicable subparts of 45 CFR 46 as well as other pertinent laws and regulations whether or not such research is otherwise exempted from 45 CFR 46. Therefore, any proposals must include a description of plans for including children, unless the offeror presents clear and convincing justification for an exclusion. In the technical proposal, the offeror should create a section titled "Participation of Children." This section should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. The RFP will contain a review criterion addressing the adequacy of plans for including children as appropriate for the scientific goals of the research, or justification of exclusion.

All investigators proposing research involving human subjects should read the "NIH Policy and Guidelines on the Inclusion of Children as Participants in Research Involving Human Subjects" which was published in the NIH Guide for Grants and Contracts on March 6, 1998 and is available at the following URL address:

http://www.nih.gov/grants/guide/notice-files/not98-024.html

Offerors may also obtain copies from the contact person listed in the RFP.

(14) **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.

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

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 for Protection from Research Risks (OPRR), 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 OPRR. 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 OPRR, OLAW, negotiate an acceptable Animal Welfare Assurance with those Contractor(s). For further information, OPRR, 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.

(16) **Privacy Act**

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.

(17) **Selection of Offerors**

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

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

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

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

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

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

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

While it is the 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 limited negotiations after Final Proposal Revisions (FPRs) in accordance with HHSAR 315.670.

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

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

(18) **Small Business Subcontracting Plan**

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

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

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

c) The offeror understands that:

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

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

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

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

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

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

d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, small

disadvantaged, women-owned, and HUBZone small business concerns as subcontractors.

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

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

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

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

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

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

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

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

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

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

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

(19) **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.

(20) **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 Major Groups 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 **Technical Evaluation Criteria**, 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 Major Groups, as contained in the Standard Industrial Classification (NAICS) Manual, and region, if any, the authorized SDB procurement mechanisms and applicable factors (percentages). The NAICS codes can be found at: http://www.census.gov/epcd/www/naicstab.htm

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

Offerors shall include with their offers, SDB targets, expressed as dollars and percentages of total contract value, in each of the applicable, authorized NAICS Major Group(s). **The applicable authorized NAICS Major Group(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 Major Group 87

	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.

(21) **Salary Rate Limitation in Fiscal Year 2000**

Offerors are advised that pursuant to P.L. 106-113, no NIH Fiscal Year 2000 (October 1, 1999 - September 30, 2000) 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 II* (direct salary is exclusive of Overhead, Fringe Benefits and General and Administrative expenses). 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 II*. The salary rate limitation set by P.L. 106-113 applies only to Fiscal Year 2000 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 II* annual salary rate limit also applies to individuals proposed under subcontracts. P.L. 106-113 states in pertinent part:

"None of the funds appropriated in this Act for the National Institutes of Health and the Substance Abuse, and Mental Health Services Administration shall be used to pay the salary of an individual

through a grant or extramural mechanism at a rate in excess of Executive Level II."

***This rate may change periodically. For your information, the rate can be found at: http://www.opm.gov/oca/2000tbls/Execses/html/execschd.htm**

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

EACH INSTITUTION MUST:

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

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

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

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

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

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

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

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

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

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

4) the Institution will otherwise comply with the regulations.

Institutional Management of Conflicting Interests

(a) The designated official(s) must: (1) review all financial disclosures; and (2) determine whether conflict of interest exists, and if so, determine what actions should be taken by the Institution to manage, reduce or eliminate such

conflict of interest. **A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the NIH-funded research**.

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

(i) public disclosure of significant financial interests;
(ii) monitoring of research by independent reviewers;
(iii) modification of the research plan;
(iv) disqualification of the Investigator(s) from participation in all or a portion of the research funded by the awarding component;
(v) divestiture of significant financial interests; or
(vi) severance of relationships that create actual or potential conflicts of interests.

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

(23) **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.

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

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

a) Submission of Offers in the English Language, FAR Clause 52.214-34, (April 1991).
b) Submission of Offers in U.S. Currency, FAR Clause 52.214-35, (April 1991).
c) Facsimile Proposals, FAR Clause 52.215-5, (October 1997)
d) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
e) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
f) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), FAR Clause 52.222-24, (February 1999).

b. TECHNICAL PROPOSAL INSTRUCTIONS

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

(1) **Technical Discussions**

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

a) **Statement of Work**

(1) Objectives

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

(2) Approach

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

(3) Methods

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

(4) Schedule

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

b) **Personnel**

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

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

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

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

(4) Resumes

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

(2) **Technical Evaluation**

Proposals will be technically evaluated in accordance with the factors, weights, and order of relative importance as described in the TECHNICAL EVALUATION FACTORS FOR AWARD.

(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.

(5) **Information Technology Systems Security**

If this project involves Information Technology, the proposal must present a detailed outline of its proposed Information Technology systems security program which complies with the requirements of the Statement of Work, the Computer Security Act of 1987 Office of Management and Budget (OMB) Circular A-130, Appendix III, "Security of Federal Automated Information Systems," and the DHHS Automated Information Systems Security Program Handbook (Release 2.0, dated May, 1994). The proposal will also need to include similar information for any subcontract proposed.

NOTE: OMB A-130 is accessible via web site: http://www.whitehouse.gov/WH/EOP/OMB/html/circular.html

a. BUSINESS PROPOSAL INSTRUCTIONS

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(1) Basic Cost/Price Information

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

(2) Proposal Cover Sheet

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

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

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

b) The information submitted shall be at the level of detail described below.

1. **Direct Labor**

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

2. **Materials**

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

3. **Subcontracted Items**

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

4. **Raw Materials**

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

5. **Purchased Parts**

Includes material items not covered above. Provide priced quantities of items required for the proposal.

6. **Fringe Benefits**

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

7. **Indirect Costs**

Indicate how offeror has computed and applied offeror's indirect costs, including cost breakdowns, and provide a basis for evaluating the reasonableness of proposed rates. Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

8. **Special Equipment**

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

9. **Travel**

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

10. **Other Costs**

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

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

(3) **Qualifications of the Offeror**

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

(1) **General Experience**

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

(2) **Organizational Experience Related to the RFP**

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

(3) **Performance History**

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

(4) **Pertinent Contracts**

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

(5) **Pertinent Grants**

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

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

(4) **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, "Contractor's Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

b) **Royalties**

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

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

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

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

d) **Financial Capacity**

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

e) **Incremental Funding**

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

> Sufficient funds are not presently available to cover the total cost of the complete multiple year project described in this solicitation. However, 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 that clause, which will be included in the resultant contract, initial funds will be obligated under the contract to cover an initial period of performance. Additional funds are intended to be allotted from time to time, 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.

The "Limitation of Funds" clause to be included in the resultant contract shall supersede the "Limitation of Cost" clause found in the General Clauses.

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

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

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

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

(End of Provision)

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

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

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

(5) **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.

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

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

(7) **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.

(8) **Travel Costs/Travel Policy**

a) **Travel Costs - Commercial**

In accordance with Title II, section 201 of the Federal Civilian Employee and Contractor Travel Expense Act of 1985 (Public Law 99-234), 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

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