



## Electronic Request for Proposal

### SECTION A – SOLICITATION/CONTRACT FORM

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

<b>Purchase Authority: Public Law 92-218, as amended.</b> <b>NOTE: The issuance of this solicitation does not commit the government to an award.</b>			
<b>RFP Number:</b>  NIH-NIAID-DMID-04-49	<b>Just In Time:</b>  <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Small Bus. Set-Aside <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No 8(a) Set-Aside <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No NAICS Code: none Size Standard: none	<b>Level of Effort:</b> <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No <b>Total Effort:</b> <input type="checkbox"/> N/A
<b>TITLE:</b> Production and Testing of a Modified Vaccinia Ankara (MVA) Vaccine			
<b>Issue Date:</b> December 4, 2003	<b>Due Date:</b> February 4, 2004 <b>Time:</b> 4:00 PM, EST	<b>Technical Proposal Page Limits:</b> <input type="checkbox"/> Yes (see "How to Prepare and Submit Electronic Proposals") <input checked="" type="checkbox"/> No	
<b>ISSUED BY:</b> Jacqueline C. Holden Senior Contracting Officer Contract Management Program, DEA NIH, NIAID 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, MD 20892-7612	<input checked="" type="checkbox"/> <i>We reserve the right to make awards without discussion.</i>		
	<b>NO. OF AWARDS:</b>  <input type="checkbox"/> Only 1 Award <input checked="" type="checkbox"/> Multiple Awards	<b>PERIOD OF PERFORMANCE:</b>  3 years beginning on or about 07/30/2004	
Offers will be valid for 120 days unless a different period is specified by the Offeror on the form entitled "Proposal Summary and Data Record, NIH-2043" (See SECTION J - Attachments)			
The Official Point of Receipt for the purpose of determining timely delivery is the Contract Management Branch as stated above. The paper copy with original signatures is the official copy for recording timely receipt. If the paper copy of your proposal is not received by the Contracting Officer or Designee at the place and time specified, then it will be considered late and handled in accordance with HHSAR 352.215-70 entitled "Late Proposals and Revisions" located in this Solicitation. FACSIMILE SUBMISSION OF PROPOSALS IS NOT ACCEPTABLE.			
<b>POINT OF CONTACT -- Brenda Brooks --COLLECT CALLS WILL NOT BE ACCEPTED--</b>			
<b>Telephone: Direct</b> 301-435-2765 <b>Main</b> 301-496-0612	<b>Fax</b> 301-402-0972	<b>E-Mail</b> <a href="mailto:bbrooks@niaid.nih.gov">bbrooks@niaid.nih.gov</a>	

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## INTRODUCTION AND BACKGROUND

### **Production and Testing of a Modified Vaccinia Ankara (MVA) Vaccine RFP-NIH-NIAID-DMID-04-49**

#### **Introduction**

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

The events of the past two years have significantly changed the world's perception of the nature and degree of the threats posed by the use of infectious agents as weapons of bioterrorism. The risk of using such weapons once appeared to be restricted to military encounters. However, the deliberate exposure of postal workers, other government employees and the American public at large to *Bacillus anthracis* spores highlighted the need to devise appropriate and effective measures to protect all U.S. citizens from the harmful effects of those biologic agents of most concern.

#### **Background**

Variola virus, the etiological agent of smallpox, is considered to have been one the greatest scourges on human health. The mortality rate of smallpox infection is approximately 30%, and individuals who recover from the infection frequently have disfiguring scars. It has been estimated that throughout recorded history more people died of smallpox than from all other infectious diseases combined. Fortunately, vaccination with a related, live, replicating, attenuated Orthopoxvirus (vaccinia virus) eventually led to the global eradication of this disease in 1979. Routine vaccination was halted shortly thereafter because the risks associated with vaccination outweighed the threat of the disease. Recent knowledge on the possible weaponization and availability of smallpox stocks to rogue nations has increased concern about the reemergence of this dreadful disease. As a result of this assessment, the U.S. Government is procuring enough replication-competent smallpox vaccine and bifurcated needles for every U.S. citizen.

Although the replicating smallpox vaccine (Dryvax<sup>®</sup>) presently employed to vaccinate U.S. military and first response personnel is highly efficacious, it is associated with significant local and/or systemic reactions in over 90% of vaccinees. Common mild side effects include redness and swelling at the site of vaccination, fever, and myalgia. Although rare in healthy individuals, more serious side effects include post-vaccinal encephalitis, eczema vaccinatum, disseminated vaccinia and death. The number of U.S. citizens at risk for these rare events has increased over the years due to: 1) life-saving drugs and medical procedures which compromise the immune system such as those drugs administered following organ transplant and, 2) the increased number of individuals infected with HIV. Concerns have also been raised over the possible association of vaccinia virus with angina, myo/pericarditis, ischemic heart disease and myocardial infarction. These facts have raised concerns about vaccinating every U.S. citizen with live, replicating vaccinia vaccine. Dryvax is presently contraindicated in individuals with a history of atopic dermatitis, eczema, heart disease, immunodeficiency, autoimmunity, or who are pregnant or lactating. It is also contraindicated to all who have close household contact with individuals who are immunocompromised, pregnant, or have a history of dermal disease. As of June 20, 2003, only 37,802 civilians, out of the 450,000 first-responders originally anticipated, had been vaccinated. The need for a safer smallpox vaccine is self-evident.

Modified vaccinia virus Ankara (MVA), a live, non-replicating form of vaccinia virus, was developed in Germany during the smallpox eradication period (1964-1970) as a "pre-vaccine" that was administered by intradermal injection followed by scarification with Lister-Elstree one to two weeks later. The goal of the combined vaccination was to induce immunity with MVA that would subsequently reduce the reaction to the replicating vaccine. While this dual vaccination strategy was tested in over 150,000 individuals (many of whom were at risk for vaccination with the replicating vaccine) with no adverse events, it was never tested for efficacy in preventing smallpox in endemic areas. MVA was derived from a more virulent form of a smallpox vaccine termed CVA by >500 serial passages in primary chick embryo fibroblasts (CEF). As a result of continuous passage *in vitro*, the viral genome suffered six major deletions and numerous mutations; of importance, MVA is missing at least two host range genes required for growth in mammalian cells, and several genes essential for viral immune evasion. MVA is incapable of amplification in human cells, and data suggest it can safely be administered to newborn mice, rabbits, chickens and immunosuppressed primates. MVA has been shown to protect nonhuman primates against challenge from monkeypox virus and variola virus, and more recently has been used safely as a gene delivery vector for HIV and cancer vaccines.

In February 2003, two contracts were awarded by NIAID as a result of RFP-NIH-NIAID-DMID-03-44. The main objectives of this solicitation were to: (a) produce 5,000 doses of MVA vaccine under manufacturing conditions that would enable the government to file an Investigational New Drug (IND) application for this product, (b) assess the immunogenicity and protection against lethal Orthopoxvirus challenge provided by MVA in small animal models, (c) develop a Clinical Plan for MVA and initiate a Phase I clinical trial, and (d) develop a feasibility plan to manufacture, formulate, fill, test and deliver up to 30 million doses of MVA vaccine for the U.S. Government.

### **Objectives**

The primary purpose of this RFP (NIH-NIAID-DMID-004-49) is to continue advanced development and manufacture of an MVA vaccine. It is intended to target MVA vaccine candidates that can be produced at a scale to support commercial manufacturing, and that have demonstrated safety and immunogenicity in extensive preclinical studies. Although licensure of an MVA vaccine is not planned within the timeframe of this RFP, all activities and studies conducted in response to this RFP shall be those required for a licensure path.

This advanced vaccine research and development effort is milestone-driven and funding is expected to occur in phases. Periodic assessments of progress will be conducted by NIAID (*See Notes to Offerors #5 and #9*). Continuation of effort on initial and subsequent milestones and associated funding will be based on contractor performance, timeliness and quality of deliverables, and consultations between the contractor, NIAID staff, interagency working group members, and a Blue Ribbon Panel if one is appointed by NIAID.

Data provided in support of the proposed vaccine candidate will be based on a vaccine and manufacturing process that approximates the final product and process to be licensed. Either preclinical and/or clinical studies may be necessary to bridge between product manufactured at pilot lot and intermediate scales. Due to associated time and risk considerations, studies to bridge between products that are different, or that are produced by different manufacturing schemes, will not be acceptable unless adequate data are presented in the proposal to confirm that milestones and deliverables contained in this RFP can be met.

In addition, it is deemed critical that the offerors understand that the NIAID, on behalf of the U.S. Government, is committed to furthering the database on MVA vaccines in order to facilitate their use in protecting the public. This NIAID MVA vaccine development effort continues an advanced research and development program intended to generate data that will provide the U.S. Government with critical information regarding future procurement of MVA vaccine for the National Strategic Stockpile. Funding advanced development of more than one vaccine candidate should facilitate the process of gathering essential data. Developing multiple MVA vaccine candidates will also help insure a successful outcome by reducing the risk inherent in a contract effort based on a single vendor. Based on the fact that more than one candidate vaccine will be developed, it is the responsibility of the NIAID to compare their immunogenicity and efficacy. Accordingly, it should be expected that during the course of this contract the NIAID will directly fund, under another contract, animal immunogenicity and efficacy studies that will compare the candidate vaccines. The design of the essential animal challenge studies will be recommended and coordinated through the MVA Interagency Working Group, which includes representation from the NIH, Center for Biologics Evaluation and Research (CBER), United States Army Medical Research Institute of Infectious Diseases (USAMRIID) and Centers for Disease Control and Prevention (CDC). In addition to conducting its own animal studies, the NIAID is expecting to perform independent clinical studies that will compare the immunogenicity, reactogenicity, and preferred route of administration of candidate vaccines.

Participation in NIAID's initial RFP (NIH-NIAID-DMID-03-44) is not a pre-requisite for participation in this RFP.

### **Awards**

It is anticipated that one or more completion type contract(s) will be awarded under this RFP. Each contract will manufacture, fill, finish, and release 3 million doses of MVA from at least three cGMP consistency lots within the first two years of award. The vaccine shall be of a quality suitable for a path to licensure in the U.S. The third year of the contract will allow for preclinical study and clinical trial follow-up, maintenance and storage of the vaccine inventory, stability testing, etc. As such, the budget for third year efforts will represent a small portion of the total budget proposed.

Dryvax<sup>®</sup> is a registered trademark of Wyeth.

## STATEMENT OF WORK

### **Production and Testing of a Modified Vaccinia Ankara (MVA) Vaccine RFP-NIH-NIAID-DMID-04-49**

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

See Notes #4 and #12 to Offerors.

**Milestones:** Consistent with the urgent requirements of this RFP, the Contractor shall submit and execute a plan to accomplish the following milestones. Unless otherwise agreed, all milestones will conclude with delivery of a final milestone report to the NIAID.

See Notes #1, #3, #6 and #7 to Offerors.

1. **Milestone 1—Product Development Plan:** Within 2 months of contract award submit a Product Development Plan (PDP) that is integrated with the quality, testing, and regulatory plans. Activities in this plan, for both the Active Pharmaceutical Ingredient (API) and final dosage form, shall focus on the following: (a) development, scale-up and validation of the manufacturing processes; (b) development optimization, and qualification/validation of the test methods necessary for product characterization, release testing, stability testing, and potency evaluation; and (c) stability studies for each formulation and container/closure. The PDP shall include all planned development activities including GMP as well as non-GMP studies. Timing of these activities relative to the manufacture of 3 million doses of MVA vaccine, as well as ultimate FDA licensure of the product (although not a requirement of this RFP), should be stated. Development, validation and stability programs must comply with current regulations and relevant FDA and ICG guidance documents.

See Note #2 to Offerors.

The NIAID is requesting that the API be at a concentration of  $1 \times 10^8$  TCID<sub>50</sub> per dose, and the final dosage form be in a liquid formulation.

See Notes #15 and #16 to Offerors.

2. **Milestone 2—Quality Systems Plan:** Within 3 months of contract award submit a Quality Systems Plan (QSP) that is integrated with the manufacturing, testing and regulatory plans. Activities in this plan shall focus on cGMP compliance for the production and release of both the Active Pharmaceutical Ingredient (API) and the 3 million doses of MVA. It shall include appropriate documentation of cells and/or cell banks used, change control, document control, environmental and utility monitoring, laboratory controls, maintenance and calibration, materials management (including shipping), Quality management, equipment qualification, computer validation, cleaning validation, production records (including deviations), laboratory records (including out of specifications results), and training. Quality systems must comply with current regulations and relevant FDA and ICH guidance documents.
3. **Milestone 3—Clinical Testing Plan:** Within 4 months of contract award submit a Clinical Testing Plan (CTP) to licensure that is integrated with the animal testing, manufacturing and regulatory plans using the most current and available information including consultation with DMID, CBER and other experts in the field. Clinical trial activities performed as a result of this solicitation shall include: (a) a dose-response trial in healthy adult populations (male and female) which are vaccinia naïve and previously vaccinated against smallpox, (b) a safety and immunogenicity trial with a fixed effective dose of MVA as determined in the dose-response trial, (c) a safety and immunogenicity trial in subjects with diagnosed atopic dermatitis, and (d) a safety and immunogenicity trial in subjects with HIV infection. At least one study shall include a healthy cohort(s) that may be followed for at least two years. Unless otherwise specified, all MVA vaccinations shall be administered via the subcutaneous route. Alternative routes of vaccine delivery will be studied by the DMID during the course of this contract. Although Phase III trials are not a requirement of this RFP, the CTP shall include future plans for these studies.

It is recommended that the dose-response clinical trial be initiated as soon as possible. It is also expected that the Contractor shall provide the NIAID with all relevant information and/or the ability to cross-reference an IND in order to support NIAID filing a U.S. Government held IND. To facilitate rapid product development, the Contractor shall

provide NIAID with copies of all communications with FDA, and include NIAID staff in conference calls with the FDA. For information regarding the filing of an IND see <http://www.fda.gov/cber/ind/ind.htm>.

Standardized protocols, characterized reagents, and validated assays shall be used in all human trials. DMID will facilitate attaining necessary resources to ensure that immunological assays of samples obtained from all clinical trials are evaluated using standardized validated assays. The CTP shall include arrangements for delivery of clinical trial samples to the DMID and/or its designee(s).

4. **Milestone 4—Animal Testing Plan:** Within 5 months of contract award, submit an Animal Testing Plan (ATP) to vaccine licensure that is directed towards meeting the requirements of 21 CFR 601.91 (FDA Animal Rule) and that is integrated with the clinical testing, manufacturing and regulatory plans using the most current and available information derived from consultations with DMID, CBER, and other experts in the field. The ATP shall: a) be such that efforts and budget for all animal studies are “front-loaded” so that the maximum amount of data are acquired within the first two years of the contract; b) include a description of the animal experiments (supporting and pivotal) that will be conducted to study immunogenicity and efficacy, and ultimately support licensure under 21 CFR 601.91; and c) include a description of the assays (including a plan for validation) that will be used to study both humoral and cell-mediated immunity.

The following is a list of points to consider in preparing the ATP: a) an appropriate animal model is chosen that will provide data of sufficient statistical significance or greater to support licensure under 21 CFR 601.91; b) a murine model is selected that demonstrates protection against a lethal aerosol challenge by ectromelia virus; c) a nonhuman primate model is utilized that is suitable for testing the efficacy of the vaccine to protect against challenge with monkeypox virus; and d) all pivotal studies leading towards licensure are conducted using Good Laboratory Practices (GLP). These points to consider are not meant to reflect official U.S. Government policy with regards to fulfillment of the requirements of 21 CFR 601.91; they are provided as a minimal framework for the ATP, and points for discussion with the CBER.

In addition to the animal experiments proposed in fulfillment of 21 CFR 601.91, the ATP shall include separate section describing a formal toxicology study plan suitably tailored to measure the unique safety aspects of MVA. The Contractor shall initiate immunogenicity and toxicity studies only upon Project Officer approval.

5. **Milestone 5—Regulatory Support Plan:** Within 6 months of contract award submit a Regulatory Support Plan (RSP) that is integrated with all testing and manufacturing activities. Activities in this plan shall include Investigational New Drug (IND) maintenance, communications with the CBER, and the compilation of data and materials that will be required in the Biological License Application (BLA).
6. **Milestone 6—Summary Report:** Within 8 months of contract award, or sooner if available, provide a formal summary report to the DMID based on items described in the PDP and QSP. The report shall document the quality assurance procedures, performance measures, and quantitative performance targets associated with manufacture of 3 million doses of MVA vaccine. The Contractor shall demonstrate to the DMID that the final production facility is suitable for the manufacture of FDA-licensable MVA vaccine. The facility and production processes shall be maintained at current Good Manufacturing Practice (cGMP) standards throughout all manufacturing operations. Quality Control (QC) and Quality Assurance (QA) programs must be in place and sufficient to ensure cGMP manufacture of 3 million doses of MVA vaccine product. Quality programs must be maintained at cGMP standards throughout all manufacturing operations. Completion of this milestone is contingent upon a successful preproduction audit to be conducted by the DMID and/or its designee(s).
7. **Milestone 7:** Within 11 months of contract award, complete manufacture, test, fill, finish, release, store and/or deliver to the NIAID 500,000 single doses of MVA. The formulation, vial/closure of this vaccine shall be the same as that to be used to fulfill Milestone 13. The manufacture of this lot of vaccine shall be accomplished using the intermediate-scale technologies and procedures proposed in the Technical Section of the Proposal, and its intended purpose is to provide vaccine for both Contractor and NIAID sponsored clinical trials.

See Note #14 to Offerors.

8. **Milestone 8:** Within 12 months of contract award, refine and submit for DMID approval, a plan to maintain, test and replenish the MVA vaccine inventory for the period of the contract. This milestone pertains to all activities required to maintain the vaccine inventory.

See Note #13 to Offerors.

9. **Milestone 9—Large-Scale Production Plan:** Within 12 months of contract award, provide a Large-scale Production Plan (LPP) to manufacture, formulate, fill/finish, test, and deliver to the U.S. Government up to 50 million doses of the candidate MVA vaccine suitable for storage in a stockpile for emergency use. The purpose of the LPP is to demonstrate suitability to the U.S. Government as a supplier of MVA vaccine should the immediate need arise. The LPP shall be based on production of a stockpile produced from multiple, consistent, cGMP vaccine production campaigns, if needed. The plan shall include steps to be taken to monitor the quality of the vaccine product, and replenish the stockpile as needed to maintain its ready availability for emergency use under IND. The LPP shall include: a) details of the process to scale-up production of multiple lots, if needed b) a timeline for production and delivery of up to 50 million doses of product, c) a strategy that will be pursued to seek a U.S. license for the product and to provide continued support for maintaining an active government-held IND (this strategy shall be consistent with, and refined from, plans developed in the QSP and RSP and the Technical Proposal); d) estimates of cost/dose delivered in single-use vials; and e) a plan to monitor and replenish the stockpile as needed in consultation with managers of the U.S. Government stockpile (this plan shall be consistent with, and refined from Milestone 8).
10. **Milestone 10—Interim Clinical Trial Report:** Within 12 months of contract award or sooner if it becomes available, provide an Interim Clinical Trial Report that includes data summary and analysis, interpretation, and conclusions for the dose-response study. Also included in this report shall be a plan for refinement of follow-on clinical studies that may have been proposed in the CTP. The U.S. Government and/or the Contractor may use these data for consultations with the FDA concerning planning for subsequent product development.

See Note #17 to Offerors.

11. **Milestone 11—Interim Animal Studies Report:** Within 16 months of contract award, provide an Interim Animal Studies Report derived from experiments proposed in the ATP. Included in this report shall be data summaries, analyses, interpretations, and conclusions of experiments conducted. Also included in this report shall be a plan for follow-on animal studies that may not have been proposed in the ATP. Lastly, in line with the requirement of 21 CFR 601.91 for GLP to be followed for pivotal studies, an interim qualification/validation report shall be prepared for selected animal models and their respective assays.
12. **Milestone 12:** Within 18 months of contract award, complete manufacture and release of bulk vaccine substance from at least three cGMP consistency lots. The bulk vaccine substance produced shall be sufficient for the fill/finish of 3 million single-doses.
13. **Milestone 13:** Within 21 months of contract award, complete formulation, fill and finish of all vaccine product that shall comprise the 3 million single-dose MVA vaccine inventory.
14. **Milestone 14:** Within 24 months of contract award, deliver and/or store for the U.S. Government, the entire 3 million dose inventory as directed. Lots may be delivered as they become available if approved by the Project Officer.
15. **Milestone 15:** Within 36 months of contract award, complete the ATP outlined in Milestone 4. Each GLP study shall be initiated following Project Officer approval of the plan and when suitable cGMP vaccine is available.
16. **Milestone 16:** Within 36 months of contract award, complete the CTP and RSP outlined in Milestones 3 and 5, respectively. The U.S. Government and/or the Contractor may use these data for consultations with the FDA concerning planning for subsequent product development.
17. **Milestone 17:** Within 36 months of contract award, complete the PDP and QSP outlined in Milestones 1 and 2, respectively.
18. **Milestone 18:** Within 36 months of contract award, store, maintain, test and replenish the vaccine inventory as needed. These activities shall begin after Milestone 7, when the first lot of vaccine is delivered to the DMID.

**Meetings and Conferences:** The Contractor shall participate in regular meetings to coordinate and oversee the contract effort as directed by the Project Officer. Such meetings may include, but are not limited to, meetings of all contractors and subcontractors to discuss preclinical and clinical study designs; meetings with individual contractors and other PHS officials to discuss the technical, regulatory and ethical aspects of the program; and meetings with NIH technical consultants to discuss data provided by the Contractor.

See Note #8 to Offerors.

**[END OF STATEMENT OF WORK]**

## NOTES TO OFFERORS

### **Production and Testing of a Modified Vaccinia Ankara (MVA) Vaccine RFP-NIH-NIAID-DMID-04-49**

1. Offerors must submit a proposal in response to this RFP that has plans (Milestones 1, 2, 3, 4, 5, and 8) with sufficient detail to permit reviewers to make a realistic evaluation of the offerors likelihood of success. These milestones are included to allow successful offerors the ability to refine plans after award and after consultations with DMID and perhaps CBER. Technical detail in the proposal must be such that the preclinical, clinical, regulatory and stockpile maintenance plans requested for these milestones should require only minor changes after contract award. The cost proposal shall be broken out by Milestone. Budget detail for the clinical, regulatory and stockpile maintenance plans must be associated with, and reflect, the technical proposal.
2. It is expected that the API proposed for pilot-scale, intermediate-scale, and subsequently for large-scale manufacture, will be derived from the same Master Virus Seed (MVS) propagated in chick embryo cells. If a different MVS is used during the course of this contract, plans for animal studies and clinical trials should include control cohorts that monitor and compare the immunogenicity of different vaccine substances.
3. Plans associated with Milestones 1, 2, 3, 4, 5, and 8 must include a schedule for all activities through licensure. However, activities to be performed in response to this RFP, and consistent with the Period of Performance, must be clearly delineated. Budget shall be submitted only for activities proposed in response to this RFP that are consistent with the associated objectives, requirements, timelines and Period of Performance delineated in this RFP. Again, as much effort as possible with associated budget shall be performed in the first two years after contract award. The third year is primarily for follow-up to, and conclusion of, activities started in the first two years.
4. The Contractor shall develop and execute a Contractor's Work Plan (CWP) that describes the activities to be performed in response to the RFP requirements and a single Gantt chart that includes all activities described in the CWP with a time-phased and task-linked budget. The level of detail contained in the CWP and the corresponding Gantt chart will be sufficient to facilitate management and execution of the contract by the successful offeror. The primary milestones have potential to contain subcategories of secondary milestones such as cGMP manufacturing runs, individual animal studies and clinical trials. Minimally, cost proposals will be prepared based on the estimated cost of completion for each primary and secondary milestone.
5. The NIH reserves the right to conduct site visits when deemed necessary. These may include site visits to the contractor's or subcontractor's facilities during the proposal evaluation process and/or during contract performance. Such site visits may include other PHS officials or contractors representing NIH.
6. Cost proposals shall provide a breakdown of costs at the primary milestone and secondary milestone levels, minimally, as well as a cost estimate for the entire project.
7. The U.S. Government recognizes that some offerors may have already completed some of the tasks/milestones identified in the Statement of Work. In such instances, offerors' technical proposal must include sufficient information to support this claim and to allow for appropriate technical evaluation.
8. It is anticipated that a party of five from the Contractor shall participate in two-day visits every two months with the NIAID in Bethesda, MD.
9. The NIAID may convene an independent group composed of *ad hoc* experts and U.S. Government personnel that will provide DMID insight regarding manufacturing, testing and regulatory issues.
10. Any of the following plans and data available will be provided, if available, in the initial proposal or in the Final Proposal Revision (FPR):
  - a. A Manufacturing Feasibility Plan for intermediate and large-scale manufacturing comprised of:
    - Facility status and availability
    - Manufacturing queue access/scale
    - Personnel availability and expertise
    - Performance history



- Estimated cost per dose (labor and materials broken out separately)
  - Timelines
  - Consistency of manufacture
  - Licensure strategy
  - Fill and storage capacity
  - Stockpile maintenance plan
- b. Mouse efficacy data or NHP efficacy data or both against challenge
  - c. IND submitted or cleared
  - d. Phase I and/or II safety and immunogenicity data
  - e. An animal testing plan to licensure
  - f. A clinical plan to licensure
11. Due to the urgent need to defend the American public against agents of bioterrorism, and the considerable investment by the U.S. Government in research and development required to procure the MVA emergency-use vaccine inventory that is the subject of this RFP, the U.S. Government expects and requires that the offeror will take all steps necessary to secure access to all intellectual property, know-how and tangible materials prior to contract award that the offeror needs to fulfill its obligation under the contract. Accordingly, the U.S. Government requires evidence at the time of proposal submission that the offeror has secured access to such intellectual property, know-how and tangible materials.
  12. Funds will not be provided under the terms of this contract to develop the infrastructure required to implement large-scale manufacture.
  13. Associated budget costs for additional lots produced to replenish the emergency-use inventory during the period of performance of this contract must be included in the proposal.
  14. DMID requires that information required to conduct clinical trials under a U.S. Government-sponsored IND be submitted with the vaccine. Information required will include Pharmacology/Toxicology data, previous human data and authorization for the FDA to cross-reference either a Drug Master File or IND containing information relevant to chemistry, manufacturing and control data about the product.
  15. It is presently expected that the maximum vaccine dose will be  $10^8$  TCID<sub>50</sub> MVA. If, in the course of this contract, the Contractor obtains clinical data that supports the effective use of a lower dose with their vaccine candidate, it may be possible to adjust the final vialing of vaccine product with the approval of DMID.
  16. In light of the strict timeline requirements for characterization and production of MVA vaccine, it is suggested that it be delivered to the NIH and tested in preclinical and clinical studies in liquid formulation. However, it is recommended that associated budget costs be provided in the proposal for a concurrent small-scale investigation of a lyophilized vaccine product.
  17. DMID requires that Interim Clinical Trial Reports be submitted for all studies planned under this contract. Since the start of the trials may be different for each contractor, individual Milestone requirements will not be set for the Interim Reports, but it is expected that they be submitted to DMID as soon as they become available.

## REPORTING REQUIREMENTS

### **Production and Testing of a Modified Vaccinia Ankara (MVA) Vaccine RFP-NIH-NIAID-DMID-04-49**

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

#### **A. Technical Reports**

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

1. Monthly Technical Progress Reports—On the fifteenth of each month for the previous calendar month, the Contractor shall submit seven (7) copies of a Monthly Technical Progress Report, comprising six (6) 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—A listing of any and all deliverables submitted during the previous month, a listing of any and all relevant administrative items occurring in the previous months, a listing of all meetings held and meeting minutes submitted during the previous month, a brief summary of financial status of the Contract, and an introduction covering the purpose and scope of the contract effort;
  - c. SECTION II—The report shall detail, document, and summarize the results of work done during the period covered and shall be organized by Milestones. These reports shall be in sufficient detail to explain comprehensively the results achieved. 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. Also to be included in the report is a summary of work proposed for the next reporting period. Specific requirements are set forth in the Work Statement. A one-page summary of each ongoing and completed protocol shall be submitted at this time. A monthly report will not be required for the period when the final report is due. Preprints and reprints of papers and abstracts shall be submitted with the Annual Report.
  - d. SECTION III—Substantive performance; a description of current technical or substantive performance and any problems encountered and/or which may exist along with proposed corrective action. An explanation of any difference between planned progress and actual progress, why the differences have occurred, and if behind planned progress what corrective steps are planned. Also to be included in the report is a summary of any significant decisions taken/pending and concerns/strategies needing to be addressed.
2. Final Report—By the expiration date of the contract, the Contractor shall submit seven (7) copies of a comprehensive Final Report, as above, comprising six (6) 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. Specific requirements are set forth in the Work Statement. Preprints and reprints not submitted previously shall be submitted.
3. Summary of Salient Results - With the annual/final reports the Contractor shall submit a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

#### **B. Technical Report Distribution**

Copies of the technical reports shall be submitted as follows:

<b>Type of report</b>	<b>No. Copies</b>	<b>Addressee</b>	<b>Due Dates</b>
Monthly Progress	6	Project Officer (P.O.) NIH/NIAID/DMID 6610 Rockledge Drive MSC 6605, Room 5121 Bethesda, MD 20892-7630	Specific dates will be listed in the contract document
Monthly Progress	1	Contracting Officer (C.O.) NIH/NIAID/CMB 6700-B Rockledge Drive MSC 7630, Room 2110 Bethesda, MD 20892-7610	Same as above
Milestone Reports	3	A milestone report will be provided after the completion of each Milestone unless otherwise agreed upon by the P.I. and the P.O.	Same as above
Final	7	Submitted with Final Report (six to Project Officer and one to Contracting Officer)	Expiration date
Summary of Salient Results	3	Same as above	Same as above

**C. Deliverables**

The following are considered deliverables under this contract:

1. All Technical Reports, Milestone Reports, preprints, and protocols as described in paragraph A, above. These deliverables are due as indicated.
2. All milestones indicated in the Statement of Work, including the following plans for specific milestones: Product Development Plan (Milestone 1); Quality Systems Plan (Milestone 2); Clinical Testing Plan (Milestone 3); Animal Testing Plan (Milestone 4); Regulatory Support Plan (Milestone 5); Summary Report (Milestone 6); Large-Scale Production Plan (Milestone 9); Interim Clinical Trial Report (Milestone 10); and Interim Animal Studies Report (Milestone 11).

**D. General Requirements**

Regular weekly meetings shall be held between the Principal Investigator and the Project Officer to monitor progress and address issues and concerns as may arise. These meetings will be held at NIAID offices or another mutually agreeable location or by telephone or videoconference at the discretion of the Project Officer. Other government or contract staff members or consultants may be asked to participate as appropriate. At least two (2) business days in advance of each weekly meeting, the Contractor shall provide to the Project Officer a written (E-mail) outline of the agenda for the upcoming weekly meeting. Within five (5) business days following each weekly meeting, the Contractor shall provide to the Project Officer a written (E-mail) summary of discussions at the last meeting, including documentation of any decisions made at the meeting.

## **PART I - THE SCHEDULE**

### **SECTIONS B - H -- UNIFORM CONTRACT FORMAT - GENERAL**

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

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

## **PART II – CONTRACT CLAUSES**

### **SECTION I - CONTRACT CLAUSES**

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

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

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

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

<u>FAR Clause No.</u>	<u>Date</u>	<u>Title</u>
52.202-1	Dec 2001	Definitions
52.203-3	Apr 1984	Gratuities (Over \$100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over \$100,000)
52.203-6	Jul 1995	Covenant Against Contingent Fees (Over \$100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over \$100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over \$100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over \$100,000)
52.203-12	Jun 1997	Limitation on Payments to Influence Certain Federal Transactions (Over \$100,000)
52.204-4	Aug 2000	Printing/Copying Double-Sided on Recycled Paper (Over \$100,000)
52.209-6	Jul 1995	Protecting the Governments Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$25,000)
52.215-2	Jun 1999	Audit and Records - Negotiation (Over \$100,000)
52.215-8	Oct 1997	Order of Precedence – Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data
52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over \$500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over \$100,000)
52.215-15	Dec 1998	Pension Adjustments and Asset Reversions
52.215-18	Oct 1997	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) Other Than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	Oct 2000	Utilization of Small Business Concerns (Over \$100,000)

52.219-9	Jan 2002	Small Business Subcontracting Plan (Over \$500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over \$500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over \$100,000) (NOTE: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)
52.222-3	Aug 1996	Convict Labor
52.222-26	Apr 2002	Equal Opportunity
52.222-35	Dec 2001	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Dec 2001	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Oct 2000	Toxic Chemical Release Reporting
52.225-1	May 2002	Buy American Act - Supplies
52.225-13	Jul 2000	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over \$100,000)
52.227-11	Jun 1997	Patent Rights - Retention by the Contractor (Short Form) (NOTE: In accordance with FAR 27.303 (a) (2), paragraph (f) is modified to include the requirements in FAR 27.303 (a) (2) (i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Jun 1987	Rights in Data – General
52-232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	Jun 1996	Interest (Over \$100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Feb 2002	Prompt Payment
52.232-25	Feb 2002	Prompt Payment, Alternate I (Feb 2002)
52.232-34	May 1999	Payment by Electronic Funds Transfer--Other Than Central Contractor Registration
52.233-1	July 2002	Disputes
52.233-3	Aug 1996	Protest After Award
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over \$500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs

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

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

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

END OF GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH  
AND DEVELOPMENT CONTRACT – Rev. 4/2003]



## **ARTICLE I.2. AUTHORIZED SUBSTITUTIONS OF CLAUSES**

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

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

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

### **ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES**

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

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

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

FAR 52.215-17, Waiver of Facilities Capital Cost of Money (OCTOBER 1997).

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

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

[ ] Offeror elects to waive the evaluation preference."

FAR 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns (MAY 2001).

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

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

FAR 52.224-1, Privacy Act Notification (APRIL 1984).

FAR 52.224-2, Privacy Act (APRIL 1984).

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

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

FAR 52.229-9, Taxes-Cost-Reimbursement Contracts with Foreign Governments (MARCH 1990).

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

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

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

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

HHSAR 352.270-8, Protection of Human Subjects (JANUARY 2001).

Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this clause.

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

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

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

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

NIH(RC)-11, Research Patient Care Costs (4/1/84).

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

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

This contract incorporates the following clauses in full text.

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

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

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

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

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

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

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

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

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

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

## **PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS**

### **SECTION J - LIST OF ATTACHMENTS**

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

**[PACKAGING AND DELIVERY OF PROPOSALS](#)** (Attached to this listing)

**[HOW TO PREPARE AN ELECTRONIC PROPOSAL](#)**: (Attached to this listing)

**[PROPOSAL INTENT RESPONSE SHEET](#)**. **SUBMIT ON/BEFORE: [January 14, 2004](#)** (Attached to this listing)

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

#### **RFP FORMS AND ATTACHMENTS:**

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

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

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

Technical Proposal Cover Sheet

NIH-1688-1, Project Objectives

Technical Proposal Cost Information

Summary of Related Activities

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

- Targeted/Planned Enrollment Table
- Annual Technical Progress Report Format for Each Study

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

NIH-2043, Proposal Summary and Data Record

Small Business Subcontracting Plan Format *[if applicable]*

Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours

Offeror's Points of Contact

#### **TO BECOME CONTRACT ATTACHMENTS (INFORMATION ONLY):**

- Inclusion Enrollment Report
- NIH(RC)-4: Invoice/Financing Request and Contract Financial Reporting Instructions for NIH Cost-Reimbursement Type Contracts
- NIH(RC)-7: Procurement of Certain Equipment, (OMB Bulletin 81-16)
- NIH(RC)-11: Research Patient Care Costs
- Safety and Health, HHSAR Clause 352.223-70
- Privacy Act System of Records
- Report of Government Owned, Contractor Held Property
- Disclosure of Lobbying Activities, OMB Form LLL
- Targeted/Planned Enrollment Table

**PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL**

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

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

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

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE.

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

**A. EXTERNAL PACKAGE MARKING:**

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

**"RFP NO. NIH-NIAID-DMID-04-49  
TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"**

**B. NUMBER OF COPIES:**

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

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

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

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

<b>If Hand Delivery or Express Service</b>	<b>If using U.S. Postal Service</b>
Contract Specialist Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230 Bethesda, Maryland 20817	Contract Specialist Contract Management Program, DEA NIAID, NIH 6700-B Rockledge Drive, Room 2230, MSC 7612 Bethesda, Maryland 20892-7612

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

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

## **HOW TO PREPARE AND SUBMIT AN ELECTRONIC PROPOSAL**

### **PAGE LIMITS -- N/A to this solicitation.**

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

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

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

### **Formatting Requirements:**

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

### **SUBMISSION OF “PROPOSAL INTENT RESPONSE SHEET”:**

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

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

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

**LOG-IN / TRANSMISSION INSTRUCTIONS:**

1. Log-in Site: Will be provided by the Contract Specialist after receipt of the "Proposal Intent Response Sheet"
2. Log-in Name: Will be provided by the Contract Specialist via e-mail.
3. Log-in Password: Will be provided by the Contract Specialist via e-mail.
  
4. Procedure -- When your proposal is completed and converted to a PDF file using Adobe Acrobat, it is ready to be transmitted electronically. You must upload separate Technical and Business Proposal Files. It is recommended that proposals be transmitted a few days before the due date so that you will have sufficient time to overcome any transmission difficulties.
  - You must have Explorer 3.1 or higher.
  - It is essential that you use antiviral software to scan all documents.
  - Click on "Sign On" and enter your log-in name and password.
  - Click on "Browse" to locate your saved files on your computer.
  - Click on "Upload Proposal" after you have located the correct file.
  - After a file is uploaded, a link to the file will appear under "Upload Files" at the bottom of the screen. Click on that link to view the uploaded file.
  - If you experience difficulty in accessing your documents, please contact the appropriate NIH contracts office immediately.
  - If you wish to revise your proposal before the closing date and time, simply log in again and re-post.

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



## PROPOSAL INTENT RESPONSE SHEET

**RFP No.:** NIH-NIAID-DMID-04-49

**RFP Title:** "Production and Testing of a Modified Vaccinia Ankara (MVA) Vaccine"

Please review the attached Request for Proposal. Furnish the information requested below and return this page by January 14, 2004. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

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

DO INTEND TO SUBMIT A PROPOSAL

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

**Company/Institution Name (print):** \_\_\_\_\_

**Address (print):** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**Project Director's Name (print):** \_\_\_\_\_

**Title (print):** \_\_\_\_\_

**Signature/Date:** \_\_\_\_\_

**Telephone Number and E-mail Address (print clearly):**

\_\_\_\_\_

\_\_\_\_\_

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

**Name:** \_\_\_\_\_

**Title:** \_\_\_\_\_

**E-Mail Address:** \_\_\_\_\_

**Telephone Number:** \_\_\_\_\_

**Names of Collaborating Institutions and Investigators (include Subcontractors and Consultants) (print):**

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

*(Continue list on a separate page if necessary)*

RETURN VIA FAX OR E-MAIL TO:

CMP, NIAID, NIH

Room 2230

6700-B Rockledge Drive, MSC 7612

Bethesda, MD 20892-7612

Attn: Brenda Brooks

RFP-NIH-NIAID-DMID-04-49

FAX# (301) 402-0972

Email : bb76n@nih.gov

## **PART IV – REPRESENTATIONS AND INSTRUCTIONS**

### **SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS**

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

##### **1. REPRESENTATIONS AND CERTIFICATIONS**

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

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

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

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

## SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

### 1. GENERAL INFORMATION

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

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

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

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

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

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

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

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

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

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

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

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

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

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

- (1) If it was transmitted through an electronic commerce method authorized by the solicitation, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or
- (2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or
- (3) It is the only proposal received.

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

- (iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.
- (iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.
- (v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral solicitations may be withdrawn orally. If the solicitation authorizes facsimile proposals, proposals may be withdrawn via facsimile received at any time before award, subject to the conditions specified in the provision at 52.215-5, Facsimile Proposals. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(f) *Contract award.*

- (1) The Government intends to award a contract or contracts resulting from this solicitation to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the solicitation.
- (2) The Government may reject any or all proposals if such action is in the Government's interest.
- (3) The Government may waive informalities and minor irregularities in proposals received.
- (4) The Government intends to evaluate proposals and award a contract without discussions with offerors (except clarifications as described in FAR 15.306(a)). Therefore, the offeror's initial proposal should contain the offeror's best terms from a cost or price and technical standpoint. The Government reserves the right to conduct discussions if the Contracting Officer later determines them to be necessary. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals.
- (5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.
- (6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government's best interest to do so.

- (7) Exchanges with offerors after receipt of a proposal do not constitute a rejection or counteroffer by the Government.
- (8) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more contract line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.
- (9) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.
- (10) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.
- (11) The Government may disclose the following information in postaward debriefings to other offerors:
  - (i) The overall evaluated cost or price and technical rating of the successful offeror;
  - (ii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection;
  - (iii) A summary of the rationale for award; and
  - (iv) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(End of Provision)

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

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

**b. NAICS CODE AND SIZE STANDARD**

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

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

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

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

In accordance with FAR Clause 52.219-23, Notice of Price Evaluation Adjustment for Small Disadvantaged Business Concerns, incorporated in Section I.3., offerors will be evaluated by adding a factor of 0 percent to the price of all offers, except offers from small disadvantaged business concerns that have not waived the adjustment. (Note: A listing of other

offerors who are excepted and will not have this evaluation factor added to their offer may be found in subparagraph (b) of FAR Clause 52.219-23.

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

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

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

It is anticipated that one or more awards will be made from this solicitation and that the awards will be made on/about July 30, 2004.

It is anticipated that the awards from this solicitation will be multiple-year, cost-reimbursement, completion type contracts with a period of performance of 3 years, and that incremental funding will be used [see Section L.2.c. Business Proposal Instructions].

**e. COMMITMENT OF PUBLIC FUNDS**

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

**f. COMMUNICATIONS PRIOR TO CONTRACT AWARD**

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

**g. RELEASE OF INFORMATION**

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

**h. COMPARATIVE IMPORTANCE OF PROPOSALS**

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

**i. PREPARATION COSTS**

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

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

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

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

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

(End of Provision)

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

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

(End of provision)

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

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

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



## 2. INSTRUCTIONS TO OFFERORS

### GENERAL INSTRUCTIONS

#### INTRODUCTION

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

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

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

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

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

##### I. COVER PAGE

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

##### a. Project Objectives, NIH-1688-1

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

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

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

##### II. TECHNICAL PROPOSAL

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

##### III. BUSINESS PROPOSAL

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

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

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

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

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

**(5) Alternate Proposals**

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

**(6) Evaluation of Proposals**

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

**(7) Potential Award Without Discussions**

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

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

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

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

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

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

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

(9) **Human Subjects**

**IMPORTANT NOTE TO OFFERORS: The following 6 paragraphs [(9) through (14)] shall be addressed in a SEPARATE SECTION of the Technical Proposal entitled, "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 (JANUARY 2001)**

- 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 of Protection from Research Risks (OPRR), National Institutes of Health (NIH), Bethesda, Maryland 20892\*. 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 data through intervention or interaction with the individual, or 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 National Institutes of Health 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 OPRR\*, (telephone: 301-496-7014\*), is recommended.
- e) In accordance with 45 CFR, Part 46, prospective Contractors being considered for award shall be required to file with OPRR\* 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 OPRR\* and given detailed instructions for establishing an institutional review board and filing an Assurance of Compliance.
- f) It is recommended that OPRR\* be consulted for advice or guidance concerning either regulatory requirements or ethical issues pertaining to research involving human subjects. (End of Provision)

*\*Note: The Office for Human Research Protections (OHRP), Office of the Secretary (OS), Department of Health and Human Services (DHHS) is the office responsible for oversight of the Protection of Human subjects and should replace Office for Protection from Research Risks (OPRR), National Institutes of Health (NIH) wherever it appears in this provision. The phone number to reach this office is 301-496-7014. For more information, the OHRP website may be accessed at <http://ohrp.osophs.dhhs.gov/>. Copies of the DHHS Regulations for the Protection of Human Subjects, 45 CFR Part 46, are also available on line at [http://www.access.gpo.gov/nara/cfr/waisidx\\_01/45cfr46\\_01.html](http://www.access.gpo.gov/nara/cfr/waisidx_01/45cfr46_01.html).*

(10) **Instructions to Offerors Regarding Protection of Human Subjects**

Offerors must address the following human subjects protections issues if this contract will be for research involving human subjects (note: under each of the following points below, the offeror should indicate whether the information provided relates to the primary research site, or to a collaborating performance site(s), or to all sites:

(a) Risks to the subjects

Human Subjects Involvement and Characteristics:

- Describe the proposed involvement of human subjects in response to the solicitation.
- Describe the characteristics of the subject population, including their anticipated number, age range, and health status.
- Identify the criteria for inclusion or exclusion of any subpopulation. Explain the rationale for the involvement of special classes of subjects, such as fetuses, pregnant women, children, prisoners, institutionalized individuals, or others who are likely to be vulnerable populations.

Sources of Materials:

- Identify the sources of research material obtained from individually identifiable living human subjects in the form of specimens, records, or data. Indicate whether the material or data will be obtained specifically for research purposes or whether use will be made of existing specimens, records, or data.

Potential Risks:

- Describe the potential risks to subjects (physical, psychological, social, legal, or other) and assess their likelihood and seriousness to the subjects.
- Describe alternative treatments and procedures, including the risks and benefits of the alternative treatments and procedures, to participants in the proposed research, where appropriate.

(b) Adequacy of Protection Against Risks

Recruitment and Informed Consent:

- Describe plans for the recruitment of subjects and the procedures for obtaining informed consent. Include a description of the circumstances under which consent will be sought and obtained, who will seek it, the nature of the information to be provided to prospective subjects, and the method of documenting consent. The informed consent document for the contractor and any collaborating sites should be submitted only if requested elsewhere in the solicitation. Be aware that an IRB-approved informed consent document for the contractor and any participating collaborative sites must be provided to the Government prior to patient accrual or participant enrollment.

Protection Against Risk:

- Describe the procedures for protecting against or minimizing potential risks, including risks to confidentiality, and assess their likely effectiveness.
- Discuss provisions for ensuring necessary medical or professional intervention in the event of adverse effects to the subjects where appropriate.
- In studies that involve interventions, describe the provisions for data and safety monitoring of the research to ensure the safety of subjects.

(c) Potential Benefits of the Proposed Research to the Subjects and Others

- Discuss the potential benefits of the research to the subjects and others.
- Discuss why the risks to subjects are reasonable in relation to the anticipated benefits to subjects and others.
- Describe treatments and procedures that are alternatives to those provided to the participants by the proposed research, where appropriate.

(d) Importance of the Knowledge to be Gained

- Discuss the importance of the knowledge gained or to be gained as a result of the proposed research.
- Discuss why the risks to subjects are reasonable in relation to the importance of the knowledge that may reasonably be expected to result.

**Note:** If a test article (investigational new drug, device, or biologic) is involved, name the test article and state whether the 30-day interval between submission of offeror's certification to the Food and Drug Administration (FDA) and its response has elapsed or has been waived and/or whether the FDA has withheld or restricted use of the test article.

**Collaborating Site(s)**

When research involving human subjects will take place at collaborating site(s) or other performance site(s), the offeror must provide in this section of its proposal a list of the collaborating sites and their assurance numbers. Further, if you are awarded a contract, you must obtain in writing, and keep on file, an assurance from each site that the previous points have been adequately addressed at a level of attention that is at least as high as that documented at your organization. Site(s) added after an award is made must also adhere to the above requirements.

**(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](http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-039.html) 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/>. You may download the information at this site at no cost and modify it, if desired. In addition, the University of Rochester has made its training program available for individual investigators. 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\\_profes\\_protect.html](http://www.centerwatch.com/order/pubs_profes_protect.html). If an institution already has developed educational programs on the protection of research participants, completion of these programs also will 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 contracting officer with the title of the education program and a one sentence description of the program that the replacement has completed.

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

It is NIH policy that women and members of minority groups and their sub-populations must be included in all NIH-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the relevant Institute/Center Director that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, NIH, may determine that exclusion under other circumstances is acceptable, upon the recommendation of an Institute/Center Director, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study

would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research. This policy results from the NIH Revitalization Act of 1993 (Section 492B of Public Law 103-43), **and applies to research subjects of all ages.**

All investigators proposing research involving human subjects should read the UPDATED "NIH Policy and Guidelines on the Inclusion of Women and Minorities as Subjects in Clinical Research, Amended October 2001," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site:

[http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm)

These guidelines contain a definition of **clinical research** adopted in June 2001, as: "(1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; and (3) Outcomes research and health services research" (<http://www.nih.gov/news/crp/97report/execsum.htm>).

### **Information Required for ALL Clinical Research Proposals**

This solicitation contains a review criterion addressing the adequacy of: (1) the offeror's plans for inclusion of women and minorities in the research proposed; or (2) the offeror's justification(s) for exclusion of one or both groups from the research proposed.

Provide information on the composition of the proposed study population in terms of sex/gender and racial/ethnic groups and provide a rationale for selection of such subjects in response to the requirements of the solicitation. The description may include (but is not limited to) information on the population characteristics of the disease or condition being studied in the planned research, and/or described in the statement of work, national and local demography, knowledge of the racial/ethnic/cultural characteristics of the population, prior experience and collaborations in recruitment and retention of the populations and subpopulations to be studied, and the plans, arrangements and letters of commitment from relevant community groups and organizations for the planned research.

The proposal must include the following information:

- A description of the subject selection criteria
- The proposed dates of enrollment (beginning and end)
- A description of the proposed outreach programs for recruiting women and minorities as subjects
- A compelling rationale for proposed exclusion of any sex/gender or racial/ethnic group
- The proposed sample composition using the "Targeted/Planned Enrollment Table"(see Section J, Attachments)

**NOTE 1:** For all proposals, use the ethnic and racial categories and complete the "Targeted/Planned Enrollment Table in accordance with the Office of Management and Budget (OMB) Directive No. 15, which may be found at: <http://www.whitehouse.gov/OMB/fedreg/ombdir15.html>

**NOTE 2:** If this is an Indefinite Delivery, Indefinite Quantity (IDIQ) or Requirements contract as defined in FAR 16.5, the proposal should describe in general terms how it will comply with each bulleted item above for each task order. When the Government issues a task order request for proposal, each of the bulleted information items must be fully and specifically addressed in the proposal.

**Standards for Collecting Data.** When you, as a contractor, are planning data collection items on race and ethnicity, you shall use, at a minimum, the categories identified in OMB Directive No. 15. The collection of greater detail is encouraged. However, you should design any additional, more detailed items so that they can be aggregated into these required categories. Self-reporting or self-identification using two separate questions is the preferred method for collecting data on race and ethnicity. When you collect race and ethnicity separately, you must collect ethnicity first. You shall offer respondents the option of selecting one or more racial designations. When you collect data on race and ethnicity separately, you shall also make provisions to report the number of respondents in each racial category who are Hispanic or Latino. When you present aggregate data, you shall provide the number of respondents who selected only one category, for each of the five racial categories. If you collapse data on multiple

responses, you shall make available, at a minimum, the total number of respondents reporting “more than one race.” Federal agencies shall not present data on detailed categories if doing so would compromise data quality or confidentiality standards.

In addition to the above requirements, solicitations for **NIH defined Phase III clinical trials**<sup>1</sup> require that: a) all proposals and/or protocols provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide:

[http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm),  
Definitions - Significant Difference),

by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable; and b) all contractors to report annually cumulative subject accrual, and progress in conducting analyses for sex/gender and race/ethnicity differences.

Offerors may obtain copies of the Updated Guidelines from the sources above or from the contact person listed in the solicitation.

Also, the proposal must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups, OR
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroups) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

**Use the form in Section J, Attachments, entitled, "Targeted/Planned Enrollment Table," when preparing your response to the solicitation requirements for inclusion of women and minorities.**

Unless otherwise specified in this solicitation, the Government has determined that the work required by this solicitation does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, the NIH believes that the inclusion of women and minority populations is appropriate for this project. (See Section M of this RFP for more information about evaluation factors for award.)

**Use the format for the Annual Technical Progress Report for Clinical Research Study Populations (See Section J - List of Documents, Exhibits and Other Attachments of the RFP) entitled, "Inclusion Enrollment Report," for reporting in the resultant contract.**

### (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 *clear and compelling* reasons not to include them. **(See examples of Justifications for Exclusion of Children below).** 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.**

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<sup>1</sup>See NIH Guide [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm) for the Definition of an “NIH-Defined Phase III clinical trial.”

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

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. The "Human Subjects" section of your technical proposal 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. This solicitation contains a review criterion addressing the adequacy of: (1) the plans for including children as appropriate for the scientific goals of the research; and/or (2) the justification of exclusion of children or exclusion of a specific age range of children.

When children are included, the plan also must include a description of: (1) the expertise of the investigative team for dealing with children at the ages included; (2) the appropriateness of the available facilities to accommodate the children; and, (3) the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation.

#### **Justifications for Exclusion of Children**

It is expected that children will be included in all research involving human subjects unless one or more of the following exclusionary circumstances can be fully justified:

- The objective of the solicitation is not relevant to children.
  - There are laws or regulations barring the inclusion of children in the research to be conducted under the solicitation.
  - The knowledge being sought in the research is already available for children or will be obtained from another ongoing study, and an additional study will be redundant. You should provide documentation of other studies justifying the exclusion.
  - A separate, age-specific study in children is warranted and preferable. Examples include:
    - The relative rarity of the condition in children, as compared with adults (in that extraordinary effort would be needed to include children); or
    - The number of children is limited because the majority are already accessed by a nationwide pediatric disease research network; or
    - Issues of study design preclude direct applicability of hypotheses and/or interventions to both adults and children (including different cognitive, developmental, or disease stages of different age-related metabolic processes); or
    - Insufficient data are available in adults to judge potential risk in children (in which case one of the research objectives could be to obtain sufficient adult data to make this judgment). While children usually should not be the initial group to be involved in research studies, in some instances, the nature and seriousness of the illness may warrant their participation earlier based on careful risk and benefit analysis; or
    - Study designs aimed at collecting additional data on pre-enrolled adult study subjects (e.g., longitudinal follow-up studies that did not include data on children);
    - Other special cases justified by the offeror and found acceptable to the review group and the Institute Director



## Definition of a Child

**For the purpose of this solicitation, a child is defined as an individual under the age of 21 years.**

The definition of child described above will pertain to this solicitation (notwithstanding the FDA definition of a child as an individual from infancy to 16 years of age, and varying definitions employed by some states). Generally, State laws define what constitutes a “child,” and such definitions dictate whether or not a person can legally consent to participate in a research study. However, State laws vary, and many do not address when a child can consent to participate in research. Federal Regulations (45 CFR 46, subpart D, Sec.401-409) address DHHS protections for children who participate in research, and rely on State definitions of “child” for consent purposes. Consequently, the children included in this policy (persons under the age of 21) may differ in the age at which their own consent is required and sufficient to participate in research under State law. For example, some states consider a person age 18 to be an adult and therefore one who can provide consent without parental permission.

### (14) Data and Safety Monitoring in Clinical Trials

All offerors are directed to the full text of the NIH Policies regarding Data and Safety Monitoring and Reporting of Adverse Events that are found in the [NIH Guide for Grants and Contracts Announcements](#) at the following web sites:

<http://grants.nih.gov/grants/guide/notice-files/not98-084.html>  
<http://grants.nih.gov/grants/guide/notice-files/not99-107.html>  
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-038.html>

All offerors receiving an award under this solicitation must comply with the NIH Policy cited in these NIH Announcements and any other data and safety monitoring requirements found elsewhere in this solicitation.

The following is a brief summary of the Data and Safety Monitoring and Adverse Event Reporting Requirements:

Data and Safety Monitoring is required for every clinical trial. Monitoring must be performed on a regular basis and the conclusions of the monitoring reported to the Project Officer.

The type of data and safety monitoring required will vary based on the type of clinical trial and the potential risks, complexity and nature of the trial. A plan for data and safety monitoring is required for all clinical trials. A general description of a monitoring plan establishes the overall framework for data and safety monitoring. It should describe the entity that will be responsible for the monitoring, and the policies and procedures for adverse event reporting. Phase III clinical trials generally require the establishment of a Data Safety Monitoring Board (DSMB). The establishment of a DSMB is optional for Phase I and Phase II clinical trials.

The DSMB/Plan is established at the time the protocol is developed and must be approved by both the Institutional Review Board (IRB) and the Government and in place before the trial begins. If the protocol will be developed under the contract awarded from this solicitation, a general description of the data and safety monitoring plan must be submitted as part of the proposal and will be reviewed by the scientific review group (Technical Evaluation Panel, (TEP)) convened to evaluate the proposal. If the protocol is developed and is included as part of the submitted proposal, a complete and specific data and safety monitoring plan must be submitted as part of the proposal.

Monitoring Plans, at a minimum, must include the prompt reporting of adverse events to the IRB, the NIH Office of Biotechnology Activities (OBA), and the Food and Drug Administration (FDA). Also, in the plan you should describe the frequency of reporting of the conclusions of the monitoring activities. The overall elements of each plan may vary depending on the size and complexity of the trial. The NIH Policy for Data and Safety Monitoring at <http://grants.nih.gov/grants/guide/notice-files/not98-084.html> describes examples of monitoring activities to be considered.

The frequency of monitoring will depend upon potential risks, complexity, and the nature of the trial; therefore a number of options for monitoring trials are available. These can include, but are not limited to, monitoring by a:

- Principal Investigator (required)
- Independent individual /Safety Officer

- Designated medical monitor
- Internal Committee or Board with explicit guidelines
- Data and Safety Monitoring Board (DSMB - required for multisite trials)
- Institutional Review Board (IRB - required)

For multi-site Phase I and Phase II trials, a central reporting entity that will be responsible for preparing timely summary reports of adverse events for distribution among sites and IRBs should be considered.

Organizations with a large number of clinical trials may develop standard monitoring plans for Phase I and Phase II trials. In this case, such organizations may include the IRB-approved monitoring plan as part of the proposal submission.

#### **(15) Standards for Privacy of Individually Identifiable Health Information**

The Department of Health and Human Services (DHHS) issued final modifications to the “Standards for Privacy of Individually Identifiable Health Information,” the “Privacy Rule,” on August 14, 2002. The Privacy Rule is a federal regulation under the Health Insurance Portability and Accountability Act (HIPAA) of 1996 that governs the protection of individually identifiable health information and is administered and enforced by the DHHS Office for Civil Rights (OCR). Those who must comply with the Privacy Rule (classified under the Rule as “covered entities” must do so by April 14, 2003 (with the exception of small health plans which have an extra year to comply.

Decisions about the applicability and implementation of the Privacy Rule reside with the contractor and his/her institution. The OCR Web site (<http://www.hhs.gov/ocr/>) provides information of the Privacy Rule, including a complete Regulation Text and a set of decision tools on “Am I a covered entity?” Information on the impact of the HIPAA Privacy Rule on NIH processes involving the review, award, and administration of grants, cooperative agreements and contracts can be found at: <http://grants1.nih.gov/grants/guide/notice-files/NOT-OD-03-025.html>.

#### **(16) Care of Live Vertebrate Animals**

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

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

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

- b. The following information must be included in the offeror's technical proposal:
  - identification of the species and approximate number of animals to be used;
  - rationale for involving animals, and for the appropriateness of the species and numbers used;

- a complete description of the proposed use of the animals;
  - a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research, and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals; and
  - a description of any euthanasia method to be used.
- c. If an Animal Assurance is already in place, the offeror's proposal shall include:
- The Animal Welfare Assurance number.
  - The date last certified by OLAW. (i.e. assurance letter from OLAW)
  - Evidence of recent AAALAC Accreditation.

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

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

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

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

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

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

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

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

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

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

#### (19) Sharing Research Data

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

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

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

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

#### (20) Privacy Act (Treatment of Proposal Information)

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

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

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

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

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

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

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

- to the cognizant audit agency and the General Accounting Office for auditing.
- to the Department of Justice as required for litigation.
- to respond to congressional inquiries.

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

## **(21) Selection of Offerors**

- a) The acceptability of the scientific and technical portion of each research contract proposal will be evaluated by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of the RFP, utilizing point scores and written critiques. The committee may suggest that the Contracting Officer request clarifying information from an offeror.
- b) The business portion of each contract proposal will be subjected to a cost and price analysis, management analysis, etc.
- c) If award will be made without conducting discussions, offerors may be given the opportunity to clarify certain aspects of their proposal (e.g., the relevance of an offeror's past performance information and adverse past performance information to which the offeror has not previously had an opportunity to respond) or to resolve minor or clerical errors.
- d) If the Government intends to conduct discussions prior to awarding a contract-

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

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

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

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

- e) The process described in FAR 15.101-1 will be employed, which permits the Government to make tradeoffs among cost or price and non-cost factors and to consider award to other than the lowest price offeror or other than the highest technically rated offeror. This process will take into consideration the results of the technical evaluation, the past performance evaluation (if applicable) and the cost analysis.
- f) The Institute reserves the right to make a single award, multiple awards, or no award at all to the RFP. In addition, the RFP may be amended or canceled as necessary to meet the Institute's requirements. Synopses of awards exceeding \$25,000 will be published in the FedBizOpps.

## **(22) Small Business Subcontracting Plan**

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

- a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS OR NON-U.S. CONCERNS.
- b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.
- c) The offeror understands that:
  - (1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
  - (2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HubZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
  - (3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the offeror, the offeror shall be ineligible for an award. The Contracting Officer shall notify the Contractor in writing of the reasons for determining a subcontracting plan unacceptable early enough in the negotiation process to allow the Contractor to modify the plan within the time limits prescribed.
  - (4) Prior compliance of the offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the offeror for award of the contract.
  - (5) It is the offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HubZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the offeror's plan will be judged independent of the other.
  - (6) The offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon, and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Contractor's designated small and disadvantaged business liaison.
- d) Each plan must contain the following:
  - (1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.
  - (2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
  - (3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.
  - (4) A description of the method used to develop the subcontracting goals.
  - (5) A description of the method used to identify potential sources for solicitation purposes.

- (6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.
- (7) The name of the individual employed by the offeror who will administer the offeror's subcontracting program and a description of his/her duties.
- (8) A description of the efforts the offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.
- (9) Assurances that the offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$500,000 adopt a plan similar to the plan agreed upon by the offeror.
- (10) Assurances that the offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit required reports (SF 294 and SF 295) to the Government.
- (11) List the types of records the offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

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

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

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

**(23) 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>.

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

In accordance with FAR Subpart 15.304(c)(4), the extent of participation of Small Disadvantaged Business (SDB) concerns in performance of the contract in the authorized NAICS Industry Subsectors shall be evaluated in unrestricted competitive acquisitions expected to exceed \$500,000 (\$1,000,000 for construction) subject to certain limitations (see FAR 19.1202-1 and 19.1202-2(b)). The dollar amounts cited above include any option years/option quantities that may be included in this solicitation. The definition of a "small disadvantaged business" is cited in FAR 19.001.

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

on this factor only if that SDB concern waives the PEA. **Waiver of the price evaluation adjustment shall be clearly stated in the proposal.**

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

The Department of Commerce website for the annual determination is:

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

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

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

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

	<b>SDB Percentage of Total Contract Value</b>	<b>SDB Dollars</b>
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.

**(25) 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.

#### **(26) Salary Rate Limitation in Fiscal Year 2003**

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

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

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

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

**LINK TO EXECUTIVE SCHEDULE SALARIES:** <<http://www.opm.gov/oca/PAYRATES/index.htm>>

*(click on "Executive Schedule" for the current Fiscal Year's salary rate or scroll down to the "General Schedule Salary Tables from Previous Years" to locate the Executive Level salary rates from previous years).*

#### **(27) 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.

**(28) 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 U.S. Currency, FAR Clause 52.214-35, (April 1991).
- b) Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
- c) Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).
- d) Preaward On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000), FAR Clause 52.222-24, (February 1999).

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

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

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

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

## TECHNICAL PROPOSAL INSTRUCTIONS

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

### (1) Technical Discussions

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

#### a) Statement of Work

##### (1) Objectives

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

##### (2) Approach

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

##### (3) Methods

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

##### (4) Schedule

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

#### b) Personnel

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

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

(1) Principal Investigator/Project Director

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

(2) Other Investigators

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

(3) Additional Personnel

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

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

(4) Resumes

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

**(2) Technical Evaluation**

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

**(3) Additional Technical Proposal Information**

- a) Proposals which merely offer to conduct a program in accordance with the requirements of the Government's scope of work will not be eligible for award. The offeror must submit an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.
- b) The technical evaluation is conducted in accordance with the weighted technical evaluation criteria by an initial review panel. This evaluation produces a numerical score (points) which is based upon the information contained in the offeror's proposal only.

**(4) Other Considerations**

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

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

- b) Unique arrangements, equipment, etc., which none or very few organizations are likely to have which is advantageous for effective implementation of this project.
- c) Equipment and unusual operating procedures established to protect personnel from hazards associated with this project.
- d) Other factors you feel are important and support your proposed research.
- e) Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

## BUSINESS PROPOSAL INSTRUCTIONS

### (1) Basic Cost/Price Information

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

### (2) Information Other than Cost or Pricing Data

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

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

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

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

#### (a) Exceptions from cost or pricing data.

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

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

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

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

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

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

- (2) The offeror grants the Contracting Officer or an authorized representative the right to examine, at any time before award, books, records, documents, or other directly pertinent records to verify any request for an

exception under this provision, and the reasonableness of price. For items priced using catalog or market prices, or law or regulation, access does not extend to cost or profit information or other data relevant solely to the offeror's determination of the prices to be offered in the catalog or marketplace.

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

- (1) The offeror shall prepare and submit cost or pricing data and supporting attachments in accordance with Table 15-2 of FAR 15.408.
- (2) As soon as practicable after agreement on price, but before contract award (except for unpriced actions such as letter contracts), the offeror shall submit a Certificate of Current Cost or Pricing Data, as prescribed by FAR 15.406-2.

(End of provision)

(4) Qualifications of the Offeror

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

a) **General Experience**

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

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

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

c) **Performance History**

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

d) **Pertinent Contracts**

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

e) **Pertinent Grants**

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

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



(5) Other Administrative Data

a) **Property**

- (1) It is DHHS policy that Contractors will provide all equipment and facilities necessary for performance of contracts. Exception may be granted to furnish Government-owned property, or to authorize purchase with contract funds, only when approved by the Contracting Officer. If the offeror is proposing that the Government provide any equipment, other than that specified under Government Furnished Property in the RFP, the proposal must include comprehensive justification which includes:
  - (a) An explanation that the item is for a special use essential to the direct performance of the contract and the item will be used exclusively for the purpose. Office equipment such as desks, office machines, etc., will not be provided under a contract except under very exceptional circumstances.
  - (b) No practical or economical alternative exists (e.g., rental, capital investment) that can be used to perform the work.
- (2) The offeror shall identify Government-owned property in its possession and/or Contractor titled property acquired from Federal funds, which it proposes to use in the performance of the prospective contract.
- (3) The management and control of any Government property shall be in accordance with DHHS Publication (OS) 686 entitled, "Contractors Guide for Control of Government Property (1990)," a copy of which will be provided upon request.

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

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

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

c) **Financial Capacity**

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

d) **Incremental Funding**

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the

contract are not available at the time of the contract award. If this requirement is specified elsewhere in this RFP, the offeror shall submit a cost proposal for each year. In addition, the following provisions are applicable:

**HHSAR 352.232-75, Incremental Funding (January 2001)**

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

(End of provision)

**e) 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.

**(6) Subcontractors**

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

- a) Willingness to perform as a subcontractor for specific duties (list duties).
- b) What priority the work will be given and how it will relate to other work.
- c) The amount of time and facilities available to this project.
- d) Information on their cognizant field audit offices.
- e) How rights to publications and patents are to be handled.

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

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

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

(7) Proposer's Annual Financial Report

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

(8) Representations and Certifications

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

(9) Travel Costs/Travel Policy

a) **Travel Costs - Commercial**

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

b) **Travel Policy**

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

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

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

## SECTION M - EVALUATION FACTORS FOR AWARD

### 1. GENERAL

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

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

### 2. HUMAN SUBJECT EVALUATION

This research project involves human subjects. NIH Policy requires:

#### (a) Protection of Human Subjects from Research Risks

The offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation, or provide sufficient information on the research subjects to allow a determination by Institute that a designated exemption is appropriate.

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.

The reviewers will evaluate the proposal and provide a narrative with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. See Section L for a complete discussion of what is required to be addressed for each of these issues. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable".

If your discussion regarding the protection of human subjects from research risks is rated "unacceptable" and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your position during such discussions and in your Final Proposal Revision (FPR). If, after discussions, your proposed plan for the protection of human subjects from research risks is still found unacceptable, your proposal may not be considered further for award.

#### (b) Data and Safety Monitoring

The offeror's proposal must include a general description of the Data and Safety Monitoring Plan for all clinical trials. The principles of data and safety monitoring require that all biomedical and behavioral clinical trials be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work and Section L in the solicitation, as well as any further technical

evaluation criteria in this Section M, as applicable, for the solicitations specific requirements for data and safety monitoring.

As a part of the evaluation for proposals, the reviewers will provide a narrative that describes the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods for data analysis. Based on the evaluation of the response to this criterion, this section of the proposal may be rated “unacceptable” (i.e., concerns are identified as to the adequacy of the monitoring plan or no discussion can be found regarding the proposed monitoring plans) or “acceptable.”

If the information provided regarding Data and Safety Monitoring is rated “unacceptable” and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss and/or clarify your plan during such discussions and in your Final Proposal Revision (FPR). If, after discussions, the plan is still considered “unacceptable,” your proposal may not be considered further for award.

**(c) Women and Minorities**

Women and members of minority groups and their subpopulations must be included in the study population of research involving human subjects, unless a clear and compelling rationale and justification are provided indicating that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. In addition, for NIH-Defined Phase III clinical trials, all proposals and/or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide [http://grants.nih.gov/grants/funding/women\\_min/guidelines\\_amended\\_10\\_2001.htm](http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm), Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the Government has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

- Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender and/or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups, OR
- Plans to include and analyze sex/gender and/or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender and/or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged), OR
- Plans to conduct valid analyses of the intervention effect in sex/gender and/or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants.

*Reviewers will address the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:*

- whether the plan proposed includes minorities and both genders in adequate representation
- how the offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
- the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
- if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects and/or to the purpose of the research.
- In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:
  - the purpose of the research constrains the offeror’s selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved; or
  - overriding factors dictate selection of subjects); or
  - gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

- For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:
  - inclusion of those groups would be inappropriate with respect to their health; or
  - inclusion of those groups would be inappropriate with respect to the purpose of the research.
- For NIH-defined Phase III clinical trials, reviewers will also address whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government 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

Based on the evaluation of the response to this criterion, this section of the proposal may be rated “unacceptable” (i.e., no discussion can be found regarding the proposed gender/minority inclusion plans, or concerns are identified as to the gender or minority representation, or the proposal does not adequately address limited representation of one gender or minority; or the plan is not in accordance with NIH policy guidelines) or “acceptable.” See Section L of the solicitation for the requirements of women/minorities inclusion.

If the information you provide in your proposal regarding the inclusion of women and minorities is rated “unacceptable” and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify, or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion/exclusion of women/minorities is still considered “unacceptable” by the Government after discussions, your proposal may not be considered further for award.

#### (d) Children

Children (i.e. individuals under the age of 21) must be included in all human subject research unless there are clear and compelling reasons not to include them.

Your proposal must include a description of plans for including children. If you plan to exclude children from the required research, your proposal must present an acceptable justification for the exclusion. If you determine that exclusion of a specific age range of child is appropriate, your proposal must also address the rationale for such exclusion. Also, the plan must include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose/objective of the solicitation. Also, see Section L of the solicitation for further specific requirements on inclusion of children.

Based on the reviewers’ narrative evaluation of the offeror’s response to this evaluation criterion, this section of the proposal may be rated “unacceptable” (i.e., no discussion can be found regarding the proposed inclusion plans for children; or concerns are identified as to the offeror’s response regarding the inclusion of children; or the plan is not in accordance with NIH policy guidelines) or “acceptable.”

If the information provided in your proposal about the inclusion of children is rated “unacceptable” and the Government includes your proposal in the competitive range (for competitive proposals), or if the Government holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss, clarify or modify your plan during discussions and in your Final Proposal Revision (FPR). If your plan for inclusion of children is still considered “unacceptable” by the Government after discussions, your proposal may not be considered further for award.

### 3. MANDATORY QUALIFICATION CRITERIA

Listed below are mandatory qualification criteria. **THE OFFEROR SHALL INCLUDE ALL INFORMATION WHICH DOCUMENTS AND/OR SUPPORTS THE QUALIFICATION CRITERIA IN ONE CLEARLY MARKED SECTION OF ITS PROPOSAL.**

The below qualification criteria establish conditions that **must** be met at the time of **PROPOSAL RECEIPT/SUBMISSION** in order for your proposal to be considered any further for award.

Offerors shall submit with their proposals these deliverables or documentation and data demonstrating that the Mandatory Qualification Criteria have been successfully met. **PROPOSALS THAT DO NOT INCLUDE THE MANDATORY INFORMATION WILL BE RETURNED TO THE OFFEROR WITHOUT FURTHER REVIEW AND WILL NOT BE CONSIDERED FOR AWARD.**

- a. Offerors must provide a draft agreement signed by all parties involved outlining:
  - i. Procedures to be used for obtaining patent coverage and licensing of the resulting vaccine; and
  - ii. Procedures to be followed for the resolution of potential legal issues that may arise.
  
- b. Given the strict timeline requirements for this vaccine development effort, it is also essential that efforts funded as a result of this RFP build on the most advanced vaccine candidate(s). Therefore, only proposals that have documented the following will be reviewed:
  - i. Manufactured, filled, finished, and released a cGMP pilot lot of MVA vaccine of sufficient quality for use in a human clinical study
  - ii. Completed a thorough preclinical immunogenicity and efficacy study in appropriate murine models to support an IND. These studies are separate from and are not intended to satisfy the requirements of 21 CFR 601.91. Of further importance, is evidence that the prototype MVA vaccine is safe in an immunocompromised murine model.
  - iii. Developed appropriate immunological assays (e.g., ELISA, PRNT, ELISPOT, and others if deemed necessary) for use in the evaluation of clinical trial samples.
  - iv. Developed an appropriate plan that will enable the manufacture and release of 3 million doses of MVA within the prescribed timeframe of this RFP.

#### 4. TECHNICAL EVALUATION CRITERIA

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

<u>CRITERIA</u>	<u>WEIGHT</u>
a. <b>Technical Adequacy</b>	<b>25</b>
This criterion is based on available data that demonstrates the adequacy of <u>current</u> manufacturing and characterization of candidate MVA vaccine (see Background, Objectives and Note #10).	
b. <b>Technical Approach</b>	<b>45</b>
This criterion is based on the <u>proposed</u> technical approaches in response to this RFP. Proposals will be evaluated with respect to the following:	
i. Technical adequacy and quality of proposed Product Development Plan leading to the manufacture of required amounts of vaccine within the specified time required by this RFP. <b>(15 points)</b>	
ii. Technical adequacy and quality of proposed Quality Systems Plan and Regulatory Support Plan leading to the release of vaccine product suitable for use in Clinical Trials through Phase III. <b>(10 points)</b>	
iii. Technical adequacy and feasibility of the Animal Testing Plan that supports licensure through 21 CFR 601.91. <b>(10 points)</b>	

iv. Technical adequacy and feasibility of the Clinical Testing Plan, including proposed protocols for Phase I/II and Phase II clinical trials as described in the Statement of Work. **(10 points)**

c. **Personnel** **15**

Adequacy and appropriateness of experience, education, and training of the principal investigator and other personnel proposed to accomplish all tasks identified in the SOW.

d. **Facilities** **15**

Documented availability of adequate facilities for development, preclinical testing, clinical evaluation, and manufacture of a vaccine suitable for emergency use under IND as specified in the Statement of Work, including documentation of capacity for accomplishment of the stated tasks and access to an AAALAC-accredited (or equivalent) animal facility and compliance with current Good Manufacturing Practices (cGMP).

**Total points** **100**

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

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

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

Offers will be evaluated on the following sub-factors:

- (a) Extent to which SDB concerns are specifically identified
- (b) Extent of commitment to use SDB concerns
- (c) Complexity and variety of the work SDB concerns are to perform
- (d) Extent of participation of SDB concerns in terms of the value of the total acquisition.